2-(Thiocyanomethylthio)benzothiazole (TCMTB)

Proposed Interim Registration Review Decision
Case Number 2625

March 2023

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Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for 2-(Thiocyanomethylthio)benzothiazole (TCMTB) (PC Code 035603, case 2625). 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] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.[3] For more information on TCMTB, see EPA's public docket (EPA-HQ-OPP-2014-0405) at www.regulations.gov.

FIFRA[4] 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. EPA will review 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 reduce risk 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. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The Agency is issuing a PID for TCMTB to propose how it may (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). 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 national threatened and endangered (listed) species for pesticides under the Endangered Species Act (ESA).[5] The Agency has not yet fully evaluated TCMTB's risks to federally listed species. However, EPA will complete its listed-species assessment and meet its ESA section 7 obligations (e.g., initiate any necessary consultation with the Services) before completing the TCMTB registration review. Before completing registration review, EPA also intends to address its EDSP obligations for TCMTB under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6] For more information on the listed-species assessment and the endocrine screening for the TCMTB registration review, see Appendices C and D.

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[6] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

Historically, IDs for pesticides with identified ecological risks have often included some mitigation intended to reduce exposure to nontarget organisms from pesticides, but those measures were not developed with the specific goal of advancing EPA's ESA obligations. Rather, measures that reduce exposures to listed species were typically identified only in ESA biological opinions from the Services. EPA is working to narrow this gap by including additional mitigation to reduce exposure to all nontarget organisms that is also expected to reduce exposure to listed species during registration review. As part of this PID, EPA has considered a variety of ecological mitigation measures based on the risks and benefits of TCMTB to reduce exposures to nontarget organisms, including listed species, while the Agency works toward a final registration review decision.

In addition to reducing exposures and associated effects to nontarget organisms, these measures may facilitate more efficient consultation, if needed, by incorporating mitigation measures that are similar to the types of measures the Services are expected to provide in future Biological Opinions. While these mitigation measures do not satisfy EPA's ESA obligations, EPA believes that early mitigation may shorten the consultation process and improve protections for listed species from currently registered pesticide products. The ecological mitigation measures that EPA is proposing for TCMTB under FIFRA are discussed in Section IV.A of this document.

TCMTB is the only active ingredient in this case and is used as an antimicrobial fungicide, slimicide, and bactericide. There are currently twenty-five registered Section 3 TCMTB products. Products containing TCMTB are currently registered for use in industrial processes and water systems including oil and gas settings, wastewater treatment plants, cooling water systems, and pulp and papermills; materials preservative in leather products and clothing, pulp and paper products, adhesives, caulks, as well as sealants; and as a wood preservative to prevent sapstain. At the time of the Final Work Plan, there were registered products containing TCMTB for use in seed treatment for safflower, cotton, and rice. The last remaining products containing these uses were amended to terminate the seed treatment uses on April 1, 2021, thus this case no longer includes conventional pesticide applications.[7] Additionally, the last remaining products containing the pressure-treated wood use of TCMTB were voluntarily cancelled on June 5, 2020 (EPA Reg. Nos. 1448-100 and 1448-341).[8] EPA Reg. No. 1448-100, prior to cancellation, was also the last remaining product that included a metalworking fluid preservation use until its label was amended in 2018 to remove it.

The Agency completed a Reregistration Eligibility Decision (RED) for TCMTB in 2006.[9] The RED determined the use of TCMTB in the materials preservation of paints and textiles (except for leather) was ineligible for reregistration. The last action involving the removal of the paint use was a label amendment for EPA Reg. No. 1448-55 in 2019, and for textiles, the last action removing this use was the cancellation of EPA Reg. No. 81910-3 in 2014.

[7] The last remaining products with seed treatment uses were EPA Reg. Nos. 1448-29, 1448-403, and 1440-405. For additional details on the termination of these uses, see docket ID EPA-HQ-OPP-2020-0060-0015 (FRL-10021-91) on www.regulations.gov.
[8] Additional information on this can be found at www.regulations.gov in docket ID EPA-HQ-OPP-2018-0014-0046 (FRL-10009-98).
[9] The RED and its supporting documents can be found at www.regulations.gov in docket ID EPA-HQ-OPP-2006-0320.

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 TCMTB is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Proposed Interim 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 TCMTB Registration Review

On September 24, 2014, the Agency formally initiated registration review for TCMTB with the opening of the registration review docket for the case.[10] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of TCMTB:

- September 2014 – EPA posted the *Thiocyanomethylthio-benzothiazole (TCMTB) Preliminary Work Plan* (PWP) (September 23, 2014) and the *TCMTB Human Health Risk Assessment Scoping Document in Support of Registration Review* (September 11, 2014) to the public docket for a 60-day public comment period.

- March 2015 – EPA posted the *2-(thiocyanomethylthio) benzothiazole (TCMTB) Final Work Plan* (FWP) (March 20, 2015) to the public docket. The Agency received one comment on the PWP from the Center for Biological Diversity. The comment received did not result in changes to the schedule, risk assessment needs, or anticipated data requirements in the FWP.

- June 2017 – EPA issued a generic data call-in (GDCI) for TCMTB to obtain data needed to conduct the registration review risk assessments (GDCI-035603-1485). All data for the human health risk assessment were either submitted or waived. For ecological data, two environmental fate studies (GLNs 880.3300 and either 835.3220, 835.3240, or 835.3280) that were required on the degradates of TCMTB were outstanding at the time of the Draft Risk Assessment (DRA). These studies were subsequently waived because it was determined that the parent chemical TCMTB is more toxic to non-target organisms and could serve as the upper-bound of risk.[11] Therefore, data requirements from the GDCI are satisfied.

- November 2021 – EPA posted the *TCMTB Registration Review Draft Risk Assessment* for a 60-day public comment period. The Agency received one comment from one

[10] 40 C.F.R. § 155.50

[11] Additional information on the environmental fate and ecotoxicology data waivers can be found at www.regulations.gov in docket ID EPA-HQ-OPP-2014-0405-0012.

commenter. The Agency has summarized and responded to these comments in Section I.B., below. The comments did change the risk assessment for TCMTB, specifically they resulted in the clarification of the point in the process for paper additives used in food contact paper, which no longer presents dietary risk with the more precise, decreased rate.

- March 29, 2023 – EPA completed the PID for TCMTB and will post the PID to the public docket for a 60-day public comment period. Along with the PID, EPA plans to post the following documents to the public docket:
    - *Response to Public Comments on the 2-(Thiocyanomethylthio)benzothiazole (TCMTB) Draft Risk Assessment* (October 18, 2022)
    - *Waivers for Immunotoxicity and Neurotoxicity Toxicology Studies in Support of the TCMTB Registration Review Case (#2625)*
    - *Meeting Between U.S. EPA and Buckman Laboratories International, Inc. regarding TCMTB Risk Mitigation (December 20, 2022)*
    - *Meeting Between U.S. EPA and Buckman Laboratories International, Inc. regarding TCMTB in Oil and Gas Settings (January 30, 2023)*
    - *Meeting Between U.S. EPA and Buckman Laboratories International, Inc. regarding TCMTB Sapstain Control Risk Mitigation (March 23, 2023)*

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

During the 60-day public-comment period for the TCMTB DRA (October 29, 2021, to December 28, 2021), the Agency received one public comment. Comments were submitted by Buckman, Inc. The Agency has summarized and responded to all substantive comments and included comments that resulted in a change to the DRA or that were of a broader regulatory nature below. Further, detailed responses can be found in the document *Response to Public Comments on the 2-(Thiocyanomethylthio)benzothiazole (TCMTB) Draft Risk Assessment*.[12] The Agency thanks all commenters for participating and has considered all comments in developing this PID.

Buckman Laboratories Comment 1: EPA cannot assume 100% retention of TCMTB on food contact paper when carrying out its dietary assessment and at the same time assume only 90% retention on paper and paper sludge when carrying out its environmental risk assessment of the same paper mills that produce the food contact paper. The registrant submits that the 90% retention on paper and paper sludge is well documented in OECD, 2009 and should be used in the dietary assessment as well.

Agency Response: The 90% retention on paper and paper sludge is for the wet end of the papermaking process, as stated in the OECD (2009) document. However, TCMTB is also used as a preservative for wet lap or sheet pulp and the registrant has confirmed that this application process provides 100% retention in the fibers (see p. 5-6 of comments by Buckman Laboratories). The dietary assessment in the DRA (US EPA, 2021a) was conducted at 75 ppm for slimicides with food contact potential which resulted in TCMTB in dry finished paper (a dry-end process) instead of the wet-end process. After reviewing the registrant's comment, the

[12] This document is available in the public docket for TCMTB at www.regulations.gov in docket ID EPA-HQ-OPP-2014-0405.

dietary assessment has been revised to a slimicide with food contact potential for the wet-end process at 75 ppm (0.15 lb a.i./ton) assuming 100% retention in the whitewater/stock in paper mills. The dietary model assumes that pulp accounts for 92% of the finished paper product, and the estimated dietary concentrations have been adjusted accordingly. Use of TCMTB in the wet-end process reduces the amount of the a.i. in the final product. With these revisions, this use no longer presents dietary risks of concern. For the full, revised risk estimates, please see the *Response to Public Comments on the 2-(Thiocyanomethylthio)benzothiazole (TCMTB) Draft Risk Assessment*.

Buckman Comment 2: Buckman validated that there are no FDA clearances for the use of TCMTB in papermaking additives used in or on food-contact paper products. The registrant stated their company would be willing to amend the labels of their registrations with papermaking additives to preclude the use of their products in food-contact paper.

Agency Response: The Agency thanks Buckman for indicating that they are willing to amend their product labels to prevent their use in food-contact papermaking. EPA agrees this would generally result in no dietary risks of concern if implemented and has included this measure in this PID as proposed risk mitigation.

Buckman Comment 3: Buckman indicated that they are willing to amend the label for EPA Reg. No. 1448-55 to include the same respiratory protection as other product labels for the sapstain control use (a respirator with at least a protection factor of 10). Additionally, the registrant stated that although the DRA identified that an application rate of 0.076% TCMTB in solution (from 0.29% TCMTB in solution) would result in no dermal risks of concern, this rate would not be efficacious for sapstain control products. Buckman indicated that their company would be willing to reduce the application rate to 0.125% TCMTB in solution. Additionally, they offered that restricting their products to dip application (and not spray operations) would reduce dermal risks further. They also stated in their inhalation exposure reduction discussion that clean up crew workers would only be contracted for their services every 6-8 months for a high-volume facility and every 2-3 years for a low volume mill, and are specially trained to do their work, even wearing hazardous materials suits if they are cleaning a tank.

Agency Response: EPA thanks Buckman for indicating their willingness to amend the label for EPA Reg. No. 1448-55 to include the same respiratory requirement as other labels with the sapstain control use. EPA agrees this would result in reduced inhalation risk for workers if implemented, specifically clean up crews who were determined to have unreasonable inhalation risk of concern. This proposed mitigation measure is included in this PID.

Regarding dermal risk mitigation measures suggested, the Agency has included a proposal to reduce the application rate to 0.125% from 0.29% TCMTB in solution for sapstain control products in this PID. Human exposure data from sapstain facilities submitted to EPA indicated that more frequent, routine clean-up of the facility occurs beyond the third-party clean-up service described in your comment for tank cleaning. The Agency does not assume the clean-up crew wears hazardous materials suits for routine tasks. Additionally, the Agency does not have data to indicate that clean-up crew workers would be exposed less to a biocide if they are working in a

facility that only uses dip operations versus only spray operations and is therefore not proposing this as a mitigation measure.

Buckman Comment 4: To address occupational handler inhalation risks of concern resulting from materials preservation, the registrant stated that they were willing to add respiratory protection and reduce the application rate to 11,500 ppm for EPA Reg. No. 1448-55. For dermal risks of concern resulting from this use, the registrant stated that closed loading application could be implemented for all uses except for leather preservation. Buckman stated that the maximum application rate of 2,750 ppm identified in the DRA to mitigate dermal risks from open pouring leather preservatives was acceptable to them.

Agency Response: The Agency thanks Buckman for indicating feasible risk mitigation measures for materials preservative uses of TCMTB. EPA has included a proposal in this PID to require all materials preservative uses move to closed loading application with the exception of leather preservation and agrees this would result in no inhalation or dermal risks of concern for these uses if implemented. With closed loading, it is not necessary to require respiratory protection or an application rate reduction to address inhalation risks of concern as negligible exposure is anticipated.

For the leather preservation use, the current maximum application rate is 2,500 ppm, which is below the threshold of dermal risks of concern (identified at or above 2,750 ppm). However, open pouring would result in inhalation risks of concern, and thus this PID includes a proposal to require respirators with at least a protection factor of 10 to ameliorate occupational handler risks posed by the use of TCMTB leather preservatives.

Buckman Comment 5: The registrant suggested several risk reduction measures in their comment to reduce ecological risks of concern resulting from the use of TCMTB in recirculating and once-through cooling tower uses that discharge into wastewater treatment plants (WWTPs). Mitigation suggested by the registrant included managing blow-down water using deep well injection, measures that encourage the recycling/reuse of water rather than releases, and deleting once-through uses from their product labels.

Agency Response: The Agency thanks Buckman for their suggestions to mitigate risks of concern posed to aquatic organisms that are downstream of WWTPs where cooling water has been discharged. As a result of discussions with the registrant after the closing of the DRA public comment period, the Agency decided that rather than pursue risk reduction measures, the Agency would propose terminating the use of TCMTB in recirculating and once-through cooling water towers, at the suggestion of the registrant. This proposed mitigation is reflected in this PID. In addition to eliminating this use from contributing to ecological risks of concern, this proposed use termination would also lower aggregate human health chronic risks of concern identified from drinking water exposures, as identified in the *Response to Public Comments on the 2-(Thiocyanomethylthio)benzothiazole (TCMTB) Draft Risk Assessment*.[13]

[13] This document is available in the public docket for TCMTB at www.regulations.gov in docket ID EPA-HQ-OPP-2014-0405.

II. USE AND USAGE

TCMTB is used as a fungicide, slimicide, and bactericide. It is registered for use in industrial processes and water systems (*e.g.,* cooling towers, oil and gas settings, pulp and paper mills, and wastewater treatment plants), as a materials preservative (*e.g.,* cooling towers to protect the tower wood, pulp and paper additives, caulks, sealants, adhesives, leather products and clothing, as well as clothing, pigments, and slurries) and in sapstain control products used in wood preservation. Since the publication of the Final Work Plan in 2015, the use of TCMTB as a seed treatment for cotton, safflower, and rice was terminated in 2021, and thus this case no longer includes conventional pesticide uses.[14] In 2020, the last remaining products that included use of TCMTB in pressure treatment of wood were voluntarily cancelled, thus the only use of TCMTB as a wood preservative is as sapstain control of freshly cut timber.[15] Additionally, the label for EPA Reg. No. 1448-100 was amended to terminate the metalworking fluid use in December 2018, and later this registration was voluntarily cancelled all together by the registrant in 2020.[16]

The first product containing TCMTB was registered in 1980, and a Reregistration Eligibility Decision was completed for this active ingredient in 2006. The RED determined the use of TCMTB in the materials preservation of paints and textiles (except for leather) was ineligible for reregistration. The last action involving the removal of the paint use was a label amendment for EPA Reg. No. 1448-55 in 2019, and for textiles, the last action removing this use was the cancellation of EPA Reg. No. 81910-3 in 2014.

As of February 27, 2023, there are 25 products containing TCMTB. Of these, 18 are end-use products and 7 are used to manufacture pesticide products. Currently registered products can be applied via closed loading (*e.g.,* a metering pump), open pouring, mechanized rollers (papermaking), dispersion, dip, brush, or spray.

According to the Kline Specialty Biocides 2020 U.S. Market Analysis Report, TCMTB is a major biocide used in adhesives, sealants, leather, cooling water, and the paper industry.[17] It is not listed as a major active ingredient used in wood preservatives or in the oil and gas industry.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2021 human health risk assessment below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk

[14] The last remaining products with seed treatment uses were EPA Reg. Nos. 1448-29, 1448-403, and 1440-405. For additional details on the termination of these uses, see docket ID EPA-HQ-OPP-2020-0060 (FRL-10021-91) on www.regulations.gov.
[15] EPA Reg. Nos. 1448-100 and 1448-341 were voluntarily cancelled by the registrant on June 5, 2020 and were the last products listing use of TCMTB as a pressure treatment for wood preservation. For additional details on this voluntary cancellation, see docket ID EPA-HQ-OPP-2018-0014 on www.regulations.gov.
[16] EPA Reg. No. 1448-100 was voluntarily cancelled on June 5, 2020. For additional details on this voluntary cancellation, see docket ID EPA-HQ-OPP-2018-0014 on www.regulations.gov.
[17] Kline (2021). Specialty Biocides 2020: United States Business Analysis and Opportunities.

assessment in support of the registration review of TCMTB. For additional details on the 2021 human health risk assessment, see the *Registration Review Draft Risk Assessment for 2-(Thiocyanomethylthio)benzothiazole (TCMTB)* in EPA's public docket (EPA-HQ-OPP-2014-0405).

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

There is potential for dietary exposure to TCMTB from uses in food-contact paper (to preserve paper additives) and as a slimicide in paper and paperboard mills that produce food-contact paper. Acute dietary exposures and risks from use of TCMTB in food-contact paper and slimicide were not of concern for any subpopulation assessed (risks were less than 100% of the acute population adjusted dose (aPAD)).

In the 2021 DRA, EPA identified chronic risks from uses of TCMTB in food-contact paper and as a slimicide. Risks to children 1-2 years old were identified from use as a slimicide (105% of the chronic population adjusted dose (cPAD)), and risks to infants, children 1-2 years old, and children 3-5 years old were identified from use of TCMTB in additives used in food-contact paper (119%, 169%, and 124% of the cPAD, respectively). The dietary assessment in the DRA was conducted at 75 ppm for slimicides with food contact potential which resulted in TCMTB in dry (use in the dry-end process) finished paper. During the public comment period, Buckman argued that the Agency should not presume 100% retention of TCMTB residue on food-contact paper post-slimicide use when 90% is what is assumed in the environmental risk assessment for pulp and paper mill slimicides. After reviewing the comment that TCMTB is used in the wet-end process and not the dry-end process, the dietary assessment still maintains 100% retention for food-contact paper, but the estimated dietary concentrations were adjusted to account for model assumptions that pulp accounts for 92% of the finished paper product. Since TCMTB is only applied in the wet-end, the amount of TCMTB found in the final product is less than if dry-end applications are made. This adjustment to the assumptions results in risks that are below the 100% cPAD threshold; therefore, the chronic risks are no longer anticipated to be of concern from the pulp and papermill slimicide use. These changes are reflected in the *Response to Public Comments on the 2-(Thiocyanomethylthio)benzothiazole (TCMTB) Draft Risk Assessment*.[18] Chronic risks of concern remain for the use of TCMTB in papermill additives.

Drinking water exposure has the potential to occur when drinking water intakes are downstream of cooling towers or paper mills using TCMTB as a slimicide. Compared to these uses, drinking water exposure is expected to be minimal from the other currently registered uses of TCMTB, such as uses in wastewater treatment systems and drilling fluids, as a sapstain control in construction lumber, and as a materials preservative in leather, coatings, caulking, and sealants. Thus, quantitative exposure and risk assessments for these uses of TCMTB were not conducted.

[18] This document is available in the public docket for TCMTB on www.regulations.gov in docket ID EPA-HQ-OPP-2014-0405.

Residential Handler + Post-Application Risks

As TCMTB is used to preserve articles such as caulks, sealants, and adhesives, TCMTB is present in residential settings. However, short-term residential handler dermal and inhalation exposure, as well as post-application exposure, is expected to be minimal. This is due to TCMTB's low vapor pressure, minimal amounts handled, minimal dermal contact during use, and the infrequent use of these treated articles by residential users. Thus, quantitative exposure and risk assessments for these uses of TCMTB were not conducted.

There is also potential for short-term adult post-application dermal and inhalation exposure to treated leather products and clothing. However, based on the minimal residue transfer seen in available residue data, the low anticipated exposure to children from treated leather, and the low volatility of TCMTB, the Agency expects risk from post-application contact with TCMTB-preserved leather products and clothing to be minimal. Thus, quantitative exposure and risk assessments for these uses of TCMTB were not conducted.

Aggregate Risks

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. For TCMTB, the Agency assessed acute and chronic dietary and drinking water exposures. Residential exposures to TCMTB are not expected.

Acute Aggregate Risk

Acute dietary and drinking water exposures (lasting less than one day) to TCMTB have the potential for co-occurrence from the following uses: (1) as a slimicide in paper and paperboard mills, (2) as a materials preservative in papermaking additives, and (3) in drinking water exposure from the use of TCMTB in industrial water systems with effluent discharging into freshwater waterbodies. These acute exposures result in an aggregate (combined) risk of 17% aPAD for infants <1 year old, 14% aPAD for children 1-2 years old, and 6.9% for the general population. These exposures are less than 100%, and thus are not of concern.

Chronic Aggregate Risk

In the 2021 DRA, EPA assessed drinking water risks only for the chronic aggregate assessment because there are no residential use patterns with this exposure duration and no dietary use patterns passed their individual assessments. Based on this assessment, no chronic aggregate risks of concern were identified in the DRA.

Since the publication of the DRA, EPA received a public comment from a TCMTB registrant that resulted in modifications to the dietary model assumptions for slimicides used in food-contact paper and paperboard mills, as discussed above. Because this individual use pattern now passes, the chronic aggregate assessment was revised to include dietary exposure from the

slimicide use. There are chronic aggregate risks of concern for all infants <1 year old as well as children 1-2 years old. Their estimated risks are 107% and 118% of the cPAD, respectively. There were no chronic aggregate risks of concern identified for the general population. This change is reflected in the *Response to Public Comments on the 2-(Thiocyanomethylthio)benzothiazole (TCMTB) Draft Risk Assessment*.[19]

Cumulative Risks

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

Occupational Handler Risks

There is potential for occupational handler inhalation and dermal exposure when TCMTB is applied as a sapstain control measure during the wood preservation process, and exposure is expected to be short-, intermediate-, and long-term in duration. The inhalation Margin of Exposure (MOE) of 1.6 for sapstain control clean-up crew workers is of concern because it is less than the Level of Concern (LOC) of 10. The inhalation MOEs for other sapstain control workers are not of concern because they are greater than the LOC of 10. The dermal MOE of 78 for sapstain control clean-up crew workers is of concern because it is less than the LOC of 300. The dermal MOEs for other sapstain control workers are not of concern because they are greater than the LOC of 300.

Additionally, there is potential for occupational handler short- and intermediate-term inhalation and dermal exposure when TCMTB is added as a materials preservative (via open pouring) during the manufacturing of treated articles such as pulp/paper products, paperboard, particle board, building materials (caulks, sealants, and adhesives), and leather products and clothing. The inhalation MOE of 0.79 is of concern because it is less than the LOC of 10. The dermal MOE of 5.5 is also of concern because it is less than the LOC of 30. This exposure scenario is protective of open pour liquid applications for industrial processes and water systems: residual and distillate fuel, crude and refined oils, recirculating cooling water, cooling towers, drilling fluids, and wastewater treatment. Of these, the application rate concentration for drilling fluids (10,000 ppm) results in inhalation and dermal risks of concern. The inhalation MOE is 1.19, which is below the LOC of 10 and thus of concern. The dermal MOE is 8.24, which is below the target MOE of 30 and thus of concern. Risks of concern were not triggered by other industrial processes and water systems uses of TCMTB due to their lower application rate concentration (ranging from 5.1 to 300 ppm).

Occupational Post-Application Risks

Occupational post-application inhalation and dermal exposure to treated articles are expected to be minimal, based on TCMTB's relatively low vapor pressure, minimal amounts handled,

[19] This document is available in the public docket for TCMTB on www.regulations.gov in docket ID EPA-HQ-OPP-2014-0405.

minimal dermal contact during use, and the infrequent use of materials treated with TCMTB. Thus, quantitative occupational post-application inhalation and dermal exposure assessments were not conducted.

2. Human Incidents

OPP's Incident Data System (IDS) includes reports of reported human health incidents from various sources, including mandatory FIFRA Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS.

EPA reviewed TCMTB incidents reported to the Incident Data System (IDA). As of EPA's latest search on February 6, 2023, the IDS showed no incidents reported from the past five years that involve antimicrobial or conventional uses of TCMTB. The Agency intends to monitor human incidents for TCMTB and will conduct additional analyses if necessary.

3. Tolerances

As of June 21, 2021, there are no tolerance exemptions for residues of TCMTB under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408. However, EPA has established tolerances for residues of TCMTB, the details of which are contained within 40 CFR § 180.288. These tolerances are for fungicidal use in or on various specific food commodities and are not related to the current antimicrobial use patterns of TCMTB.

TCMTB has been cleared as an indirect food additive by the US Food and Drug Administration (FDA) under FFDCA Section 409 when used as a slimicide (21 CFR § 176.300). The clearance states that the antimicrobial agent is to be used to control slime in the manufacture of paper and paperboard. TCMTB does not have any chemical-specific limitations for its use as a slimicide listed in 21 CFR § 176.300.

There are no FDA clearances for the use of TCMTB in papermaking additives used in or on food-contact paper; however, certain products registered with EPA do not restrict the use of the additives to nonfood-contact paper. The continued use of this active ingredient in papermaking additives would meet the criteria for an FDA clearance and/or food contact notification.

The Agency anticipates the following changes to the tolerances for TCMTB. The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

Table 1: Summary of Proposed Tolerance Actions for 2-(Thiocyanomethylthio)benzothiazole (TCMTB)

40 CFR Section	Tolerance	Chemical CAS #	Maximum Residue Level	Recommended Action
180.288	Tolerances for residues in or on the following food commodities: barley	TCMTB CAS # 21564-17-0	0.1 ppm (all)	Revoke tolerances for all specified food commodities (no

40 CFR Section	Tolerance	Chemical CAS #	Maximum Residue Level	Recommended Action
	(grain), barley (straw), beet (sugar, roots), beet (sugar, tops), corn (field, forage), corn (field, grain), corn (field, stover), corn (pop, grain), corn (pop, stover), cotton (forage), cotton (undelinted seed), oat (forage), oat (grain), oat (hay), oat (straw), rice (grain), safflower (seed), sorghum (grain, forage), sorghum (grain, grain), sorghum (grain, stover), wheat (forage), wheat (grain), wheat (hay), wheat (straw)			products registered for use on these commodities)

4. Human Health Data Needs

The human health database for TCMTB is considered complete.

B. Ecological Risks

The Agency has summarized the 2021 ecological risk assessment below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of TCMTB.[20] For additional details on the 2021 ecological risk assessment, see *Registration Review Draft Risk Assessment for 2-(Thiocyanomethylthio)benzothiazole (TCMTB)* in EPA's public docket (EPA-HQ-OPP-2014-0405).

The EPA is currently working with its federal partners and other stakeholders to improve the consultation process for listed species and their designated critical habitats. The Agency has not yet fully evaluated TCMTB's risks to listed species. However, EPA will complete its listed-species assessment and meet its ESA section 7 obligations (e.g., initiate any necessary consultation with the Services) before completing the TCMTB registration review. See Appendix C for more details. As such, only potential risks for non-target species generally are described below.

[20] The 2021 ecological risk assessment only addresses potential risks to species not listed under the Endangered Species Act. EPA is working with its federal partners and other stakeholders to implement a Revised Method (EPA-HQ-OPP-2019-0185-0054) for assessing potential risk to listed species and their designated critical habitats. The Agency will complete TCMTB's listed-species assessment once EPA has fully implemented the scientific methods necessary to complete listed species' risk assessments. For more details, see Appendix C.

1. Risk Summary and Characterization

Terrestrial Risks

Based on the current use patterns of TCMTB, no terrestrial risks (including risks to pollinators) are expected due to limited exposure potential. An additional pollinator assessment is not needed.

Aquatic Risks

Although TCMTB degrades relatively rapidly in the environment, it has the potential to persist long enough to be released into aquatic environments and is very highly toxic to aquatic organisms. All TCMTB use patterns have the potential to result in aquatic exposure, but most are expected to result in minimal exposure and thus were not quantified using modeling. The 2021 DRA focused on four uses of TCMTB that are anticipated to result in significant aquatic exposure: 1) recirculating cooling water towers, 2) once-through cooling water towers, 3) slimicides used in pulp and paper mills, and 4) wood preservation as an anti-sapstain. In the absence of data, the Agency conservatively assumes that 0% of TCMTB is removed from wastewater treatment plants, and used this assumption in aquatic exposure modeling assessments. Data that would refine the exposure modeling include the following ecological fate studies on parent chemical TCMTB:

- Activated Sludge Sorption Isotherm (GLN 835.1110);
- Porous Pot Test (GLN 835.3220);
- Simulation Test – Aerobic Sewage Treatment (GLN 835.3240); and
- Simulation Tests to Assess the Primary and Ultimate Biodegradability of Chemicals Discharged to Wastewater (GLN 835.3280).

The Agency called these data in on the degradates of TCMTB but not the parent, which has since been determined to be more toxic than its degradates. At this time, EPA is not issuing a data call-in to require these data to complete this registration review of TCMTB, but may require them in the future to refine ecological assumptions. Where ecotoxicity data exists, both on an acute and a chronic basis, TCMTB is more toxic than one of its major degradates, 2-MBT. Data are not available for remaining degradates of TCMTB, BTSA and DBB; however, based on the similar chemical structure of the other degradates to TCMTB, they are assumed to be no more toxic than TCMTB. This difference in toxicity, similarity in chemical structure, plus the potential for exposure to the parent compound TCMTB resulted in the Agency's decision to consider TCMTB the residue of concern in the DRA. EPA anticipates this conservatism to be protective of potential residues resulting from the use of TCMTB in its ecological risk assessment.

Screening-level risk assessments of TCMTB used in cooling water towers and slimicides for pulp and paper mills were performed using the Exposure and Fate Assessment Screening Tool (E-FAST). All uses resulted in exposures that exceed levels of concern for freshwater fish, freshwater invertebrates, and aquatic plants. Because E-FAST screens risks to aquatic species found in flowing freshwater bodies (*i.e.,* streams), it is not appropriate to apply it to estimate risk

to estuarine or marine species. However, these risks cannot be precluded especially given that TCMTB was identified to be very highly toxic to these taxa in the 2021 DRA.

If large-sized recirculating cooling towers release effluent into low-flow streams (which represents a high-end aquatic risk scenario), concentrations of concern (COCs) are estimated to be exceeded 286-360 days per year for all assessed aquatic freshwater taxa. Risks are expected to be lower for moderate-sized cooling towers and in average-flow streams, with COC exceedances ranging from 3-360 days per year). For once-through cooling towers, COCs are exceeded 343-360 days for low-flow streams and 73-356 days for average-flow streams. Risks are higher for once-through cooling towers due to the assumption that 100% of the effluent is released directly into surface waters throughout the year, rather than 0.6% of effluent being released via blow-down to WWTPs for recirculating systems. For slimicides containing TCMTB used in pulp and paper mills, COCs are anticipated to be exceeded 89-360 days for low-flow streams and 11-344 days for average-flow streams.

Based on Agency modeling, risks were present for all assessed freshwater taxa for TCMTB uses in cooling towers and pulp and paper mills. Additionally, although TCMTB is not expected to persist in the environment, the amount of degradation and/or dissipation that could occur during wastewater treatment or in the environment could not be determined. Therefore, given the large risk exceedances estimated for many of the assessed scenarios, risks of concern to freshwater fish, freshwater invertebrates, and aquatic plants are expected from the use of TCMTB in cooling towers and in slimicides used in pulp and papermills. Based on Agency modeling, TCMTB risks from wood preservation (anti-sapstain) are not expected.

Another screening-level risk assessment was performed for TCMTB used as an anti-sapstain in treated wood in docks and indicated limited potential for risk to aquatic organisms from this use. At least 530 docks on a single standard-sized water body would need to be treated with TCMTB before resulting in chronic risk, while at least tens of thousands of docks would need to be treated with TCMTB to result in acute or aquatic plant risks. Although the Agency does not have a standard assumption for the number of docks on a water body, these risk estimates are likely overestimates of the actual exposure found in the environment, based on the conservative assumptions used in the modeling. Therefore, risks of concern to aquatic organisms from the anti-sapstain use are not expected.

2. Ecological Incidents

EPA reviewed TCMTB incidents reported to the Incident Data System (IDS). As of EPA's latest search on February 6, 2023, IDS indicated one aggregate incident on June 25, 2021 classified as "wildlife-minor" that occurred in 2005 and involved the product BUSAN 1009 (EPA Reg. No. 1448-81) which contains two active ingredients: TCMTB and methylene bis(thiocyanate). No additional details were provided regarding the incident, and it cannot be concluded whether the incident was due to one or both a.i.s. There were no non-aggregate incidents.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for TCMTB is considered complete. While not all environmental fate data were received for degradates 2-MBT and BTSA (specifically, GLNs

835.3220 – Porous Pot Test; 835.3240 – Simulation Test, Aerobic Sewage Treatment-Activated Sludge; 835.3280 – Simulation Tests to Assess the Biodegradability of Chemicals) or ecotoxicity data on degradate 2-MBT (specifically, 850.1735 – Whole Sediment: Acute Freshwater Invertebrates and 850.1740 – Whole Sediment: Acute Marine Invertebrates), because the DRA determined that TCMTB is the residue of concern for purposes of risk assessment, outstanding data for 2-MBT are not needed at this time. These data were waived, and this waiver is available at www.regulations.gov.[21] Due to the lack of data, however, acute and chronic toxicity of parent TCMTB to freshwater and estuarine/marine sediment-dwelling invertebrates remains an uncertainty within this assessment. Although these data were not included in the Data Call-In for this registration review, it may be determined in a future registration review of TCMTB products that these data are necessary to refine the risk assessment.

Additionally, the Data Call-In also required pollinator studies as well as an acute avian toxicity study to support this risk assessment; however, the use that triggered these data (seed treatment) is no longer on registered labels, and thus these data are not outstanding.

C. Benefits Assessment

This PID describes the benefits of the antimicrobial uses of TCMTB for which the Agency has identified risks of concern and is proposing mitigation measures. Where possible, information on the benefits of using TCMTB are described; for other use sites, the benefits of antimicrobial pesticides are more broadly given.

Materials Preservation

Materials Preservation: Pulp and Paper Additives

TCMTB is registered for use as a preservative of additives used in papermaking, such as alum solutions, animal glue solutions, pigment slurries, coating formulations, and starch slurries and solutions. These additives are used during "dry-end" processing of paper, which occurs after pulp is processed and dried. It follows "wet-end" processing in which paper sheet is formulated from wet pulp. The additives used in the dry-end process serve many purposes but overall are intended to impart desired properties on the paper, such as water repellency, strength, opacity, finishes (e.g., gloss vs. matte), and color.[22] Biocides are used to maintain the integrity of the chemicals eventually used in papermaking, including increasing their shelf-life. Should these additives fail due to microbial contamination, it would result in ineffective products for papermaking, and thus loss in revenue for mills if they are unable to produce paper and/or paperboard products that meet certain specifications for clients. On the less severe end of potential outcomes, paper additives that have a shorter shelf-life could increase costs for papermills to maintain a fresh stock of chemicals. There are many alternatives to TCMTB,

[21] This document, *TCMTB Environmental Fate and Ecotoxicology Data Waivers*, can be found in docket ID EPA-HQ-OPP-2014-0405-0012 at www.regulations.gov.
[22] U.S. EPA (1995). Profile of the Pulp and Paper Industry (Document Number EPA/310-R-95-015). EPA Office of Compliance Sector Notebook Project.

including bronopol, 2,2-dibromo-3-nitrilopropionamide (DBPNA), isothiazolinones, dazomet,[23] and glutaraldehyde, among others.

Materials Preservation: Sheet Pulp/Wet Lap in Papermaking

TCMTB can be applied by addition to the white water (paper process water) or stock, or to the surfaces of dewatered pulp to prevent bacterial and fungal growth during storage of sheet pulp or wet lap prior to further processing into paper. Wet lap is prone to microbial spoilage because it is damp and stored in a warm environment. Without the use of a biocide, the wet lap would become unusable if it is not processed shortly after being produced due to discoloration and odors. The Agency does not have information on the alternatives to TCMTB for this use site.

Materials Preservation: Leather

Biocides are used in leather preservation to either prevent damage to the hide or to prevent mold formation. The sale of leather is strongly tied to the meat industry, which is a major supplier of hides.[24] "Wet blue" leather (so-named due to the characteristic color that results after tanning with chrome III sulfate) accounts for the majority of tanned leather and is the primary use case for TCMTB as a fungicide. Wet blues require preservation because leather is typically tanned in the United States and exported to other countries for further processing. Without a biocide, wet blues can develop mold that causes stains that cannot be removed from the hide. Export of hides to other countries slowed since 2015 due to economic tensions between the U.S. and China (the largest importer of animal skins), demand for synthetic alternatives to leather, as well as complications posed by the COVID-19 pandemic.[25]

TCMTB is considered a major chemical for use in leather preservation, along with *para*-Chlorocresol (PCMC) and benzisothiazolinone (BIT). TCMTB is more expensive than PCMC but does not result in an undesirable phenolic smell.[26] To offset the cost of TCMTB, tanneries often use octylisothiazolinone (OIT) as a co-biocide in wet blue processing. Other chemical alternatives for leather preservation include *ortho*-phenylphenol (O-PP), polyhexamethylene biguanide (PHMB), diiodomethyl-*para*-tolyl sulfone (DIMTS), and diethyldithiocarbamate (DDC) salts.

Industrial Processes and Water Systems

Industrial Processes and Water Systems: Cooling Water Towers

In industrial settings, cooling water is used to cool machinery in manufacturing facilities and electric companies via heat transfer. As of 2015, there are approximately 1,065 existing cooling water facilities in the U.S. withdrawing at least 2 million gallons a day for cooling water from

[23] As a result of registration review, the use of dazomet as a materials preservative in paper additives is being proposed to be terminated. For additional details, see docket ID EPA-HQ-OPP-2013-0080 on www.regulations.gov.
[24] Kline and Company (2017). Specialty Biocides 2016: United States Market Analysis.
[25] Ibid.
[26] Ibid.

lakes, rivers, estuaries, or oceans.[27, 28] Roughly half of these are manufacturers (521 facilities), while the other half are power plants (544 facilities). Cooling water is also used in commercial settings to dissipate heat in buildings from heating, ventilation and air conditioning (HVAC) units.

The use of antimicrobial products in cooling water applications is needed because many systems recirculate water. Very few utilize once-through cooling because it requires significant water withdrawals, which negatively impacts the environment.[29] It should be noted that even recirculating systems still pull in large volumes of water, and both types of system intakes result in injury and death of aquatic organisms and significant loss of flow in waterways, which indirectly impacts all aquatic species. Whenever water is recirculated (as opposed to once-through use), it conserves resources, but also means that water is more prone to microbial contamination because influent water is a major source of planktonic microorganisms. Microbial growth on damp surfaces can lead to biofilm formation, which affects equipment performance and creates conditions for metal corrosion. On the other hand, recirculating the water means the system is less susceptible to biofouling from algae or bivalves during cooling water intake. Thus, the use of a biocide in recirculating systems serves the purpose of extending the time you can reuse the same cooling water. After the cooling water has been recirculated to the extent it can be reused, it is discharged ("blown down") back to surface water. There are many alternatives to products containing TCMTB including sodium bromide, hypochlorites, peroxy compounds, glutaraldehyde, chlorinated isocyanurates, hydantoins, isothiazolinones, quaternary ammonium compounds, mercaptobenzothiazole (MBT), and O-PP, among others. The Kline Report lists TCMTB as a major chemical in this industry.

Industrial Processes and Water Systems: Slimicide in Pulp and Papermills

TCMTB is registered for use as a slimicide in pulp and paper production in "wet-end" processing. Wet-end processes require a large volume of water to produce pulp that eventually becomes finished paper, and includes removal of pulp impurities (screening), cleaning, and thickening of pulp fiber mixture.[30] The papermaking process is susceptible to microbial degradation from a broad range of algae, bacteria, and fungi present during manufacturing of paper and paper products due to the warm, wet conditions and available nutrients associated with the biodegradable wood pulp material inputs to papermaking. Anaerobic bacteria and fungi, including molds, yeasts, and slime-forming bacteria, are present in the wet-end of the paper making process, in which pulp and process waters are present together before the paper is pressed and dried. The presence of microorganisms during the papermaking process can cause equipment corrosion, a loss in machine efficiency, the formation of deposits on paper machines, plugging of filters, nozzles, and felts, raw material spoilage and deterioration, and/or the

[27] US EPA (2014). Fact Sheet: Final Regulations to Establish Requirements for Cooling Water Intake Structures at Existing Facilities. https://www.epa.gov/sites/production/files/2015-04/documents/final-regulations-cooling-water-intake-structures-at-existing-facilities_fact-sheet_may-2014.pdf
[28] For additional information on Final Rule for Standards for Cooling Water Intake Structures, see docket ID EPA-HQ-OW-2008-0667 at www.regulations.gov.
[29] US EPA (2016). Antimicrobials Used in Cooling Water Systems. https://www.epa.gov/sites/production/files/2016-08/documents/antimicrobials_used_in_cooling_water_systems.pdf
[30] U.S. EPA (1995). Profile of the Pulp and Paper Industry (Document Number EPA/310-R-95-015). EPA Office of Compliance Sector Notebook Project.

presence of odor, holes, or breaks in the finished paper product. Biocides are added to the wet-end of the papermaking process to prevent a wide range of negative impacts to the papermaking process. After the paper is formed, the effluent water, containing biocides, is diverted from the paper products and may be treated before release into the environment. The paper products are dried in dryer cans, reaching temperatures as high as 275°F, during which remaining process water is driven off as steam, available microorganisms are killed, and most biocides are deactivated/destroyed.[31]

While in 2020 there were approximately 343 paper mills operating with 811 paper machines, paper consumption has been declining with the rising competition of digital media.[32,33] Some sectors are witnessing growth, such as tissues, highly specialized graphics, thermal paper, and brown board for food tetra packs. Additionally, due to the large amounts of water used in papermaking, there is increased interest in recycling water rather than intaking freshwater to support their processes. The recycling of water necessitates the use of biocides to ensure its reuse does not impact the functioning of machinery and process water, and thus the increased focus on recycling water correlates with the increased use of biocides such as TCMTB and its alternatives to manage microbial burden.

Paper mills typically try to restrict the number of chemicals used, including biocides. U.S. regulations for food ingredients includes 21 CFR § 176, which outlines the biocides that are safe to use in food packaging. Products that have 21 CFR § 176 approvals compete more successfully in this sector. Slimicides can be utilized in the manufacture of paper and paper board that come in to contact with food if they meet all the criteria as outlined in the code.[34]

There are many alternatives to TCMTB for paper mill slimicides, including glutaraldehyde, quaternary ammonium compounds, bronopol, dazomet,[35] and isothiazolinones, among others. The Agency solicits comment on the viability of these alternatives.

Industrial Processes and Water Systems: Oil and Gas Uses

Biocides are used in different processes of oil and gas production such as stimulation, hydraulic fracturing, production, pipeline, and storage. Most operators are not investing in the exploration of new oil and gas fields, rather producing oil from existing or older fields. As a result, the production processes, such as drilling and hydraulic fracturing, is active only for existing fields, which is indicative of a changing market. The use of biocides in this sector thus fluctuates as demand increases or decreases for fossil fuels. The Energy Information Administration (EIA) estimated that from 2015-2017 U.S. crude oil production would slowly fall while U.S. natural gas production is on the rise. In 2015, natural gas production reached 79 billion cubic feet per day, exhibiting a 5%

[31] Keegan, K. (2020). Use of Biocides in the Paper Industry. Center for Biocide Chemistries presentation to the EPA Antimicrobials Division on July 30, 2020. Available at https://www.youtube.com/watch?v=4H7IjZ6rEDA.
[32] Ibid.
[33] Kline and Company (2017). Specialty Biocides 2016: United States Market Analysis.
[34] Ibid.
[35] As a result of registration review, the use of dazomet as a slimicide in paper mills is being proposed to be prohibited. For additional details, see docket ID EPA-HQ-OPP-2013-0080 on www.regulations.gov.

increase from the previous year.[36] As of April 2021, EIA estimates that natural gas production reached 112,887 million cubic feet per day.[37]

TCMTB is primarily used as a bacteriocide in drilling fluids but is also registered for use in residual and distillate fuel, petroleum secondary recovery, and crude and refined oils. Drilling fluids (also known as drilling muds) help cool the drill bit as it bores through the ground, control the pressure within the borehole, and transport drill cuttings back to the surface.[38] They are circulated down to the drill pipe and returned to the surface via the walls of the hole. Water-based drilling fluids, which is what TCMTB is used to preserve, typically consist of 80% water and 20% clay and other additives (such as emulsifiers and thickeners) that impart desired properties to enhance the performance of the drilling fluid). In general, industrial processes that use a water-based fluid are susceptible to microbial contamination because they intake water from the local environment or transport it in from another source (either fresh- or saltwater), which provides a source of planktonic microorganisms. The additives also make the drilling fluid vulnerable to bacterial growth because they provide a nutrient source that encourages their presence (*e.g.,* starches). Drilling fluids can also be oil-based, gas-based, or synthetic-based fluids. Water-based fluids are typically used to drill deep wells under moderate-to-high pressures and low-to-moderate temperatures.[39]

If drilling fluids fail due to microbial contamination, drill bits might become unstable and stuck, or if pressure is not relieved underground this can cause a "blowout" where well fluids, natural gas, and/or crude oil are expelled from the borehole at a high velocity.[40] A blowout is a catastrophic failing of drilling operations and poses dangers to well operators. Resulting spills also have adverse local environmental impacts. Drilling operations typically have blowout preventors in place as safety measures, and testing of drilling fluids is a crucial step to understand whether there is excessive microbial contamination.

The Kline Report does not list TCMTB as a major biocide in this sector, though the Agency does not have market information specific to the drilling fluid use scenario. Alternatives chemicals for drilling fluids include acrolein, tetrakis(hydroxymethyl)phosphonium sulfate (THPS), glutaraldehyde, isothiazolinones, and 1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT, also known as grotan).

Wood Preservation (Sapstain Control)

Sapstain control fungicides (also known as anti-sapstains) are used to preserve the cut ends of sapwood prior to longer term preservation methods such as pressure treatment. Without an anti-sapstain treatment, wood is susceptible during transport and storage to fungal decay, which

[36] Kline & Company (2017). Specialty Biocides: Regional Market Analysis 2016 – United States.
[37] U.S. Energy Information Administration (EIA). 2021. Monthly Crude Oil and Natural Gas Production. Accessed July 30, 2021. Available at: https://www.eia.gov/petroleum/production/#ng-tab.
[38] U.S. EPA (2019). Management of Exploration, Development and Production Wastes: Factors Informing a Decision on the Need for Regulatory Action. Prepared by the Office of Resource Conservation and Recovery. Available at https://www.epa.gov/sites/default/files/2019-04/documents/management_of_exploration_development_and_production_wastes_4-23-19.pdf.
[39] Ibid.
[40] Ibid.

discolors it and makes it undesirable for aesthetic reasons. Products registered for use as anti-sapstain treatments are intended to prevent new fungi colonization and do not kill existing fungi. Mechanical equipment tends to be the source of these fungi (such as "bluestain"-causing fungi), which are non-pathogenic, as opposed to other fungi found on living trees.

Alternatives to products containing TCMTB as sapstain control include iodopropynyl butyl carbamate (IPBC) and propiconazole (as co-formulation), O-PP, and chlorothalonil. The Kline Report listed in 2017 that propiconazole and IPBC capture approximately 70% of the market share for this use, and it does not list TCMTB as a major chemical in the sapstain control industry.[41] Information from the main registrant for this case, Buckman Laboratories, indicate that TCMTB-containing products that are co-formulated with MBT lowers the total amount of biocide required and because of this is more cost-effective than propiconazole-IPBC formulations. Buckman also stated that TCMTB and chlorothalonil are the most often used active ingredients, but the Agency does not have other information to confirm this assertion.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

The Agency has concluded that there are risks of concern to mitigate for the following uses of TCMTB: industrial processes and water systems (recirculating and once-through cooling water towers, slimicides used in pulp/papermills, drilling fluids in oil and gas settings, and wastewater treatment plants), wood preservation (sapstain control), and materials preservatives (papermill additives, leather, adhesives, caulks, and sealants). Additionally, EPA notes there are a wide variety of alternatives for the registered uses of TCMTB for which the Agency proposes risk mitigation. To address dietary risks of concern, the Agency proposes to prohibit the use of TCMTB to preserve paper additives intended for food-contact paper products. EPA proposes to mitigate dermal and inhalation risks to occupational handlers of TCMTB by requiring closed loading systems to remove direct contact of the products by the applicator, for most materials preservatives uses, PF10 respirators for the sapstain control and leather preservation use, increased dermal protection for clean-up crews in sapstain control facilities, as well as use rate reductions to decrease the concentration of TCMTB in certain use scenarios. To mitigate aggregate risks to infants and children 1-2 years old, as well as aquatic organisms, the Agency proposes to prohibit the use of TCMTB in both recirculating and once-through cooling towers and to require a reduction in the use rate of papermill slimicides. Additionally, EPA proposes to revoke tolerances currently listed in the Code of Federal Regulations for residues of TCMTB in or on food commodities, as they are no longer in use.

Proposed Ecological Mitigation Measures

As noted previously, EPA has determined that PIDs and IDs issued under FIFRA should move the Agency forward in addressing its obligations under ESA. The proposed ecological mitigation measures in this section were developed to reduce exposure to nontarget species, including listed species, based on the risks and benefits of TCMTB. These measures are designed to help facilitate future ESA consultations by making early progress on incorporating mitigation

[41] Kline & Company (2017). Specialty Biocides: Regional Market Analysis 2016 – United States.

measures that are similar to the types of measures the Services are expected to provide in future Biological Opinions. Early mitigation is expected to shorten the current multiyear consultation process by frontloading mitigation measures that are likely to be required during consultation. It is also expected to further EPA's ESA obligations by improving the conservation status of listed species and possibly reduce the likelihood of a future jeopardy/adverse modification finding. In general, when a species is protected from threats, its vulnerability to extinction decreases, which in turn reduces the likelihood of a future jeopardy finding. The full extent of listed species protection, however, cannot be determined until formal consultation with the Services, when needed, is completed.

The proposed ecological mitigation measures for TCMTB are as follows:

- Prohibit the use of TCMTB in cooling water tower applications (both recirculating and once-through systems).
- Prohibit whitewater and other wet-end processes as an application point for papermill additives.
- Reduce use rate of slimicides used in pulp and papermills.

The proposed ecological mitigation measures in this PID are not designed to fully address ESA obligations for TCMTB. Rather, they are designed to reduce exposure to nontarget species, which may include listed species, while EPA moves toward full ESA compliance and a final registration review decision. Thus, EPA may propose additional mitigation measures as part of its various ESA initiatives (see the ESA Workplan Update[42]) to help further its ESA obligations. Additional measures may also be necessary when EPA consults, as necessary, with the Service(s) on TCMTB and receives a Biological Opinion with ESA-specific measures.

A. Proposed Risk Mitigation and Regulatory Rationale

1. Proposed Termination of Uses: Recirculating and Once-through Cooling Water Towers

The Agency proposes to terminate the use of TCMTB in cooling water towers. EPA identified aggregate risks of concern to children (from infants to age two) and ecological risks of concern to aquatic organisms (all taxa) associated with this use. For aggregate risks, the potential for exposure from this use occurs when intakes for drinking water supplies are downstream of cooling water tower systems that use products containing TCMTB. Exposure from the use of TCMTB in cooling towers was assessed and determined to be protective of exposure from the use of TCMTB in other industrial water systems, which comparatively release less effluent. When the cooling water tower use is removed from the aggregate risk assessment, the remaining use that contributes to the drinking water is effluent released from papermills, which is significantly less than when combined with cooling tower systems. The removal of the cooling tower use would result in no aggregate risks of concern when combining the remaining dietary and drinking water exposures to TCMTB.

[42] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf

For ecological risks, the potential for exposure arises downstream of areas where effluent from cooling towers is discharged. The prohibition of the use of TCMTB in cooling water tower systems would eliminate the potential for any effluent containing TCMTB from this use, and would eliminate the risks of concern posed to aquatic organisms from this use. Although the Agency is not making a complete endangered species finding at this time, because this change would be expected to eliminate exposure to aquatic taxa from the cooling water tower use of TCMTB, this change would also be expected to reduce the effects on listed species whose range and/or critical habitat co-occur with the use of TCMTB.

The registrants for products with cooling water tower uses committed to removing this use from their labels. Market data available to the EPA indicate that TCMTB is a widely used biocide for this use pattern; however, there are available and viable alternatives. The Agency does not have any information indicating important niche uses of TCMTB in cooling water tower systems. Moderate impacts are anticipated from the termination of this use.

2. Proposed Label Clarification: Prohibit Paper Additive Use on Food-Contact Paper

The Agency proposes to require label amendments to prohibit the use of TCMTB in paper additives intended for food-contact paper products. This action would remove chronic dietary risks of concern identified in the DRA for infants, children 1-2 years old, and children 3-5 years old. Additionally, there are no FDA clearances for this use of TCMTB. In public comments, the registrant indicated their company is willing to amend their labels to clarify that this use is not permitted, limiting the use of their products to non-food contact paper products only. The Agency expects low impacts from this label clarification.

3. Proposed Use Limitation: Prohibit Application Point for Wet Lap/Sheet Pulp Preservation

EPA proposes to prohibit the application of materials preservatives containing TCMTB from process water in papermills (also referred to as whitewater) for the purposes of preserving wet lap/sheet pulp. This would partially address risks of concern posed to aquatic organisms by preventing this use from contributing to papermill effluent. By removing this point of application, remaining wet lap/sheet pulp preservation would be limited to “dry-end” application in papermills, which does not result in ecological exposure to aquatic receptors. Although the Agency is not making a complete endangered species finding at this time, because this change would be expected to reduce exposure to aquatic taxa from the wet-end uses (*i.e.*, whitewater) of TCMTB, this change would also be expected to reduce the effects on listed species whose range and/or critical habitat co-occur with the use of TCMTB.

The use of TCMTB to preserve wet lap would still be allowed when applied with applicator rolls or another application method that does not end up in the effluent of a papermill. The registrant has agreed to this adjustment on their labels. The Agency expects low impacts from prohibiting the application method for wet lap/sheet pulp preservation in whitewater.

4. Proposed Closed Loading Requirements: Materials Preservation (excluding Leather Preservation and Wet Lap/Sheet Pulp) and Drilling Fluids (Oil and Gas Settings)

To address inhalation and dermal risks of concern posed to occupational handlers, EPA proposes to require engineering controls that achieve closed loading for all materials preservation uses (with the exception of leather preservation) as well as for drilling fluid uses. In a public comment, the registrant indicated that it was important for leather preservation facilities to be able to apply TCMTB via open pouring on the wet blue leather, and risks identified from this use can be effectively mitigated with other measures. Additionally, in conversations with the registrant, they indicated that TCMTB is applied via rollers for the wet lap/sheet pulp preservation use scenario in papermills. Based on the maximum allowable use rate for this scenario (600 ppm), this use does not result in inhalation or dermal risks of concern and does not need to be subject to the closed loading requirement since roller application is important for this use.

The occupational exposures from the materials preservation uses were evaluated and determined to be protective of occupational exposures from industrial processes and water systems uses of TCMTB. Drilling fluids are the only industrial processes and water systems use that triggers risk of concern based on the maximum allowable use rate for this scenario (10,000 ppm). All other industrial processes and water systems uses have lower use rates by comparison and do not trigger risks of concern for occupational handlers. By moving to closed loading, this would result in no unreasonable inhalation or dermal risks of concern to workers who apply products containing TCMTB for these uses. The Agency anticipates that for these uses, closed loading/metering systems are the normal practice and that this action would result in low impacts.

5. Proposed Label Mitigation: Application Rate Reductions for Sapstain Control and Papermill Slimicides Uses

Sapstain Control

To mitigate dermal risks of concern posed to clean-up crews, EPA proposes to reduce the maximum application rate allowed for anti-sapstain products to 0.125% TCMTB (from 0.29%), which raises the MOE to 181 from 78, which is still of concern because it is below the LOC of 300. The registrant indicated in their public comment this is the lowest concentration at which the sapstain control products would still be efficacious for wood preservation. The registrant also stated that clean-up activities occur less frequently than assumed in the DRA and are performed by a contracted third-party that wears hazardous materials suits. Submitted human exposure data from sapstain control facilities, which was used to inform the DRA, indicate that there is more routine clean-up occuring beyond the tank cleaning as suggested in the registrant's comment, and the Agency assumes that PPE (e.g., long sleeves, pants, and gloves) described on sapstain control labels is worn by clean-up crews . Because of this, additional mitigation is required to reduce dermal risks to clean-up crews in this setting, which is described in the next subsection. The Agency anticipates low impacts from this mitigation measure.

Pulp and Papermill Slimicides

The Agency proposes to lower the maximum allowable application rate for slimicides for use in pulp and papermills to address ecological risks of concern posed to aquatic organisms. It should be noted that this measure would also further reduce aggregate risks to children when combined with the mitigation proposed above to prohibit the use of TCMTB in cooling water towers. During the public comment period, the registrant clarified that the maximum use rate for use in the wet-end of papermaking (*i.e.*, slimicide use) is 75 ppm, and that the preservation of wet lap is not a slimicide use (maximum use rate 600 ppm). The Agency agrees with this characterization after the mitigation proposed above to prohibit the application point for wet lap preservation from being added to the whitewater or stock. However, even with this lowered application rate to 75 ppm, exceedances of concentrations of concern remain for average use scenarios, especially for freshwater fish. EPA proposes to further reduce the maximum application rate for slimicides containing TCMTB used in papermaking to 45 ppm. The registrant indicated this is the lowest use rate that would still be efficacious, but the Agency acknowledges that this does not fully eliminate risks of concern for aquatic organisms. The Agency solicits public comment on the viability of alternative chemistries used in papermill slimicides, or for data that would refine conservative modeling of exposures. EPA anticipates low impacts from this mitigation measure.

Although the Agency is not making a complete endangered species finding at this time, because this change would reduce exposure to aquatic taxa from the pulp and papermill slimicide use of TCMTB, this change would also be expected to reduce the effects on listed species whose range and/or critical habitat co-occur with the use of TCMTB.

6. Proposed Label Mitigation: Personal Protective Equipment for Sapstain Control and Leather Preservation Uses

EPA proposes adding a respirator statement to TCMTB products with anti-sapstain uses requiring a respirator with a protection factor (PF) of 10. With this mitigation measure, there would no longer be inhalation risks of concern posed to workers who clean tanks after use of products containing TCMTB. This requirement already is captured on all anti-sapstain products with the exception of EPA Reg. No. 1448-55, and the registrant has agreed to submit a label amendment to address this. The Agency expects low impacts from adding a PF10 respirator requirement for this use.

Because dermal risks of concern remain for sapstain control products containing TCMTB after reducing the application rate to the lowest efficacious rate, the Agency also proposes to require additional dermal protection for clean-up crews in the form of chemical-resistant coveralls composed of PVA, PVC, neoprene, or NBR (Buna-N) in addition to the required base PPE. EPA is exploring the feasibility of this mitigation measure and seeks public comment on any barriers to implementation, or alternative approaches to reducing dermal risks of concern. EPA anticipates moderate impacts from this proposed measure.

For leather preservation, EPA also proposes to require a PF10 respirator to address inhalation risks of concern. In a public comment, the registrant indicated it is important to retain the ability to apply TCMTB via open pouring for this use, and no dermal risks of concern are triggered at

the existing maximum application rate (2,500 ppm, the threshold for dermal risk was identified at or above 2,750 ppm in the DRA). In lieu of requiring closed loading for this use, EPA has determined it is acceptable to require use of a respirator to address inhalation risks of concern. This requirement already is captured on all products with the exception of EPA Reg. No. 1448-55, and the registrant has agreed to submit a label amendment to update the labels accordingly. The Agency expects low impacts from adding a PF10 respirator requirement for this use.

B. 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. The Agency seeks information on any other 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 TCMTB compared to the general population or who may otherwise be disproportionately affected by the use of TCMTB as a pesticide.

C. Tolerance Actions

The Agency proposes to revoke tolerances in 40 C.F.R. § 180.288 for residues of TCMTB in or on food commodities. There are no registered products for use on these food commodities. EPA will use its FFDCA rulemaking authority to pursue tolerance changes.

D. Proposed Interim Registration Review Decision

The Agency is issuing this PID in accordance with 40 C.F.R. §§ 155.56 and 155.58.[43] Based on the Agency's review of TCMTB at this time in the registration process, EPA has proposed in this proposed interim decision certain necessary changes to the affected registrations and their labeling. EPA proposes that the mitigation specified in Sections IV.A and Appendices A and B will address the majority of the risks of concern identified at this point in the ongoing registration review process. For the remaining ecological risks of concern from the use of TCMTB in papermill slimicides, the proposed mitigation is directionally correct and intended to reduce these risks in acknowledgment of the conservatism of the modeling assumptions and the benefits provided by this use.

At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[44] Issuance of this PID is not a proposed decision on whether TCMTB registrations "continue to satisfy the FIFRA standard for

[43] This document does not "complete" a registration review within the meaning of 7 U.S.C. section 136a(g) and is not a "registration review decision" within the meaning of 40 C.F.R. 155.57.
[44] 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]").

registration." EPA may include additional mitigations in its proposed registration review decision.

The Agency conducted detailed human health and environmental risk assessments. In these risk assessments, EPA identified inhalation and dermal risks of concern to occupational handlers from the use of TCMTB in materials preservation and industrial processes and water systems, dietary risks of concern to infants and children from paper additives used in food-contact paper, aggregate risks of concern to infants and children from cooling water towers and paper mill slimicides, and ecological risks of concern to all aquatic taxa from cooling water towers and paper mill uses (slimicides and additives applied via whitewater/stock). The Agency proposes to mitigate these risks by terminating the use of TCMTB in recirculating and once-through cooling water towers, prohibiting application of paper mill additives in food-contact paper and via whitewater/stock for non-food contact paper, requiring a reduction in use application rates for multiple uses (paper mill slimicides, sapstain control), requiring PF10 respirators for sapstain control and leather preservation uses, and requiring closed loading application methods for materials preservatives (excluding leather preservation) and drilling fluids. EPA proposes that the mitigation described in Section IV.A. is necessary due to risks identified for aquatic taxa resulting from TCMTB use in industrial water systems and as a wood preservative for sapstain control.

The proposed mitigation described in Section IV.A. is also intended to meet EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the *Federal Register* between December 29, 2022, and October 1, 2026, for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]."

The proposed mitigations identified in this PID would reduce TCMTB's effects on listed species or any critical habitat because exposures to aquatic environments would be reduced.

Section 711 also requires EPA to "take into account the input" of the Secretary of Agriculture and other members of the interagency working group, established under FIFRA Section 3(c)(11), in developing such measures. EPA plans to obtain input on various types of mitigation measures, including those described in this PID, consistent with section 711, prior to issuing the Interim Decision for TCMTB. EPA will take any input provided on the measures detailed above into account during the development of the Interim Decision for TCMTB.

EPA also determined that continuing to register TCMTB provides benefits for registered uses, which include controlling microbial growth in papermaking to encourage recycling of water (decreasing intake of water from the local environment), facilitating commerce of paper, leather, and wood by preventing fungal growth in materials and wood preservatives, and preventing spoilage of additives intended to make drilling operations safer in oil and gas extraction.

The Agency proposes to revoke all tolerances for residues of TCMTB in or on specific food commodities that are no longer in use, using EPA's authority under FFDCA.

In this PID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of TCMTB. Similarly, the Agency is not making a complete endangered species finding, though the proposed termination of cooling water tower uses and mitigation of pulp and papermill slimicide uses, if finalized, are expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range or critical habitat co-occur with the use of TCMTB. The Agency will complete a listed-species assessment and meet its Endangered Species Act (ESA) section 7 obligations (e.g., initiate any necessary Section 7 consultation with the Services). Additionally, EPA also intends to address its EDSP obligations under FFDCA section 408(p) before issuing a final registration review decision for TCMTB. For more information, see Appendices C and D.

E. Data Requirements

EPA does not anticipate calling in additional data for TCMTB's registration review at this time.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of the TCMTB PID and open a 60-day comment period. The Agency may issue an Interim Registration Review Decision (ID) for TCMTB after the close of this comment period if commenters do not submit significant comments or additional information that lead the Agency to change the proposed interim decision in Section IV.D, above. The Agency may make a final registration review decision for TCMTB without previously issuing an ID. However, a final registration review decision for TCMTB will only be made after EPA completes (1) a nationwide endangered species determination and, (2) meets the Agency's ESA section 7 obligations (e.g., initiate any necessary consultation with the Services, consistent with ESA § 7(a)(2)). The Agency also intends to address its EDSP obligations under FFDCA section 408(p).

B. Implementation of Mitigation Measures

If EPA posts an ID to the public docket, the TCMTB registrants will be expected to submit amended labels, include the label changes described in Appendices A and B, and requests for amendment of registrations within 60 days.

Appendix A: Summary of Proposed Actions for TCMTB

Registration Review Case #: 2625 PC Code: 035603					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
• Infants, children 1-2, children 3-5	• Dietary	• Ingestion (indirect dietary exposure)	• Chronic	• Chronic toxicity	• Prohibit the use of paper additives in food-contact paper • Tolerance revocation
• Infants, children 1-2	• Aggregate (dietary + drinking water)	• Ingestion (indirect dietary exposure and drinking water)	• Chronic	• Chronic toxicity	• Use termination of cooling water towers • Use rate reduction for pulp and papermill slimicides • Tolerance revocation
• Occupational handlers	• Open pour applications • Cleaning up during ongoing application of chemical	• Inhalation • Dermal	• Acute • Sub-chronic • Chronic	• Inhalation toxicity • Dermal toxicity • Dermal sensitization	• Closed loading for materials preservatives (except leather and sheet pulp/wet lap preservation) and drilling fluids • Use rate reduction for sapstain control • Respiratory PPE (PF10 respirator) for sapstain control and leather preservation • Coveralls requirement for clean-up crew in sapstain control settings
• Aquatic organisms (all)	• Effluent from wastewater treatment plants downstream of use	• Ingestion • Dermal absorption • Foliar absorption	• Acute • Chronic	• Reproductive • Reduction in growth • Survival • Reductions in biomass (aquatic plants)	• Use termination of cooling water towers • Use rate reduction for pulp and papermill slimicides • Prohibit application of sheet pulp/wet lap preservative in whitewater/stock

Appendix B: Proposed Labeling Changes for TCMTB Products

Description	Proposed Label Language for TCMTB Products	Placement on Label
Technical and Manufacturing Use Products		
Use Deletion	Remove the following use sites: cooling water towers (recirculating and/or once-through).	N/A
End Use Products		
Use Deletion	Remove the following use sites from the label: cooling water towers (recirculating and/or once-through).	N/A
Updated Respirator Language for PF10	**For sapstain control and leather preservation products:** [**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products. [**Note to registrant:** For respiratory protection from organic vapor **and** particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full-face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Respirator Fit Testing Requirements for Non-WPS Uses	**For sapstain control and leather preservation products:** **"Respirator fit testing, medical qualification, and training**	In the Personal Protective Equipment (PPE) within the Precautionary Statements

	Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements."	
Additional Dermal PPE Requirement for Sapstain Control Clean-Up Crews	"Clean-up crews must wear chemical-resistant coveralls composed of PVA, PVC, neoprene, or NBR (Buna-N) in addition to base PPE described in this section."	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Clarification of Use Site for Paper Additives	"This product is not to be used as a materials preservative in paper intended for food-contact uses."	Directions for Use
Closed Loading Requirement for Materials Preservation Uses (Excluding Leather and Wet Lap Preservation) and Drilling Fluids in Oil and Gas Settings	"This product must be applied in a way that achieves closed loading."	Directions for Use
Use Rate Reductions for Sapstain Control Use	The maximum allowable use rate for sapstain control must not exceed 0.125% TCMTB in solution.	Directions for Use
Use Rate Reductions for Papermill Slimicide Use	The maximum allowable use rate for papermill slimicides must not exceed 45 ppm TCMTB.	Directions for Use
Application Restriction for Wet Lap/Sheet Pulp Preservation	Remove references to whitewater, stock, and/or other wet-end applications for wet lap/sheet pulp preservation.	Directions for Use

Appendix C: Listed-Species Assessment

This Appendix provides general background about the Agency's assessment of the effects of pesticides on listed species and designated critical habitats under the Endangered Species Act (ESA).

Developing Approaches for ESA Assessments and Consultation for FIFRA Actions

In 2015, EPA, along with the Services—the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[45] for assessing the effects of pesticides to listed species. The agencies jointly developed these Interim Approaches in response to the 2013 National Academy of Sciences' recommendations that discussed specific scientific and technical issues related to the development of assessments of pesticides' effects to listed species. Since that time, the agencies have been continuing to work to improve the approaches for assessing effects to listed species. After receiving input from the Services and USDA on proposed revisions to the interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* ("Revised Method") in March 2020.[46]

The agencies also continue to work collaboratively through a FIFRA Interagency Working Group (IWG). The IWG was created under the 2018 Farm Bill to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[47]

Consultation on Chemicals in Registration Review

EPA initially conducted biological evaluations (BEs) using the interim method on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned as the start of an iterative process. Later that year, NMFS issued a final biological opinion for these three pesticides. In 2019, EPA requested to reinitiate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 biological opinion. EPA received a final malathion biological opinion[48] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.[48] The Agency plans to implement

[45] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report
[46] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional
[47] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act
[48] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.

both biological opinions according to the 18-month timeframes specified in the biological opinions.

In 2020, EPA released draft BEs for the first two chemicals conducted using the 2020 Revised Method—carbaryl and methomyl. Subsequently, EPA has used the Revised Method to complete final BEs for carbaryl, methomyl, atrazine, simazine, glyphosate, clothianidin, imidacloprid, and thiamethoxam. EPA is currently in consultation with the Services on these active ingredients.

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy[49] to evaluate potential effects of new conventional pesticide active ingredients to listed species and their designated critical habitat and initiate consultation with the Services, as appropriate, before registering these new pesticides. Before the Agency registers new uses of pesticides for use on pesticide-tolerant crops, EPA will also continue to make effects determinations. If these determinations are likely to adversely affect determinations, the Agency will not register the use unless it can predict that registering the new use would not have a likelihood of jeopardizing listed species or adversely modifying their designated critical habitats. EPA will also initiate consultation with the Services as appropriate.

In April 2022, EPA released a comprehensive, long-term approach to meeting its ESA obligations, which is outlined in *Balancing Wildlife Protections and Responsible Pesticide Use.*[50] This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

On November 16, 2022, EPA released the *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions*.[51] As part of this update, EPA announced its plan to consider and include, as appropriate, a menu of FIFRA Interim Ecological Risk Mitigation intended to reduce off-target movement of pesticides through spray drift and runoff in its registration review actions. These measures are intended to reduce risks to nontarget organisms efficiently and consistently across pesticides with similar levels of risk. EPA expects that these mitigation measures may also reduce pesticide exposures to listed species.

[49] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides.
[50] https://www.epa.gov/endangered-species.
[51] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for TCMTB, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA §408(p), TCMTB is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

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." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1[52] chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[53] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. TCMTB is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, visit the EPA website.[54]

EPA's EDSP is actively pursuing the application of new approach methods (NAMs) to create a more efficient and robust screening program. In October 2020, EPA underwent a reorganization and the EDSP was moved to the Office of Pesticide Programs. This reorganization provides

[52] See https://www.regulations.gov/document/EPA-HQ-OPPT-2004-0109-0080 for the Final First List of Chemicals for Tier 1 Screening in the EDSP.
[53] See https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0477-0074 for the Final Second List of Chemicals for Tier 1 Screening in the EDSP.
[54] https://www.epa.gov/endocrine-disruption

better alignment of the EDSP with the procedures and methods used by the program offices. On July 28, 2021, the Office of Inspector General (OIG) released its new report on the EDSP and made ten recommendations. EPA looks forward to working with stakeholders and the scientific community to accelerate the implementation of this important program into pesticide risk assessments and decision making.

In this PID, EPA is making no human health or environmental safety findings associated with the EDSP screening of TCMTB. Before completing this registration review, the Agency intends to address its EDSP obligations under FFDCA §408(p).