Docket Number EPA-HQ-OPP-2023-0094
www.regulations.gov

Tolclofos-Methyl Preliminary Work Plan

Registration Review: Initial Docket
Case Number 7069

March 2023

Approved by: _____
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Director
Pesticide Re-evaluation Division

Date: 03/30/2023

Table of Contents

References:

This Preliminary Work Plan summarizes the Environmental Protection Agency's current position based on the following documents:

1. *Tolclofos-methyl: Problem Formulation for Registration Review*. Mohammed Ruhman and Hannah Yingling. March 2, 2023.

2. *Tolclofos Methyl. Scoping Document: Recommendation for Anticipated Data and Human Health Risk Assessments for Registration Review*. Adrian Britt, Sheila Piper, and Victoria Kurker. January 11, 2023.

3. *Tolclofos-Methyl: Summary of Hazard and Science Policy Council (HASPOC) Meeting on September 1st, 2022: Recommendations on the Need for a Multi-Generation Reproduction Study, 90-Day Inhalation Toxicity, 90-Day Dermal Toxicity Studies, a Developmental Neurotoxicity Study, a Developmental Toxicity Study in the Rabbit, and an In-Vivo Cytogenetics Study*. Zachary Staley. September 8, 2022.

4. *Tolclofos-Methyl: Tier I Scoping Review of Human Incidents and Epidemiology*. Shanna Recore, Elizabeth Evans, and Erin Jones. March 16, 2022.

These and other supporting documents for the tolclofos-methyl registration review case may be found in the docket EPA-HQ-OPP-2023-0094 at www.regulations.gov.

OVERVIEW

The docket for tolclofos-methyl is now open, initiating the first public comment period for this registration review case (docket EPA-HQ-OPP-2023-0094). Tolclofos-methyl (PC Code 128905) is a fungicide used as a seed treatment to protect against soil-borne and seed-borne fungal pathogens that cause seed decay and seedling blights. The mode of pesticidal action as a fungicide is via oxidative deterioration of fungal lipids. Tolclofos-methyl is a member of the FRAC[1] 14 mode-of-action group.

Tolclofos-methyl is registered for seed treatment use on various crops, turf grass, ornamental flowers, and conifers. There are eight active Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3 end-use product registrations and one technical registration for tolclofos-methyl. The end-use product registrations are for both commercial and on-farm seed treatment. The end-use products are formulated as a liquid with tolclofos-methyl alone or combined with other fungicides (*e.g.,* difenoconazole, fludioxonil, imidacloprid, ipconazole, mefenoxam, metalaxyl, thiabendazole). There are no residential uses of tolclofos-methyl.

This Preliminary Work Plan (PWP) explains what the United States Environmental Protection Agency (hereafter, EPA, or the Agency) knows about tolclofos-methyl, highlights anticipated data and risk assessment needs, identifies the types of information that would be especially useful to the Agency in conducting registration review, and provides an anticipated timeline for completing the registration review of tolclofos-methyl.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders and the general public. EPA intends, by sharing this information in the docket, to inform the public and solicit information that would be helpful for the Agency to consider as it moves toward a registration review decision on tolclofos-methyl. The Agency encourages all interested stakeholders to review the PWP and Appendix and to provide comments and additional information that will help EPA's decision-making process for this chemical. In addition to general topics relating to tolclofos-methyl, there are some gaps identified in the PWP and Appendix about which the Agency specifically seeks comments and information. Interested stakeholders could include environmental non-profit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, and other users of pesticides; or the public at large.

The PWP begins with an overview of tolclofos-methyl. Next, it discusses the statutory and regulatory authority for registration review. Then, the document provides chemical facts, use and usage information, recent actions, the anticipated data needs and risk assessments, and a projected registration review timeline for tolclofos-methyl. Finally, the Appendix to this document includes identification and discussion of some areas that are considered generally in registration review along with some additional chemical case-specific information.

[1] The fungicide resistance action committee (FRAC) assigns fungicides a code to group active ingredients which demonstrate potential for cross resistance because they have the same target site.

STATUTORY AND REGULATORY AUTHORITY

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act (FQPA) of 1996, 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. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The initial registration review covered all pesticide products registered prior to October 1, 2007, which included over 1,100 pesticide active ingredients. Subsequent registration reviews begin on a revolving basis, with chemicals going through the process no later than 15 years after either the date on which the initial registration review is completed or the date products containing the active ingredient were first registered. The publication of this PWP initiates the first round of registration review of tolclofos-methyl.

The regulations governing registration review begin at 40 CFR § 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop a Final Work Plan (FWP) and anticipated schedule for the registration review of tolclofos-methyl.

CHEMICAL AND REGULATORY INFORMATION

Table 1 provides a summary of the chemical identification and pesticide registration for tolclofos-methyl.

Table 1: Chemical Facts for Tolclofos-Methyl	
PC code(s)	128905
Case Number	7069
CAS Number	57018-04-9
Year first registered	2013
Pesticide Type	Fungicide
Chemical class	Organophosphorous compound
Mode of Action Group Number	FRAC 14

Table 1: Chemical Facts for Tolclofos-Methyl	
Date of last Registration Review Decision	N/A
Cumulative group	Not applicable. Tolclofos-methyl is an organophosphorus fungicide but is not included in the organophosphate (OP) chemical class due to differences in the mode of action, toxicity, and chemical structure relative to other registered OPs. As a result, EPA concludes that tolclofos-methyl does not have a common mechanism of toxicity with other substances.
Tolerances	Tolerances are not required for the registered seed treatment uses of tolclofos-methyl as they are determined to be non-food uses.
Dual-use	Products containing tolclofos-methyl are registered for conventional pesticidal uses only and have no registered antimicrobial or biopesticidal uses.
Non-pesticidal uses	There are no identified non-pesticidal uses of tolclofos-methyl.
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USE AND USAGE INFORMATION

Tolclofos-methyl is a fungicide that was first registered for use in 2013. There are eight FIFRA Section 3 end-use registrations and one technical registration. Tolclofos-methyl is registered for use solely as a seed treatment for the control and suppression of various soil-borne and seed-borne fungal pathogens for the following crops: crop group 1A root vegetables (excluding burdock, turnip-rooted chervil, ginseng, horseradish, salsify, black salsify, Spanish salsify and skirret); crop group 3-07 bulb vegetables (such as pearl or green onions but excluding daylily bulb, Elegans Hosta, fritillaria bulb and leaves, garlic bulb, great-headed garlic bulb, serpent garlic bulb, lily bulb, Chinese onion bulb, macrostem onion bulb, potato onion bulb, tree onion tops, Welsh onion tops, and shallot bulb and fresh shallot leaves); crop group 4 leafy vegetables (except brassica vegetables); crop group 5 brassica (cole) leafy vegetables; crop group 6 succulent or dried legume vegetables; crop group 8-10 fruiting vegetables; crop group 9 cucurbit vegetables; crop group 15 cereal grains (except rice and wild rice); crop group 17 grass forage, fodder, and hay; crop group 18 non-grass animal feeds (forage, fodder, straw and hay); crop group 19 herbs and spices; crop group 20 oilseeds (except cotton); cotton; ornamental flowers; and conifers. Tolclofos-methyl may be applied to the seed in commercial facilities as well as on-farm.

There are limited commercial or on-farm seed treatment data upon which to make reliable and quantifiable estimates of tolclofos-methyl usage at this time. Thus, the absence of a seed treatment usage analysis here should not be interpreted as lack of seed treatment usage. Table 2 summarizes the use and usage information for tolclofos-methyl.

Table 2: Tolclofos-Methyl Use and Usage Information	
Summary of Use	Fungicide member of FRAC 14
Use Sites	Registered for seed treatment use only on cereal grains; conifers; cotton; grass/non-grass (forage, fodder, straw, and hay); herbs and spices; oilseeds; ornamental flowers; and vegetables (brassica, bulb, cucurbits, fruiting, leafy, legumes, and root).
Summary of Usage	There are limited data available. The absence of seed treatment usage analysis should not be interpreted as lack of seed treatment usage.
Formulation Type(s)	Liquid
Application Method(s)	Commercial and on-farm seed treatment seed treatment
Technical Registrant(s)	Valent U.S.A. Corporation
No. of Registrations	1 FIFRA Section 3 technical registration 8 FIFRA Section 3 end-use registrations 0 FIFRA Section 24(c) (special local needs—SLN) registrations
Restricted Use	Tolclofos-methyl has no products that are classified as restricted use.

Guidance for Commenters: Additional areas of *use and usage related information* requested for this registration review, and of particular interest to EPA, are described below.

- Usage data for tolclofos-methyl by use site. Data of interest includes application rate per seed, maximum seeding rate, and percent of seed treated with tolclofos-methyl by registered crop and geographic unit (*e.g.,* national, region, state).
- Additional supplementary use/usage information beyond what is requested in the previous bullet, that the commentor thinks would be useful to the Agency.
- Foreign technical registrants not listed above who supply technical tolclofos-methyl to the U.S. market.

RECENT ACTIONS

Products containing tolclofos-methyl were first registered in 2013. Additional end-use products were registered in 2018 and 2020. In 2022, four more end use products containing tolclofos-methyl were registered. There are now eight end-use product registrations and one technical registration for tolclofos-methyl.

In April 2017, EPA received a petition filed by the Center for Food Safety (CFS) with and on behalf of beekeeper, farmer, and public interest groups asking the Agency to interpret or amend the treated article exemption at 40 C.F.R. 152.25(a) so that it does not cover seeds treated with

systemic pesticides, and to aggressively enforce registration and labeling requirements for such treated seed. CFS claims that EPA did not adequately assess the risks from use of seed treatment pesticides that have systemic properties and thus the treated article exemption does not apply to seed treated with such pesticides. EPA issued the response to the petition on September 28, 2022, explaining the background of the treated article exemption at 40 C.F.R. 152.25(a) and the conditions that must be met for pesticide treated seed to be exempt from registration requirements under that regulatory exemption.[2] EPA also explained that it intends to issue an advanced notice of proposed rulemaking (ANPRM) by the end of 2023 to seek additional information on whether or to what extent pesticide-treated seed is being distributed, sold, or used in a manner inconsistent with treating pesticide labeling. As part of the ANPRM, EPA will also explore the option of issuing a rule pursuant to FIFRA section 3(a) to regulate pesticide-treated seed to ensure distribution, sale, and use of the treated seed is consistent with treating pesticide and treated seed labeling instructions. Comments received on the ANPRM and potential rulemaking could affect registration review cases for active ingredients with seed treatment uses, including tolclofos-methyl.

ANTICIPATED DATA NEEDS

The Agency anticipates calling in data in support of the tolclofos-methyl registration review case. These data are needed to assess the potential risks to human health and the environment. EPA anticipates issuing a data call-in (DCI) to obtain these data. The anticipated data needs are outlined in Table 3. Additional pollinator data are necessary to fully evaluate risks to nontarget terrestrial invertebrates based on the June 2014 *Guidance for Assessing Pesticide Risks to Bees*. The anticipated pollinator studies are also listed in Table 3.

Table 3: Anticipated Data Needs for the Tolclofos-Methyl Registration Review

Guideline Number	Study Title	Test Material	Estimated Timeframe (Months from receipt of DCI)
835.4400	Anaerobic aquatic metabolism (using two systems - river and pond)	TGAI or PAIRA	24
850.1400	Fish early-life stage toxicity test (using freshwater fish)	TGAI	12
850.4400	Aquatic plant toxicity test (using *Lemna spp.*)	TEP or TGAI	12
850.4550	Cyanobacteria (*Anabaena flos-aquae*) toxicity	TEP	12
850.4500[3]	Algal toxicity (using marine diatom)	TEP or TGAI	12
870.3465	90-day inhalation toxicity	TGAI	24

[2] EPA's response to the petition can be found in the public docket (EPA-HQ-OPP-2018-0805) at www regulations.gov.

[3] OCSPP 850.4500 (Algal toxicity using marine diatom) was formerly OPPTS 850.5400 (Algal toxicity).

Table 3: Anticipated Data Needs for the Tolclofos-Methyl Registration Review			
Guideline Number	**Study Title**	**Test Material**	**Estimated Timeframe (Months from receipt of DCI)**
Pollinator Data Requirements[4]			
Non-guideline (OECD TG 213)	Honey bee adult acute oral toxicity (Tier 1)	TGAI	12
Non-guideline (OECD TG 237)	Honey bee larvae acute toxicity (Tier 1)	TGAI	12
Non-guideline (OECD TG 245)	Honey bee adult chronic oral toxicity (Tier 1)	TGAI	12
Non-guideline (OECD TG 239)	Honey bee larvae chronic toxicity (Tier 1)	TGAI	12
Non-guideline	Semi-field testing for pollinators (Tier 2)	TEP	24
Non-guideline	Field feeding study for pollinators (Tier 2)	TEP	24
Non-guideline	Field trial of residues in pollen and nectar (Tier 2)	TEP	24
850.3030	Honey bee toxicity of residues on foliage (Tier 2)	TEP	12
850.3040	Field Testing for Pollinators (Tier 3)	TEP	24
TGAI = technical grade active ingredient; PAIRA = Pure active ingredient radio-labeled; TEP = typical end-use product			

For additional discussion of the anticipated data needs, see the *Tolclofos-methyl: Problem Formulation for Registration Review* and *Tolclofos Methyl - Scoping Document: Recommendation for Anticipated Data and Human Health Risk Assessments for Registration Review*.

ANTICIPATED RISK ASSESSMENTS FOR REGISTRATION REVIEW

The most recent comprehensive human health risk assessment for tolclofos-methyl was completed on November 20, 2012, when tolclofos-methyl was initially registered with EPA. The most recent ecological and environmental fate risk assessment was completed on August 3, 2012, for the same purpose. Findings and conclusions from these risk assessments are summarized in the *Tolclofos-methyl: Problem Formulation for Registration Review* and *Tolclofos Methyl - Scoping Document: Recommendation for Anticipated Data and Human Health Risk Assessments for Registration Review*.

During registration review, the Agency does anticipate the need to conduct new assessments or update elements of existing risk assessments for tolclofos-methyl. The anticipated assessments are outlined in Table 4. If toxicological endpoints or points of departure are revised based on the data that are anticipated to be required for registration review, they will be considered in the new

[4] The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

assessments, as well as any changes to the standard operating procedures or default exposure assumptions.

The Agency may need to reevaluate existing databases as well as any new data that may be submitted and any new routes of exposure will be considered. As EPA policies and models develop, assessment approaches may also change. Additionally, EPA teams plans to review labels to identify areas that may be lacking use parameters critical to risk assessment.

Table 4: Anticipated Risk Assessments for the Tolclofos-Methyl Registration Review

Type of Risk Assessment	Conduct?	Notes
Ecological and Environmental Fate		
Non-listed species	Yes	The Agency will use data expected during registration review to update risk assessments for estuarine/marine fish on a chronic basis, vascular aquatic plants, nonvascular marine diatom, and honeybees on an acute and chronic basis.
Drinking Water	No	Given the limited pattern of use (*i.e.,* seed treatment), the Agency does not expect exposure from drinking water; hence, a drinking water assessment is not needed at this time.
Incidents	Yes	The Agency will continue to monitor for ecological incidents and will conduct an incidents search as part of the planned risk assessment.
Human Health		
Dietary		
Food	No	Given the limited uses, non-food use determination, and low rates of application a dietary assessment is not needed at this time.
Residential		
Handlers	No	Products are not registered for residential use sites and therefore not used by residential handlers.
Post-application	No	Products are not registered for use on residential sites or golf courses.
Occupational		
Handlers (mixers, loaders, applicators)	Yes	The Agency will complete an updated occupational exposure assessment to reflect the updated seed treatment assessment.
Post-application	Yes	The Agency will complete an updated occupational exposure assessment to reflect the updated seed treatment assessment.
Non-occupational Exposure		
Spray drift	No	The Agency does not expect exposure in residential and non-occupational settings.
Bystander	No	The Agency does not expect exposure in residential and non-occupational settings.
Other Human Health		

Table 4: Anticipated Risk Assessments for the Tolclofos-Methyl Registration Review		
Type of Risk Assessment	**Conduct?**	**Notes**
Aggregate	No	An aggregate assessment combines pesticide exposures and risks from three major sources: food, drinking water, and residential/non-occupational exposures. The Agency does not expect exposure from food, drinking water, or in residential/non-occupational settings.
Cumulative	No	Tolclofos-methyl does not have a common mechanism of toxicity with other substances.
Tolerance changes required	No	No tolerances are required for the registered seed treatment uses of tolclofos-methyl as they are non-food uses.
Incident analysis, literature review	Yes	For a discussion of reported human incidents for tolclofos-methyl, see page 5 of the Scoping Document and the *Tolclofos-Methyl: Tier I Scoping Review of Human Incidents and Epidemiology*.
Other Considerations		
Domestic Animal Incidents	No	There are no residential pet uses.

Guidance for Commenters: Additional *ecological information, and human health information* requested for this registration review, and of particular interest to EPA, is described below.

- The amount of tolclofos-methyl added to 100 pounds of seed for each crop.
- Ecological incidents (nontarget plant damage and avian, fish, reptilian, amphibian, and mammalian mortalities) and human health incidents not already reported to the Agency.
- Water quality monitoring data (see Appendix for further details).

TIMELINE

EPA has created the following estimated timeline for the completion of the tolclofos-methyl registration review in Table 5.

Table 5: Projected Tolclofos-Methyl Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket	
Open Docket and 60-day Public Comment Period	April 2023
Close Public Comment	June 2023
Case Development	
Final Work Plan	October 2023
Issue DCI	April 2024
Data Submission	April 2026

Table 5: Projected Tolclofos-Methyl Registration Review Timeline	
Activities	**Estimated Date**
60-day Public Comment Period for Draft Risk Assessments[5]	August – September 2027

NEXT STEPS

After the 60-day public comment period closes, the Agency will review and respond to any comments received and then issue a Final Work Plan for the registration review of tolclofos-methyl.

[5] The regulations governing registration review generally require the Agency to provide a public comment period of at least 30 calendar days for draft risk assessments; see 40 CFR § 155.53(c). For conventional pesticides, the Agency plans to provide a 60-calendar day public comment period generally for draft risk assessments.

Appendix – Additional Areas Considered in the Tolclofos-Methyl Registration Review

PUBLIC COMMENTS AND FEEDBACK:

Guidance for Commenters: The areas below highlight topics of special interest to the Agency where your comments, data submissions, or reference to sources of additional information could be of particular use.

Trade Irritants:

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. The Agency will work to harmonize tolerances and international maximum residue limits (MRLs) and may modify tolerance levels to do so, when possible. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. Because tolclofos-methyl is not registered for food/feed uses in the U.S., it has no U.S. tolerances; therefore, the Agency does not anticipate any trade irritant issues.

Water Quality:

The Agency may establish a Total Maximum Daily Load, or TMDL, for pollutants, including a pesticide, to identify the maximum amount of a pollutant allowed to enter a waterbody so that the waterbody will meet and continue to meet water quality standards for that particular pollutant. More information on impaired water bodies and TMDLs can be found at the Agency's website.[6] The Agency invites submission of water quality data for this pesticide. Refer to the *OPP Guidance for Submission of State and Tribal Water Quality Monitoring Data*[7] for information on how EPA's Office of Pesticide Programs uses water monitoring data in pesticide risk assessment and the information that would be useful to include in submissions of water quality data.

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. To help address potential environmental justice issues related to registration review decisions, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to tolclofos-methyl compared to the general population or who may otherwise be disproportionately affected by the use of tolclofos-methyl as a pesticide. Please comment if you are aware of any such issues and can provide information to help the Agency to more fully consider and address potential environmental justice issues.

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[6] https://www.epa.gov/tmdl.

[7] https://www.epa.gov/pesticide-reevaluation/opp-guidance-submission-state-and-tribal-water-quality-monitoring-data.

FEDERALLY-THREATENED/ENDANGERED (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[8] 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.[9]

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.[10]

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[11] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.[12] The Agency plans to implement

[8] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report.
[9] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional.
[10] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act.
[11] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.
[12] 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[13] 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*.[14] 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*.[15] 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 and other FIFRA actions. These measures are intended to reduce risks to nontarget organisms efficiently and consistently across pesticides with similar levels of risks and benefits. EPA expects that these mitigation measures may also reduce pesticide exposures to listed species.

ENDOCRINE DISRUPTOR SCREENING PROGRAM:

As required by FFDCA § 408(p), tolclofos-methyl is subject to the Endocrine Disruptor Screening Program (EDSP).

The 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

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

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 is intended to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. 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. For further information on the status of the EDSP, please visit the EPA website.[16]

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 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[17]. On January 19, 2023 EPA released a draft White Paper for public comment, entitled Availability of New Approach Methodologies (NAMs) in the Endocrine Disruptor Screening Program (EDSP)[18], that describes validated NAMs that EPA may now accept as alternatives for certain EDSP tests. The draft White Paper presents several NAMs that would allow EPA to screen chemicals faster and more efficiently using alternatives to vertebrate animal testing and other in vitro, or in-the-laboratory, assays. NAMs are defined as any technology, methodology, approach, or combination that can provide information on chemical hazard and risk assessment to avoid the use of animal testing. EPA is also developing a strategic planning document for EDSP which will be available for public comment in 2023. EPA expects additional documents for public release in 2023-2024 that address aspects of EDSP chemical determinations. 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.

[16] https://www.epa.gov/endocrine-disruption.
[17] https://www.epa.gov/office-inspector-general/report-epas-endocrine-disruptor-screening-program-has-made-limited.
[18] https://www.regulations.gov/document/EPA-HQ-OPP-2021-0756-0002.