Thiencarbazone-methyl

Combined Work Plan and Proposed Interim Registration Review Decision Case Number 7276

December 2019

Approved by: _____

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I. INTRODUCTION

The docket for thiencarbazone-methyl (TCM) (PC Code 015804, case 7276) is now open, initiating the first public comment period for this registration review. This document is the Environmental Protection Agency's (the EPA or the agency) combined Work Plan, and Proposed Interim Registration Review Decision (PID) for TCM and is being issued pursuant to 40 CFR §§155.50 and 155.58. This document explains what the EPA's Office of Pesticide Programs (OPP) knows about TCM, including updated draft risk assessment findings, and provides an anticipated timeline for completing the TCM registration review. It also includes the agency's PID for TCM. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, a registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose 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. The agency is also issuing Draft Human Health and Ecological Risk assessments for TCM Registration Review at this time pursuant to 40 CFR §§155.56. Additional information on TCM can be found in the EPA's public docket (EPA-HQ-OPP-2019-0481) at www.regulations.gov.

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 the 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 EPA is issuing this combined Work Plan and PID for TCM so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, "the Services") to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although the EPA has not yet fully evaluated risks to federally-listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for TCM prior to completing the TCM registration review. Likewise, the

agency will complete endocrine screening for TCM, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the TCM registration review.

TCM is in the sulfonyl-amino-carbonyl-triazolinone (SACT) chemical family and is an acetolactate synthetase (ALS) inhibiting herbicide that is absorbed by foliage and roots and translocated throughout the plant. Currently, there are 15 registered products containing TCM, which provides both pre- and post-emergence control of a wide range of grasses and broadleaf weeds. TCM products are registered for use on agricultural and non-agricultural use sites, including corn (field, sweet, and pop); soybean; winter and spring wheat; as well as turf and ornamentals for commercial and residential settings. TCM is co-formulated and tank-mixed with other herbicides to increase the weed control spectrum allowing for single pass applications. The first product containing TCM was registered with EPA in 2008 and therefore, TCM was not subject to reregistration.

This document is organized in five sections: the *Introduction,* which includes this summary; *Use and Usage*, which describes how and why TCM is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Combined Work Plan, Draft Risk Assessment (DRA) and Proposed Interim Registration Review Decision (PID),* which describes the regulatory rationale for the EPA's PID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of TCM Registration Review

Pursuant to 40 CFR § 155.50, the EPA is initiating registration review for TCM with the opening of the registration review docket for the case.

- December 2019 - The agency is now announcing the availability of the combined Work Plan and PID in the docket for TCM for a 60-day public comment period. Along with the combined Work Plan and PID, the following documents are also posted to the TCM docket:
    - *Thiencarbazone-methyl: Scoping Document and Draft Risk Assessment for Registration Review*, dated November 14, 2019.
    - *Thiencarbazone-methyl (TCM): Problem Formulation, Draft Ecological Risk Assessment for Registration Review and Human Health Drinking Water Assessment for Registration Review*, dated November 18, 2019.
    - *Thiencarbazone-methyl: Tier I (Scoping) Review of Human Incidents and Epidemiology*, dated August 13, 2019.
    - *Thiencarbazone-methyl (015804) Screening Level Usage Analysis (SLUA),* dated April 29, 2019.

II. USE AND USAGE

TCM is in the sulfonyl-amino-carbonyl-triazolinone (SACT) class of herbicides and is an acetolactate synthetase (ALS) inhibitor in the Weed Science Society of America (WSSA) mode of action Group 2. Products containing TCM are registered for use on corn (field, sweet, and pop); soybean; winter and spring wheat; as well as turf and ornamentals for commercial and residential settings. Products containing TCM provide both pre- and post-emergence control of a wide range of grasses and broadleaf weeds. It is available in liquid and dry flowable powder formulations, including emulifable concentration, water dispersible granule, and granular, and may be applied by ground or aerial applications.

From 2013-2017, an average of 206,000 pounds of active ingredient (lb a.i.) of TCM was used each year to treat approximately 11 million acres of corn, soybeans, sweet corn, and spring and winter wheat[1,2]. The majority of thiencarbazone-methyl usage was on corn, with an average of 100,000 lb a.i. applied per year between 2008 and 2017[3]. In terms of percent crop treated (PCT) and acres treated, TCM usage was concentrated on corn (10 PCT, 8.6 million acres) and spring wheat (20 PCT, 2.1 million acres) from 2013-2017[2, 3]. On average, 1% of sweet corn acres grown were treated with TCM and less than 1% of soybeans and winter wheat acres grown were treated[4]. Recent available data does not report TCM usage on turf and ornamentals[4].

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment is presented 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 TCM. For additional details on the human health assessment for TCM, see the *Thiencarbazone-methyl: Scoping Document and Draft Risk Assessment for Registration Review*, which is available in the public docket.

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

The agency identified no dietary risks of concern for TCM. An acute dietary risk assessment was not conducted because no adverse effects attributable to a single dose were observed for TCM. No dietary cancer assessment was conducted because TCM is classified as not likely to be carcinogenic to humans. The chronic dietary (food and drinking water) risk estimates are

[1] Agricultural Market Research Data (AMRD), 2013-2017
[2] USDA National Agricultural Statistics Service (NASS), 2013-2017
[3] EPA Screening-Level Usage Analysis (SLUA), 2019
[4] Non-Agricultural Market Research Data (NMRD), 2012 & 2014

below the agency's level of concern (LOC) (<100% of the chronic population adjusted dose (cPAD)) for the general U.S. population and all population subgroups.

Residential Handler and Post-Application Risks

There is potential for residential handler (dermal and inhalation) and post-application (dermal) exposure to TCM associated with registered use on residential lawns, gardens, and trees. For residential handler assessment, EPA calculated combined risk estimates for dermal and inhalation exposure because the endpoint for each route of exposure is similar. There are no residential handler risks of concern with margins of exposure (MOEs) ranging from 18,000 to 1,500,000 (LOC = 100). The residential post-application risk assessment identified MOEs between 7,800 to 670,000, which are not of concern (LOC = 100).

Bystander Risks

A quantitative spray drift assessment for TCM was not required. The residential post-application assessment evaluated risks associated with TCM use on turf and is considered to be protective of bystander exposure to spray drift.

Aggregate Risks

EPA evaluated potential aggregate risk associated with the combined exposure from dietary and residential sources of TCM. An acute aggregate risk assessment was not conducted since an acute population adjusted dose (aPAD) was not identified in the dietary risk assessment. The chronic aggregate risk assessment is based on exposures to thiencarbazone-methyl in food and drinking water only, and is not of concern to the agency (risk estimates were <1% of the cPAD for all population subgroups).

A short- and intermediate-term aggregate risk assessment was performed for adults and children since there is potential for combined dietary and residential exposure from registered uses of TCM. The short-term aggregate assessments combined short-term post-application residential exposures with average background food and drinking water exposures and resulted in risk estimates below the LOC (<100% cPAD) for all population subgroups.

Cumulative Risks

The EPA has not made a common mechanism of toxicity to humans finding as to TCM and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the EPA has not assumed that TCM has a common mechanism of toxicity with other substances for this assessment.

Occupational Handler and Post-Application Risks

There is potential for occupational handlers to experience short- and intermediate term dermal and inhalation exposure to TCM, however risk estimates indicate no occupational handler risks

of concern. The MOEs range from 8,500 to 530,000 (LOC = 100) with baseline attire and chemical-resistant gloves, which are required based on existing TCM labels.

Occupational post-application exposure to TCM is also expected. EPA did not conduct a quantitative occupational post-application inhalation exposure assessment for TCM, however, the inhalation exposure assessment for occupational handlers discussed above resulted in higher exposure estimates than are expected for post-application exposure and is therefore considered to be protective of occupational post-application exposure scenarios.

EPA's occupational post-application risk assessment indicates that the dermal MOEs are not of concern (MOEs ranged from 2,000 to 250,000; LOC = 100). Therefore, the agency identified no occupational post-application risks of concern for TCM.

2. Human Incidents and Epidemiology

The agency has reviewed the available incident data for TCM (S. Recore, 8/13/2019, D453603) from January 1, 2014 to July 18, 2019. There were six incidents reported in the main incident data system (IDS) and nine incidents reported in the aggregate IDS. Based on the low frequency and low severity of TCM incidents reported to both the OPP IDS and the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides, there does not appear to be a concern at this time. The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

3. Tolerances

Tolerances currently established under 40 CFR §180.645 were updated in 2008[5] to comply with the HED Interim Guidance on Tolerance Expressions. There are no additional recommended changes to 40 CFR §180.645 at this time.

There are no established Codex MRLs for residues of TCM. There are established tolerances in Canadian MRLs for corn, wheat, and livestock commodities. The Canadian and US tolerance levels and MRLs are harmonized. Canada does not set MRLs on livestock feed items.

4. Human Health Data Needs

The toxicology database is complete for TCM. The agency does not anticipate any further human health data needs for the TCM registration review.

B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a streamlined risk

[5] Thiencarbazone-Methyl. Petition to Establish Permanent Tolerances for Use on Field Com, Pop Com, Sweet Com, and Wheat. Summary of Analytical Chemistry and Residue Data. May 28, 2008

assessment in support of the registration review of TCM. For additional details on the ecological assessment for TCM, see the *Thiencarbazone-methyl (TCM): Problem Formulation, Draft Ecological Risk Assessment for Registration Review and Human Health Drinking Water Assessment for Registration Review*, which is available in the public docket.

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its endangered species assessment for TCM. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

1. Risk Summary and Characterization

Terrestrial Risks

Mammals, Birds, Reptiles, and Terrestrial-Phase Amphibians

Acute risk estimates were not calculated for mammals and birds because mortality was not observed at the highest dose tested (limit dose). There were no chronic risks of concern identified for mammals or birds. In the ecological risk assessment, birds are used as surrogates for reptiles and terrestrial-phase amphibians, therefore there are no chronic risk quotient (RQ) exceedances for reptiles or terrestrial-phase amphibians. The chronic risk estimates were below the agency's LOC of 1 with dietary based RQs ranging from < 0.01 to 0.05 and dose based RQs ranging from <0.01 to 0.19 for mammals, and dietary based RQs of <0.01 to 0.12 for birds.

Terrestrial Invertebrates (honeybees)

The EPA did not identify a risk concern for acute exposure of adult honeybees to TCM. TCM is classified as "practically non-toxic" to adult honey bees on both acute contact and oral exposure basis. However, chronic risks to adult honey bees and acute risks to larval bees have not been determined at this time based on current information. Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators, based on the June 2014 Guidance for Assessing Pesticide Risks to Bees[6]. Therefore, the EPA is currently determining whether additional pollinator data are needed for TCM. If the agency determines that additional pollinator exposure and effects data are necessary, then the EPA will issue a data call-in (DCI) to obtain these data. The pollinator studies that could be required are listed in

Table 1 below.

[6] Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Table 1: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline (OECD 245)	Honey bee adult chronic oral toxicity
Non-Guideline (OECD 239)	Honey bee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar (tunnel or colony feeding studies)
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† 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.

Terrestrial Plants

The ecological risk assessment identified potential risks of concern for terrestrial plants with RQ's exceeding the LOC of 1 for monocots and dicots based on the highest TCM use rates (turf and ornamentals, spring wheat, and corn combined with post-harvest cropland). Potential risk to non-target plants could result from both spray drift (at 900+ feet from the field edge) and runoff from the treatment site. RQs range from 4.56 to 34.4 in dry areas, 25.1 to 189 for semi-aquatic areas, and 2.28 to 127 for spray drift only. The adverse effect endpoint is based on decreased biomass of plants in terrestrial and aquatic habitats. Incident data indicate damage to crops associated with the use of TCM.

Aquatic Risks

Fish, Aquatic-Phase Amphibians, and Aquatic Invertebrates

There were no acute or chronic risks of concern identified for fish and aquatic invertebrates. Acute RQs were not calculated for fish because mortality was not observed at the limit dose. There were no available chronic data for saltwater fish however, effects are not expected. The agency identified a chronic RQ of <0.01 for freshwater fish, which is below the agency's LOC of 1. Acute RQs were not calculated for freshwater invertebrates because the compound is practically non-toxic and no mortality was observed at the limit dose, butut the chronic RQ is <0.01, which is not of concern to the agency. For saltwater invertebrates, both acute and chronic RQs are <0.01, and not of concern.

Aquatic Vascular and Non-Vascular Plants

TCM is more toxic to vascular aquatic plants than to nonvascular aquatic plants. For nonvascular aquatic plants, the RQs for all uses of TCM are below the agency's LOC of 1. For vascular aquatic plants, the agency identified potential risks of concern with RQs up to 1.1 associated with TCM use on ornamentals and corn combined with post-harvest cropland. The observed adverse outcome included effects on plant length and growth rate.

2. Ecological Incidents

Since TCM was registered in 2008, there have been 25 incidents reported in IDS associated with the use of this compound, none of which involved adverse effects to animals. All of the reported incidents involved terrestrial plants (wheat, alfalfa, soybeans, corn) in the Midwest.

3. Ecological and Environmental Fate Data Needs

Given the uncertainties surrounding potential risks to terrestrial invertebrates, additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. The potential pollinator data are described in Table 1 of this document and EPA may issue a DCI for these data, if required.

C. Benefits Assessment

TCM is an acetolactate synthetase (ALS) inhibitor (Group 2) that is absorbed by foliage and roots and translocated throughout the plant[7]. It provides both pre- and post-emergence control of a wide range of grasses and broadleaf weeds[6, 7]. Examples of weeds TCM controls include johnsongrass (Sorghum halepense), wild buckwheat (Polygonum convolvulus), barnyardgrass (Echinochloa crus-galli var. crus-galli), wild mustard (Sinapis arvensis), and common lambsquarters (Chenopodium album) as well as suppression of canada thistle (Cirsium arvense) and field bindweed (Convolvulus arvensis) [8,9]. TCM is co-formulated and tank-mixed with other herbicides to increase the weed control spectrum allowing for single pass applications[8]. It is commonly mixed with safeners so that it may be directed at crops, thus increasing the ease of use of TCM[7]. TCM can provide control of glyphosate-resistant weeds, and can be used for resistance management[7].

IV. COMBINED WORK PLAN AND PROPOSED INTERIM REGISTRATION REVIEW DECISION

[7] Weed Science Society of America (WSSA). 2014. Herbicide Handbook. 10th Edition.
[8] Santel, H. (2012). Thiencarbazone-methyl (TCM) and Cyprosulfamide (CSA) – a new herbicide and a new safener for use in corn. 25th German Conference on Weed Biology and Weed Control. https://ojs.openagrar.de/index.php/JKA/article/download/1772/2115/0 [Accessed August 2019]
[9] PPDB. (2019). Thiencarbazone-methyl. Pesticide Properties DataBase. https://sitem.herts.ac.uk/aeru/ppdb/en/Reports/1241.htm [Accessed August 2019]

A. Proposed Risk Mitigation and Regulatory Rationale

As discussed in the ecological risk section of this document, the agency identified potential risks to non-target terrestrial and aquatic plants from spray drift and runoff. To address risks to non-target plants, the agency is proposing mandatory and advisory spray drift language to reduce the potential risks of concern. The agency is also proposing advisory language for surface water and groundwater, updated label language for gloves, and an updated REI. The technical registrant, Bayer CropScience, has agreed in principle to the proposed risk mitigation measures to address potential risk concerns using spray drift advisories. The EPA is also proposing label changes to address generic labeling requirements for all TCM products and uses. In evaluating potential risk mitigation for TCM, the EPA considered the risks, the benefits, and the use pattern. Although there are potential terrestrial plant risks of concern associated with the use of TCM, with the adoption of the mitigation measures discussed in this section, any remaining ecological risks are outweighed by the benefits associated with use of TCM.

1. Updated Glove Statements

The agency is proposing to update the glove statements currently on labels to be consistent with the Label Review Manual[10]. The proposed new glove language does not fundamentally change the personal protective equipment that workers need to use, and therefore should impose no impacts on users.

For gloves in particular, all statements that refer to the chemical resistance category selection chart are proposed to be removed from TCM labels, as they might cause confusion for users. These statements are proposed to be replaced with specific chemical-resistant glove types, as appropriate.

2. Spray Drift Management

The agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all TCM products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of TCM.

The agency is proposing the following spray drift mitigation language to be included on all TCM product labels for products applied by liquid spray application. The proposed spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The agency is providing recommendations which allow TCM registrants to standardize all advisory language on TCM product labels. Registrants must ensure that any existing advisory

[10] https://www.epa.gov/pesticide-registration/label-review-manual

language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this PID, once effective.

- Applicators must not spray during temperature inversions.
- For aerial applications, do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.
- For ground boom applications, users must only apply with the release height recommended by the manufacturer, but no more than 3 feet above the ground or crop canopy.
- For ground and aerial applications, select nozzle and pressure that deliver medium or coarser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE S572.1).
- For ground boom and boom-less ground applications, do not apply when wind speeds exceed 15 mph at the application site.

Current TCM labels require 25 foot buffers for ground applications or 200 foot buffer for aerial applications to sensitive terrestrial habitats to address potential risks concerns from spray drift. While the agency has not assessed the impact of buffers specific to TCM, generally, buffers can impact revenue and production.

When the agency mitigated potential spray drift risk concerns for the other ALS-inhibitors in registration review, it did not require buffers. Instead, the agency required mandatory and advisory spray drift management language similar to with what is being proposed for TCM. The EPA required these label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift to ensure consistency where possible across the ALS-inhibiting chemicals. As mentioned above, EPA expects that these measures will reduce the extent of environmental exposure and risk to non-target organisms. EPA is proposing to mitigate potential risks from TCM in a similar manner, and is therefore proposing the removal of buffers to sensitive areas from all TCM labels.

The agency is proposing a restriction on droplet size, because coarser droplets have been demonstrated to decrease spray drift, and therefore, reduce potential risks to non-target species. Because chemical-specific data for the performance of droplet sizes is limited, EPA was not able to evaluate the effects of medium or coarser droplet sizes (as defined by ASABE S572.1) specifically for TCM. Therefore, the EPA does not know the effect this requirement will have on the performance of the TCM across various use patterns. In general, potential negative impacts to growers from requiring larger droplets could include reductions in efficacy, increased selection pressure for the evolution of herbicide resistance due to a decrease in lethal dose delivered to target weeds, increased application rates used by growers, increased costs associated with reduced yield, more herbicide applications, purchase of alternative products, or an inability to use tank mix or premix products. The EPA encourages comments on any potential impacts to growers from specifying a mandatory minimum droplet size on product labels.

In addition to including the spray drift restrictions on TCM labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all TCM labels where such information currently appears. The proposed new language above, which cites ASABE S572.1, eliminates the need for VMD information.

3. Proposed Advisory Language

In addition to standardizing spray drift label language, EPA is proposing to add two precautionary statements to inform users of potential environmental hazards when using TCM. The agency is proposing the inclusion of a non-target organism advisory and a groundwater advisory on TCM product labels.

Non-target Organism Advisory

The protection of pollinating organisms is a priority for the agency. Risk to pollinators from the use of TCM is uncertain. It is possible that pollinators may be exposed to TCM from residues in pollen or nectar through spray drift. This may negatively impact forage and habitat of pollinators and other non-target organisms. It is the agency's goal to reduce spray drift whenever possible and to educate growers on the potential for indirect effects on the forage and habitat of pollinators and other non-target organisms. Therefore, the EPA is proposing non-target organism advisory language to be placed on TCM labels to address this potential concern. See Appendix B for the proposed advisory statement.

Groundwater and Surface Water Advisories

The agency is also proposing surface water and ground water advisory statements for TCM because the environmental fate characteristics indicate that products containing TCM might be transported to surface water and groundwater. This language is consistent with current labeling

practices as noted in the agency's FIFRA Label Review Manual[11]. See Appendix B for the proposed advisory statements.

4. Restricted Entry Intervals

The current restricted entry interval (REI) on the labels is 12 hours or 4 hours, depending on the TCM formulation. The current human health risk assessment supports a 12-hour REI for TCM, the active ingredient, but the different TCM formulations were not assessed. According to PRN 95-3: Reduction of Worker Protection Standard (WPS) Interim Restricted Entry Intervals (REIs) for Certain Low Risk Pesticides, certain TCM formulations may qualify for a reduced 4-hour REI. TCM registrants may use the existing label amendment process to request a reduction in the existing 12-hour REI to a 4-hour REI on the label, on a formulation by formulation basis.

5. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.[12] Consistent with the Notice, the EPA is proposing the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide PID.

The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide resistant weeds have been known since the 1950s, the number of species and their geographical extent, has been increasing rapidly. Currently there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide resistant weeds, both in mitigating established herbicide resistant weeds and in slowing or preventing the development of new herbicide resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

The EPA is requiring measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

[11] https://www.epa.gov/pesticide-registration/label-review-manual
[12] PRN 2017-2, "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship". Available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year

B. Tolerance Actions

No changes to the tolerance levels, crop listings, or the tolerance expression are anticipated at this time. Refer to Section III.A.3 for details.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP), the Endangered Species Act (ESA), and pollinator components of this case, the agency has made the following PID: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV. A and Appendices A and B.

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of TCM, nor is it making a complete endangered species finding. Although the agency is not making a complete endangered species finding at this time, the proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of TCM. The agency's final registration review decision for TCM will be dependent upon the result of the agency's ESA assessment and any needed § 7 consultation with the Services and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

- *For Pollinators:*

No additional data are anticipated to be needed to be called-in for this chemical at this time. The EPA will consider requiring submission of pollinator data as a separate action.

- *For Reference Standards:*

The analytical reference standard for TCM's metabolite, MMT glucoside has expired and must be submitted to the EPA's National Pesticide Standards Repository (see https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository).

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this combined Work Plan and PID for TCM, along with the Draft Human Health and Ecological Risk assessments for Registration Review and will allow a 60-day comment period on the documents. If there are no significant comments or additional information submitted to the docket during the comment period that

leads the agency to change its PID, the EPA may issue an interim registration review decision for TCM. However, a final decision for TCM may be issued without the agency having previously issued an interim decision. A final decision on the TCM registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination and (2) an endangered species determination under the ESA and any needed § 7 consultation with the Services.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the TCM registrants must submit amended labels that include the label changes described in Appendices A and B. The revised labels and requests for amendment of registrations must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Appendix A: Summary of Proposed Actions for TCM

Registration Review Case#: 7276
PC Code: 015804
Chemical Type: Herbicide
Chemical Family: Sulfonyl-amino-carbonyl-triazolinone (SACT)
Mode of Action: WSSA Group 2 (ALS inhibitors)

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
• Terrestrial Plants • Aquatic Plants	• Spray Drift • Runoff • Residue (on site of treatment)	• Foliar and root absorption	• NA	• Decreased biomass, effects on plant length and growth rate	• Mandatory spray drift management • Advisory spray drift reduction measures • Non-target organism statement • Surface water advisory measures • Groundwater advisory measures

Appendix B: Proposed Labeling Changes for TCM Products

Description	Proposed Label Language for Thiencarbazone-methyl Products	Placement on Label
	End Use Products	
Mechanism of Action Group Number	Note to registrant: • Include the name of the ACTIVE INGREDIENT in the first column • Include the word "GROUP " in the second column • Include the MODE/MECHANISM OF ACTION CODE in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide (i.e., HERBICIDE or FUNGICIDE or INSECTICIDE) in the fourth column. **THIENCARBAZONE-METHYL** | **GROUP** | **2** | **HERBICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Non-target Organism Advisory Statement	"NON-TARGET ORGANISM ADVISORY STATEMENT: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."	Environmental Hazards
Surface water Advisory	"SURFACE WATER ADVISORY STATEMENT: This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several days after application. Outdoor Residential Consumer Product Statement: To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.	Environmental Hazards

Description	Proposed Label Language for Thiencarbazone-methyl Products	Placement on Label
	A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of thiencarbazone-methyl from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours."	
Groundwater Advisory	"GROUNDWATER ADVISORY STATEMENT: This chemical has properties and characteristics associated with chemicals detected in groundwater. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow."	Environmental Hazards
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action **Applies to all products delivered via liquid spray applications**	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Spray Drift Management Language	Remove buffer requirements from all TCM products.	Directions for Use, in a box titled "Mandatory Spray Drift"

Description	Proposed Label Language for Thiencarbazone-methyl Products	Placement on Label
Spray Drift Management Application Restrictions for products delivered via liquid spray applications and that allow aerial application	**"MANDATORY SPRAY DRIFT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a medium or coarser droplet size (ASABE S572.1) for all applications. • If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Aerial Applications," and before use rates and/or application instructions
Spray Drift Management Application Restrictions for products that are delivered via liquid spray application and that allow ground boom applications	**"MANDATORY SPRAY DRIFT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 3 feet above the ground or crop canopy. • Applicators are required to use a medium or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications	**"MANDATORY SPRAY DRIFT** **Boomless Ground Applications:** • Applicators are required to use a medium or coarser droplet size (ASABE S572.1) for all applications. • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Boomless Applications"

Description	Proposed Label Language for Thiencarbazone-methyl Products	Placement on Label
and that allow boom-less ground sprayer applications		
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Thiencarbazone-methyl Products	Placement on Label
	TEMPERATURE AND HUMIDITY When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for products that are applied as liquids and allow boom-less ground sprayer applications	**"SPRAY DRIFT** **Boomless Ground Applications:** • Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Appendix C: Endangered Species Assessment

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides[13]. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations. These initial consultations were pilots and were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, advancements to the initial pilot interim methods have been proposed based on experience conducting the first three pilot BEs. Public input on those proposed revisions is currently being considered.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role on this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for TCM does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although the EPA has not yet completed effects determinations for specific species or habitats, for this PID, the EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of TCM. This will allow the EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for TCM as part of completing this registration review.

[13] https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process

Appendix D: Endocrine Disruptor Screening Program

"As required by FIFRA and FFDCA, the 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, the 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 TCM, 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), TCM is subject to the endocrine screening part of 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 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 the 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, the 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 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,[14] 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. TCM 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, please visit the EPA website.[15]

In this PID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of TCM. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.

[14] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[15] https://www.epa.gov/endocrine-disruption