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Picloram

Proposed Interim Registration Review Decision
Case Number 0096

December 2020

Approved by: _____

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for picloram. This case includes the picloram acid (PC code 005101), the triisopropanolamine salt (PC code 005102), and potassium salt (PC code 005104) and is being issued pursuant to 40 CFR § 155.56 and § 155.58. 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, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require determine that 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. Additional information on picloram, can be found in EPA's public docket (EPA-HQ-OPP-2013-0740) 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 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.

EPA is issuing a PID for picloram 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 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 picloram prior to completing the picloram registration review. Likewise, the Agency will complete endocrine screening for picloram, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices D and E, respectively, for additional information on the listed species assessment and the endocrine screening for the picloram registration review.

Picloram is a pyridine carboxylic acid herbicide with selective toxicity to woody plants and broadleaf weeds. Products containing picloram are currently registered for use to control weeds

on a variety of agricultural crops, conservation reserve program land (CRP), forests, rights-of-ways, pasture and rangeland, and other non-crop areas. Products containing picloram were first registered in 1964, and the Reregistration Eligibility Decision (RED) was issued in August 1995. In 1978 the Agency classified picloram as a Restricted Use pesticide based on hazard to nontarget plants.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why picloram is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Picloram Registration Review

Pursuant to 40 CFR § 155.50, EPA formally initiated registration review for picloram with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of picloram.

- December 2013 - The *Picloram Preliminary Work Plan* (PWP*), Picloram Human Health Assessment Scoping Document in Support of Registration Review*, and *Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Picloram* were posted to the docket for a 60-day public comment period.

- May 2014 – The *Picloram Final Work Plan* (FWP) was issued. There were 35 public comments from various stakeholders received on the PWP. The comments did not change the schedule, risk assessment needs, or anticipated data requirements for registration review.

- December 2015 - A Generic Data Call-In (GDCI-005101-1396) for picloram was issued for data needed to conduct the registration review risk assessments. Not all data have been submitted. The following studies are considered outstanding:

    - Non-guideline honey bee acute larval oral toxicity test (the registrant has submitted a waiver request for this study, which is currently in review)

- May 2020- The Agency announced the availability of the *Picloram Draft Human Health Risk Assessment for Registration Review of the Herbicide* and the *Picloram: Draft Ecological Risk Assessment for Registration Review* for a 60-day public comment period. Seven comments were received during this comment period. The comments and the Agency's responses are summarized below.

- December 2020 - The Agency is now completing the PID in preparation for issuance for a 60-day public comment period. Along with the picloram PID, the following documents are also available in the picloram registration review docket (EPA-HQ-OPP-2013-0740):
    - *Picloram. Response to Comments on the Draft Human Health Risk Assessment in Support of Registration Review*
    - *Picloram: EFED Response to Public Comments on the Draft Ecological Risk Assessment for Registration Review*
    - *Picloram Use, Usage and Benefits*

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

During the 60-day public comment period for the picloram draft risk assessments, which opened on May 4, 2020 and closed on July 6, 2020, the Agency received seven public comments. Four comments were submitted to the picloram docket in error, with three comments pertaining to rotenone and one comment pertaining to novaluron. Comments relevant to picloram were submitted by Corteva Agriscience, the technical registrant, the U.S. Department of Agriculture (USDA), and an anonymous public commenter. Substantive comments, comments of a broader regulatory nature, and the Agency's responses to those comments are summarized below. The Agency thanks all commenters for their comments and has considered them in developing this PID.

Comments Submitted by USDA (Docket ID: EPA-HQ-OPP-2013-0740-0065)

Comment: USDA noted that picloram is unlikely to pose any risks of concern to mammals, fish, invertebrates, and aquatic plants, and even though EPA identified potential chronic risks of concern to birds, there is some uncertainty due to the avian studies used for risk assessment. USDA stated that labels already have language to mitigate risks to non-target plants from exposure to residues in contaminated compost, and exposure to surface water and water used for irrigation. USDA also commented on the hexachlorobenzene (HCB) risk assessment. HCB is a manufacturing impurity present in picloram end-use products and the Agency completed a separate risk assessment for HCB. USDA encouraged EPA to consider typical usage rates of picloram rather than maximum rates on the label. USDA also encouraged EPA to consider potential risk refinements such as including personal protective equipment (PPE) and engineering controls before proposing additional mitigation or restrictions for handlers of picloram.

In the human health risk assessment, EPA recommended that labels be revised to require a bioassay showing non-detectable residues before rotating to non-labeled crops in order to avoid phytotoxicity and inadvertent residues. USDA noted that this recommendation is unlikely to impact U.S. producers, given the low usage and the fact that current plant-back restrictions are considered prohibitive.

EPA Response: EPA appreciates USDA's comments on the ecological and human health risks assessments. The Agency's standard practice is to assess the maximum labeled parameters when

assessing human health and ecological risk. In response to USDA's suggestions for refining the HCB risk assessment, the Agency is aware that growers frequently use less than the maximum labeled rates. When necessary, additional refinements can be made to the dietary exposure assessment by using Pesticide Data Program data, which reflect "real-world" residues. However, since HCB is a manufacturing impurity and not a registered pesticide, these data were not available. The HCB cancer risk estimates reflect labeled PPE (single layer clothing and gloves) and engineering controls were incorporated for two applicable scenarios: aerial application to high acreage field crops and forestry. At this time, EPA is not planning on completing additional refinements to the human health and ecological risk assessments since there are no human health risks of concern and ecological risks are primarily to non-target plants.

In response to comments about the bioassay requirement, the Agency notes that the current labels already require that a bioassay be conducted for all non-labeled crops except for sorghum grain and rye. Since sorghum grain and rye are not registered uses, planting these crops in picloram-treated soils before performing a bioassay may result in inadvertent residues, which are not covered by existing tolerances, and are not accounted for in the dietary exposure assessment. EPA has provided a detailed response to the comments on the HCB cancer assessments in the *Picloram Response to Comments on the Draft Human Health Risk Assessment in Support of Registration Review*, located in the docket.

Comments Submitted by Corteva Agriscience (Docket ID: EPA-HQ-OPP-2013-0740-0066)

Comment: Corteva commented on the ecological risk assessment. Corteva stated that they have submitted additional bee data (MRIDs 50504401 & 50504402) to address data gaps. Corteva noted that the environmental fate summary did not consider a two-year retrospective groundwater monitoring study (MRIDs 45400701 and 47125701). The rate of detection of detectable residues was less than 1% in over 1,000 samples from 95 monitoring sites and this should be considered as a line of evidence in the risk assessment.

Corteva noted that of the three irrigation water incidents reported, two were the result of misapplication. Corteva argued that current label instructions indicate widespread contamination when this is not the case. Corteva also argued that the wrong K_{oc} value (7.2 L/kg) was used instead of the updated K_{oc} value of 24 L/kg (from MRID 49753801). Use of the updated K_{oc} data could lower groundwater estimated environmental concentrations and impact the conclusion of risk for irrigation water.

Corteva does not think the vegetative vigor endpoints are applicable in characterizing compost risk because compost use most closely aligns with the route of exposure represented by the seedling emergence studies.

For the human health risk assessment, Corteva commented on clinical chemistry effects noted in the toxicological effects summary. Corteva summarized the results from three subchronic rat studies (MRID 00110537 for picloram acid, MRID 42297001 for the 2-ethylhexyl ester, and MRID 41442701 for the triisopropanolamine ester) and one subchronic dog study (MRID 00110534). Corteva noted that across the four studies, the clinical chemistry results were inconsistent and did not show toxicological significance.

EPA Response: The Agency appreciates the comments submitted by Corteva Agriscience. The submitted chronic toxicity studies for adult and larval honey bees (MRIDs 50504401 & 50504402) are currently in review. A waiver was requested for the acute toxicity study for larval honey bees (MRID 51298901), which is also under review by the Agency. EPA agrees that non-target ambient water monitoring data offers useful information about the extent of possible impact; the Agency will review the submitted groundwater monitoring study reports (MRIDs 45400701 & 47125701). To clarify, the risk assessment did not indicate widespread contamination of groundwater. Use of the updated K_{oc} value (24 L/kg) would not significantly impact the risk conclusions or the risk characterization. Moreover, the low number of irrigation water incidents does not mean that incidents are not occurring. Many stakeholders do not know how to report incidents to the Agency, and even when incidents occur, it is difficult to identify the cause of the incident without laboratory testing, which can be expensive.

The Agency concludes that both vegetative vigor and seedling emergence endpoints are applicable in characterizing risk to terrestrial plants from residues in compost. The vegetative vigor study generally captures plant exposure via both soil uptake and foliar exposure. While terrestrial plants are often exposed to compost during seedling emergence, it is also common to use compost as mulch or as top-dressing during the growing season and to add compost to transplanted plants. This creates potential exposure for plants in the later stages of development, which is captured in the vegetative vigor study. Please see the *Picloram EFED Response to Public Comments on the Draft Ecological Risk Assessment for Registration Review* for additional information.

In response to Corteva's comment on the human health risk assessment, EPA acknowledges that the way the subchronic rat studies were summarized in the hazard characterization implied an incorrect interpretation of the study conclusions. The detailed explanation of the subchronic rat studies provided by Corteva also reflects the Agency's understanding of the study conclusions individually. The subchronic dog study (MRID 00110534) served as the basis for the points of departure (PODs) and endpoints established for incidental oral exposure and for short-term inhalation exposure, with a POD of 35 mg/kg/day and LOAEL of 175 mg/kg/day based on bodyweight decrease, altered clinical chemistry, and increased liver weight. The altered clinical chemistry the Agency noted was based on increased cholesterol. EPA has provided a detailed response to Corteva's comments in the *Picloram Response to Comments on the Draft Human Health Risk Assessment in Support of Registration Review*, located in the docket.

II. USE AND USAGE

Picloram is registered for agricultural uses such as pasture and rangeland, fallow, forestry, spring wheat, barley, and Conservation Reserve Program lands. It is also registered for use in non-agricultural settings such as forests, rights of ways, industrial/commercial areas, and other non-crop areas. It can be applied as a broadcast spray with ground boom or aerial equipment or as a targeted spray using specialized ground equipment such as backpack sprayer, mechanically-pressurized handgun, and manually-pressurized hand wand. Additional application methods include basal bark treatments, trunk injections, and cut surface and frill applications to stumps and stems.

Agricultural usage data for picloram are available for barley, fallow, pastureland and rangeland, spring wheat, and winter wheat which are summarized in Table 1. From 2014-2018, an average of 5% of pastures and rangeland acres were treated with picloram, while less than 1% of barley, fallow, and wheat acres were treated. On average from 2014-2018, approximately 650,000 pounds of picloram were applied to approximately 5 million acres annually. The majority of agricultural picloram usage from 2014-2018 is for applications to pastures and rangeland, which accounted for over 95% of total acres treated (TAT) per year.[1] In terms of total acres treated, 93% of picloram was applied via broadcast application while 7% was applied as a spot treatment.[1] Spot treatments were made to an average of approximately 20% of winter wheat, 10% of barley, pastureland, and less than 1% of fallow from 2014-2018, based on total acres treated.[1] The low picloram usage in grain production (barley and wheat) may be due to growers' concern about picloram's persistent soil activity and its potential to damage the next crop.

Less than 10% of all reported applications in agricultural crops are made by aerial application.[1] However, of those aerial applications made, more than 95% of all reported aerial applications of picloram are made to pastureland.[1] More than 95% of all reported aerial applications of picloram are made by commercial applicators.[1]

Table 1. Average Annual Agricultural Usage of Picloram (2014-2018)[1]

Crop	Volume (lbs AI)	Total Acres Treated	Percent Crop Treated (PCT)
Barley	<500	2,000	<1
Fallow	30,000	160,000	<1
Pastureland	620,000	4,700,000	5
Wheat, Spring	<500	10,000	<1
Wheat, Winter	5,000	40,000	<1

Table 2 summarizes the available nonagricultural picloram usage data. Data are limited (i.e., not published annually) and, therefore, may not provide a complete picture of nonagricultural usage for a given year. In 2017, the greatest nonagricultural usage of picloram, in terms of pounds applied, was reported for rights-of-way, which includes use on roadways, railroads, electric utilities, and pipelines. Usage was also reported for forestry sites. In 2017, nearly all pounds of picloram applied in the forestry sector targeted invasive species, while less than 2% of pounds applied to rights-of-way targeted invasive species.

[1] Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Database Subset: 2014-2018.

Table 2. Nonagricultural Usage of Picloram (2017)[2]

Year	Segment	Subsegment	Pounds AI
2017	Forestry	**Total**	**20,000**
		*Invasive Species**	*20,000*
	Railroads	**Total**	**50,000**
	Roadways	**Total**	**90,000**
		*Invasive Species**	*2,000*
	Utilities/Pipelines	**Total**	**40,000**

For additional information on the usage of picloram, see the document *Picloram (005101): Use, Usage, Benefits Information and Impacts from Potential Mitigation document.*

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 picloram. For additional details on the human health assessment for picloram, see the *Picloram Draft Human Health Risk Assessment for Registration Review*, which is available in the public docket.

Risk Summary and Characterization

Dietary Risks

The Agency's dietary (food + water) risk assessment did not identify risks of concern. An acute dietary risk assessment was not conducted due to lack of an endpoint attributable to a single dose. Chronic dietary risk estimates were calculated but found to not be of concern. Children 1-2 years old were the highest-exposed population subgroup, with risk estimates equal to 13% of the chronic population adjusted dose (cPAD), where the Agency's level of concern for dietary risk is 100% of the PAD. Therefore, there are no dietary risks of concern for picloram.

Dietary Cancer Risks

A dietary cancer risk assessment was conducted for the manufacturing impurity, hexachlorobenzene (HCB), which might be present in small amounts in picloram end-use formulations. HCB is classified as a probable human carcinogen. EPA performed a highly refined cancer dietary assessment for exposure to HCB through registered picloram uses, using average percent crop treated estimates and peak monitoring drinking water data associated with

[2] Nonagricultural Market Research Data (NMRD). 2017. Studies on industrial vegetation management conducted and sold by a consulting and research firm. Accessed August 2020.

picloram use sites. When assessed at the maximum actual concentration of HCB in the confidential statements of formula (CSF), the risk estimate is $5x10^{-7}$. When assessed at the maximum upper limit (i.e., maximum allowable) concentration for HCB on the CSFs, the risk estimate is $2x10^{-6}$. Beef and milk contribute significantly to these exposures and risk estimates (84-88% of the exposure estimate).

Because HCB is not a registered pesticide, and because conservative assumptions were made to account for HCB's physicochemical properties, exposure estimates were difficult to refine. EPA made several conservative assumptions, as follows:

1) The dairy cattle dietary burden was used for all ruminant commodities, which is 1 order of magnitude higher than beef cattle dietary burden.
2) Raw data for grass forage field trials were not available, so tolerance-level picloram residues estimates were used as the basis for HCB residues.
3) The ratio of picloram to HCB in grass forage was assumed to match that of the applied formulation, whereas data show that the ratio of HCB to picloram in harvested grass forage is less than the ratio of HCB to picloram in the formulation.
4) It was assumed that cattle are feeding on picloram-treated forage on the day of treatment, while picloram labels specify pre-grazing interval of 7 days.

EPA believes that due to these conservative assumptions the actual HCB exposure estimate is lower than the risks estimates provided and that there are no cancer dietary risks of concern.

Residential Risks

There are no residential uses associated with picloram, and no commercial uses that would result in exposure to picloram in residential settings; therefore, residential handler and post-application exposure assessments were not conducted.

Aggregate Risks

Aggregate risks typically reflect combined dietary (food and drinking water) and residential exposures. However, picloram is not registered for residential use. Therefore, aggregate risk estimates are equivalent to the non-cancer and cancer (HCB only) dietary risk estimates described above.

Non-occupational Spray Drift

Non-occupational spray drift risk estimates reflect exposures for children and adults who have contact with turf where residues are assumed to be deposited via spray drift. A quantitative spray drift assessment for picloram was conducted to assess spray drift exposure from both aerial and ground boom application across all use sites and found no risks of concern. Children 1-2 years old are considered the most sensitive population subgroup. The margins of exposure (MOEs) at the field edge for children 1-2 years old from hand to mouth exposure ranged from 8,100 to 530,000 which are not of concern, since the MOEs are above the LOC of 100.

Cumulative Risks

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

Occupational Handler Non-Cancer Risks (Picloram)

Occupational handlers are individuals who are involved in the pesticide application process (including mixers, loaders, and applicators). All handlers are assumed to wear baseline attire, which consists of long-sleeved shirt, long pants, and shoes plus socks, except for aerial applicators who are assumed to be in enclosed cabs. No dermal assessment was completed since no dermal hazard was identified in the toxicity database. Only short-term inhalation exposure durations (i.e., exposure from 1 to 30 days) were assessed. Most end-use products labeled for crop and non-cropland are applied only twice per year. Products applied for weed control in forests are applied once every two years. A few products can be applied twice in one season which is considered a series of short-term exposures. Short-term inhalation risks for occupational handlers are not of concern. Inhalation MOEs ranged from 600 to $2.1x10^{7}$ and are not a concern, since the MOEs are above the LOC of 100.

Occupational Handler Cancer Risks (HCB)

For the HCB occupational handler cancer assessment, EPA assessed exposure by adjusting the picloram application rates by the concentration of HCB observed in the CSFs. Exposure was assessed based on the maximum actual concentration observed on the CSFs and using the maximum upper limit (or maximum allowable) concentration of HCB in the CSFs. The maximum actual concentration is expected to be a more realistic exposure estimate while the upper limit is considered a worst-case upper bound risk estimate. This approach is considered protective for all picloram end-use products. Risk estimates were generated for both private farmers (i.e., the farmer or one of the workers under the farmers' supervision applying pesticide to land owned/operated by the farmer) and commercial applicators (i.e., applicators who are completing applications for multiple clients). Handlers were assumed to be wearing labeled PPE (long-sleeved shirt, long pants, shoes plus socks, gloves). Engineering controls were assessed for two scenarios: aerial applicators for high acreage field crops and forestry.

When assessed at the maximum actual concentration of HCB on the CSFs, the occupational handler risk estimates range from $1x10^{-11}$ to $4x10^{-7}$ for private farmers (assuming 10 days of exposure per year) and from $3x10^{-11}$ to $1x10^{-6}$ for commercial farmers (assuming 30 days of exposure per year) using the baseline personal protective equipment (PPE). When assessed at the maximum upper limit for HCB on the CSFs, the occupational handler risk estimates range from $7x10^{-11}$ to $3x10^{-6}$ for private farmers and from $2x10^{-10}$ to $8x10^{-6}$ for commercial farmers using baseline attire plus gloves. Exposure estimates greater than or equal to $1x10^{-6}$ were assessed with additional PPE. These occupational handler cancer risks are not of concern.

Occupational Post-Application Non-Cancer Risks (Picloram)

Post-application exposure describes exposures that occur when individuals are present in an environment that has been previously treated with picloram and includes activities such as scouting for pests or hand-harvesting. Dermal post-application exposure was not evaluated, due to the lack of toxicity observed in the database from the dermal route.

Picloram acid and its salt forms are classified as Toxicity Category III via the dermal route and Toxicity Category IV for skin irritation potential. The salts, but not the acid, are dermal sensitizers. A dermal point of departure (POD) was not selected; therefore, post-application risk estimates were not estimated for post application activities. Based on the toxicity categories, the current restricted entry interval (REI) of 12 hours on the labels is protective. The REIs for picloram on registered labels range from 12 to 48 hours and are considered protective of post-application exposure.

A quantitative occupational post-application inhalation exposure assessment was not performed. Handler exposure from outdoor application is likely to result in higher exposure than post-application exposure. Since occupational inhalation handler exposure is not of concern, it is expected that occupational post-application inhalation exposure is also not a risk of concern.

Occupational Post-Application Cancer Risks (HCB)

EPA assessed occupational post-application exposure and risk from HCB by adjusting the picloram application rates by the concentration of HCB observed in the CSFs. Exposure was assessed based on the maximum actual concentration of HCB observed in the CSFs, and also based on the maximum upper limit (or maximum allowable) concentration of HCB in the CSFs. When assessed at the maximum upper limit for HCB on the CSFs, the occupational post-application risk estimates range from $6x10^{-10}$ to $4x10^{-11}$ on day 0 and from $2x10^{-10}$ to $1x10^{-11}$ using the 30-day average dose. When assessed at the maximum upper limit for HCB on the CSFs, the occupational post-application risk estimates range from $4x10^{-9}$ to $3x10^{-10}$ on day 0 and $1x10^{-9}$ to $8x10^{-11}$ using the 30-day average dose. These occupational post-application cancer risks are not of concern.

Human Incidents and Epidemiology

The last picloram human incidents search was conducted in December 2013 in support of the scoping document and incidents were found to be low in frequency and severity. An updated search for human incidents was conducted in January 2020 in support of the human health risk assessment. Both the Incident Data System (IDS) and NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides databases were searched.

The February 2020 search of the IDS covered incidents from January 1, 2014 to January 30, 2020 and found 18 picloram incidents reported in Main IDS, all involving people using products containing multiple pesticide active ingredients. One incident was not related to the use of picloram, one incident was classified as major severity, 15 incidents were classified as moderate severity, and one incident was classified as minor severity. In addition, 151 picloram incidents

were reported in Aggregate IDS. Of these, 12 incidents had no or unknown effects, and 139 were classified as minor severity.

A query of SENSOR-Pesticides from 2010-2015 identified 10 cases involving picloram. Nine of these incidents were classified as low severity and one incident as classified as moderate severity. Based on the continued low frequency and mostly low severity of picloram incidents reported to both IDS and SENSOR-Pesticides, there does not appear to be a concern at this time.

The Agricultural Health Study (AHS) is a federally funded study that evaluates associations between pesticide exposures and cancer and other health outcomes and represents a collaborative effort between the US National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), CDC's National Institute of Occupational Safety and Health (NIOSH), and the US EPA. Two published AHS studies investigating the potential association between picloram exposure and human health effects were reviewed. Based on EPA's review of these studies, the evidence is insufficient at this time to conclude that a clear associative or causal relationship exists between picloram and the two non-carcinogenic health outcomes in the AHS studies (sleep apnea and wheeze). No carcinogenic effects were reported by the AHS 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.

Tolerances

Tolerances for picloram are established under 40 CFR §180.292. EPA is not anticipating the establishment of any new tolerances. The Agency follows the Organisation for Economic Cooperation and Development (OECD) rounding class practice. As a result, EPA anticipates that trailing zeros from a number of tolerances be removed to conform to OECD guidelines. The Agency anticipates the following changes to the tolerances for picloram. The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

Summary of Anticipated Tolerance Revisions for Picloram: 40 CFR §180.292			
Commodity/Correct Commodity Definition	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Barley, pearled barley	3.0	3	The Agency anticipates removing trailing zeros to be consistent with OECD Rounding Class Practice
Barley, straw	1.0	1	
Grain, aspirated fractions	4.0	4	
Oat, forage	1.0	1	
Oat, groats/rolled oats	3.0	3	
Oat, straw	1.0	1	
Wheat, bran	3.0	3	
Wheat, forage	1.0	1	
Wheat, germ	3.0	3	
Wheat, middlings	3.0	3	

Wheat, shorts	3.0	3	
Wheat, straw	1.0	1	

Human Health Data Needs

The Agency does not anticipate any further data needs for the registration review of picloram at this time.

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 risk assessment in support of the registration review of picloram. For additional details on the ecological assessment for picloram, see the *Picloram: Draft Ecological Risk Assessment for Registration Review*, which is available in the public docket.

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 picloram. See Appendix D for more details. As such, potential risks for non-listed species only are described below.

Risk Summary and Characterization

Terrestrial Risks

Mammals

There are no acute or chronic risks of concern for mammals. Acute risk quotients (RQs) range from <0.01 to 0.04 and are below the Agency's acute level of concern (LOC) of 0.5. Chronic RQs range from <0.01 to 0.11 and are below the Agency's chronic risk LOC of 1.0.

Birds, Reptiles and Terrestrial-Phase Amphibians

There are no acute risks of concern identified for birds (RQs < 0.01- 0.46). The acute dietary-based toxicity endpoint is non-definitive (the amount of substance required to kill 50% of the test population was not determined) as no mortality was observed up to the highest tested dose. Therefore, risk to birds and to reptiles and terrestrial-phase amphibians for which birds serve as surrogates, on an acute dietary exposure basis, is presumed to be low.

Chronic RQs were not calculated for birds due to a non-definitive endpoint based on reductions (8-9%) in 14-day hatchling body weight at all test levels in northern bobwhite quail (MRID 49735802). Because a no observed adverse effect concentration (NOAEC; greatest amount of a substance observed which causes no detectable adverse effect in the target organism) could not

be determined, there is potential risk to birds on a chronic basis from exposure to picloram and its salts. However, it is uncertain if the reductions in hatchling body weight were treatment-related because of the non-dose-responsive trend in the data. Thus, the next most sensitive endpoint in the study, 14-day hatchlings/eggs set, was also considered. The NOAEC for 14-day hatchlings/eggs set was 700 mg a.i./kg-diet (milligrams active ingredient per kilogram diet) based on an 18.31% reduction in hatchlings/eggs set compared to the control. Comparing this definitive NOAEC to exposure levels indicates that it is greater than the highest dietary estimated environmental concentration (EEC) of 264 mg/kg diet for birds. This indicates that EECs for the use of picloram and its salts at an application rate of 1.1 lb a.e./A (acid equivalents per acre) are not high enough to elicit effects observed in the study. Therefore, there is uncertainty regarding the potential for chronic risk to birds; this uncertainty could be resolved with additional data. Since the issuance of the ecological risk assessment for picloram, a rebuttal of EFED's DER associated with MRID 49735802 has been submitted, which is currently in review.

Terrestrial Invertebrates (honey bees)

A full quantitative Tier 1 risk assessment was not conducted at the time of the ecological risk assessment, due to missing data. While data were submitted for acute risks to adult honey bees, RQs were not calculated due to non-definitive endpoints from both honey bee adult acute contact and oral toxicity studies. No statistically significant mortalities occurred up to the highest dose tested in the contact toxicity study, and no sublethal effects were noted. No treatment-related mortality or sub-lethal effects were observed in the oral toxicity study. Given that the highest concentration tested in the adult oral toxicity study is more than 20x the EEC (0.213 μg a.i./bee), this indicates that risk to adult bees on an acute oral exposure basis is unlikely.

Since the issuance of the ecological risk assessment for picloram, two chronic bee studies were identified [honey bee adult chronic oral toxicity (MRID 50504401) and honey bee larval chronic oral toxicity (MRID 50504402)] and are currently being reviewed. A honey bee acute larval oral study is still outstanding, but the registrant has submitted a waiver request for this study which is currently in review. After these additional studies are reviewed, the terrestrial invertebrate risk assessment and risk conclusions will be revisited.

Terrestrial Plants

As expected from an herbicide, there is a potential risk concern for terrestrial plants. Terrestrial plant RQs exceeded the LOC and ranged from <0.1 to 1,150 from ground spray applications (where RQs above 1 exceed the LOC). RQs for aerial application also exceeded the LOC and ranged from 0.37 to 1,240. The distance from the field edge to below toxicity threshold for aerial application ranged from 69 to >1,000 feet depending on plant species and droplet size used during application. Increasing the droplet size for aerial application did not significantly reduce the distance to below toxicity threshold for sensitive crop species such as tomato, sunflower, sugar beet, soybean, and cucumber.

The distance from the field edge to below toxicity threshold for ground boom application ranged from 69 to >1,000 feet depending on plant species, boom height, and droplet size used during application. These distances are reduced when droplet size and boom height parameters are

adjusted. At high boom and fine to medium-coarse droplets, the distance from the field edge to below toxicity threshold ranged from 10 ft to 810 ft. At low boom and fine to medium-coarse droplets, the distance from the field edge to below toxicity threshold ranged from 7 ft to 620 ft.

Compost contamination

Picloram is persistent and there have been incidents reported of non-target plant damage from residues in compost. From 2000 to 2013, five compost incidents concerning picloram have been reported. Two of these incidents involved plant damage after application of compost to a home-garden, and three of the incidents involved crop damage after application of mulch or manure fertilizer to fields. The common routes of contribution to composting facilities and compost in general is application of picloram on pastures and rangeland using treated hay as animal bedding and feed. Both materials (used bedding and manure) are commonly composted, and once a composting facility is contaminated with picloram, non-target plants further downstream in the compost distribution chain can be adversely impacted (*e.g.*, gardens, ornamental plants).

Due to this history of incidents, risk to plants via exposure from residues in compost was assessed. The concentration of picloram after 97 days of composting in both vegetative and manure compost was compared to plant toxicity endpoints in the context of typical compost application rates. Compost RQs were generated based on manure and grass clippings. Compost RQs (where RQs above 1 exceed the LOC) ranged from 0.2 (home gardens) to 43,000 (for large farms) based on grass clippings. Compost RQs ranged from 0.9 (home gardens) to 180,000 (large farms) based on manure compost. The most sensitive species were soybean, sugar beet, sunflower, tomato, and cucumber, where RQs ranged from the 100s to the 1000s no matter the setting (home garden or large farm).

Picloram in groundwater and irrigation water

Picloram and its salts are mobile and persistent; thus, residues in surface or groundwater and/or the use of picloram in irrigation water could result in injury to non-target plants. However, the standard exposure scenarios for terrestrial plants (i.e., spray drift and total loading = spray drift + surface runoff) do not consider this exposure pathway. Nineteen states have reported detections of picloram in groundwater at the time of risk assessment, and three incidents have been reported involving irrigation from a water source after the application of picloram and its salts nearby. The probability of picloram and its salts having caused injury to non-target plants in each of these cases ranged from probable to highly probable. Furthermore, less than $1/500^{th}$ of an inch of irrigation water would be required to reach the most sensitive vegetative vigor endpoint for tomato (NOAEC of 0.00013 lb ae/A) based on groundwater estimated environmental concentrations.

Aquatic Risks

RQs did not exceed the LOC for freshwater or estuarine/marine fish (or the aquatic-phase amphibians for which freshwater fish serve as surrogates). Although RQs were not of concern for fish for acute or chronic exposure to picloram, there were five reported incidents for fish (two accidental misuse and 3 from registered uses). This suggests that there may be concerns

regarding exposure of fish to picloram and its salts. However, based on the available data, the potential for direct risk to freshwater and estuarine/marine fish exposed to picloram and its salts on an acute and chronic basis is considered low. The potential for indirect effects on fish as a result of reductions in dissolved oxygen concentrations and/or food is not possible to quantify at this time.

No risks of concern were identified for freshwater or estuarine/marine invertebrates or aquatic vascular and non-vascular plants. Acute and chronic RQs range from <0.01 to 0.07 across all aquatic species and do not exceed the level of concern. Picloram has been detected in surface water.

Ecological Incidents

A search of the Incident Data System (IDS) for picloram was conducted on August 19, 2019. The search reflects all reported incidents since the first products containing picloram were registered until the date of the search. IDS returned 88 incidents, 88% of which involved damage to terrestrial plants. Incidents are classified according to certainty, from "highly probable" to "unlikely." The certainty categories regarding the likelihood that the use of picloram and its associated salts caused the 88 incidents ranged from possible (51%), probable (39%), and highly probable (9%). Many of the incidents were attributable either to direct application of a picloram product to the affected crop, often corn, or to spray drift to adjacent crops. At least 13 of the terrestrial plant incidents involved the exposure of non-target plants from spray drift. An additional 5 more were reported showing residues in compost as the potential cause of the incident. See appendix C for additional details on the compost incidents.

Three of the reported incidents involved the use of irrigation water. Of these, one was considered an accidental misuse. The other two irrigation incidents were from registered use and are as follows:

- a "probable" incident (location and date not reported) indicated that a picloram product was applied to weeds near a well. The well water was subsequently used to irrigate 90 acres of potatoes, which were injured. The legality of the use was not determined.
- a "probable" Virginia incident in 1998 reported that tobacco plants were reportedly injured after irrigation from a pond. Water taken from the pond contained picloram and water from a spring that feeds the pond contained 3.71 ppb picloram. The original use was considered a registered use of picloram.

There were five incidents of fish kills reported in IDS. Two of the incidents were from accidental misuse. The rest were from registered use, those are as follows:

- a "probable" incident in 1989 where thousands of trout at a fish hatchery were killed after a picloram product was sprayed by a road crew a quarter mile upstream from the hatchery following heavy rain.
- a "highly probable" incident in 1994 where one fish was found dead in a pond after trees were treated with picloram nearby.

- a "possible" incident in 1997 in Oklahoma where an unknown number of fish were killed after application of a picloram and 2,4-D product following runoff from heavy rain into a nearby pond.

The Agency will continue to monitor the ecological incident information. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

Ecological and Environmental Fate Data Needs

In support of registration review for picloram, a generic data call-in (GDCI-005101-1396) was issued, requiring the submission of several environmental fate and ecotoxicity studies. In the ecological risk assessment, three honey bee studies were identified as outstanding: adult chronic oral toxicity, acute larval oral toxicity, and chronic larval oral toxicity. Since the issuance of the ecological risk assessment for picloram, two chronic bee studies were identified (honey bee adult chronic oral and honey bee larval chronic oral) and are currently being reviewed. A honey bee acute larval oral study is still outstanding, but the registrant has submitted a waiver request for this study which is currently in review. Once Tier I pollinator data has been reviewed, EPA will determine if higher tiered pollinator data are needed.

C. Benefits

Agricultural Use Sites

Usage of picloram provides benefits to users in both agricultural and non-agricultural settings. Picloram's main usage is in pasturelands (95% of all picloram TAT is on pastureland), where it provides users ability to control invasive species as well as other herbaceous species, cacti, and woody plant control[3,4]. Picloram weed control on pastures and rangelands is important as ranchers manage these areas so that palatable plants have little competition in providing more food to livestock. Alternatives to picloram on pastures and rangelands include other pyridines (clopyralid and triclopyr), 2,4-D, metsulfuron, and dicamba.

For fallow lands, picloram is used to control several hard to control weed species such as field bindweed and kochia, but literature indicates that fluroxypyr, carfentrazone, quinclorac,[5] and atrazine[6] are more often recommended for controlling weeds on fallow lands. Low picloram

[3] Lyons, R.K., M. Clayton, W. Hamilton, L. Redmon, B. Rector, and C. Kneuper. 2019. Chemical weed and brush control – suggestions for rangeland. Accessed 10/2020. https://www.agrilifebookstore.org/v/vspfiles/downloadables/ERM-1466.pdf

[4] Young, 2017. Chemical Weed and Brush Control for New Mexico Rangelands. New Mexico State University. Circular 597. Accessed 11/2020. https://aces.nmsu.edu/pubs/_circulars/CR597/welcome.html

[5] North Dakota State University .2019. North Dakota Weed Control Guide. Accessed 11/2020. https://www.ag.ndsu.edu/lamourecountyextension/2019-weed-control-guide

[6] Kansas State University. 2018. Sunflower District: Kochia Control. A Kansas State University Research and Extension publication. Accessed 11/2020. https://www.sunflower.kstate.edu/agronomy/weed_control/kochia_control.html

usage on fallow lands may be an indication that picloram is not an important weed control option for this use site.

Non-Agricultural Use Sites

Picloram's broad-spectrum control also extends to nonagricultural use where it provides benefits to preserve conservation land and for invasive species elimination. Non-agricultural benefits of picloram were assessed for forest and right-of-way uses. The U.S. Forest Service reports that picloram use in forestry programs is primarily for the control of noxious weeds and that rights of way management are a minor use for picloram. When picloram is used by the U.S. Forest Service, it is commonly applied at rates on the lower end of the suggested application rates specified on picloram labels, with some applications made at rates even lower than the lowest recommended rate. [7] The U.S. Forest Service reported that nearly all picloram usage occurred in the Great Plains and Rocky Mountain region with little usage in the Pacific Northwest and southern United States.[8] For rights-of-ways, picloram is used on 2-3% of all areas receiving an herbicide treatment.

Invasive Weed Control

Picloram is also used to control invasive species in natural areas to help preserve native plant communities, and in areas where livestock graze to allow the growth of more edible native plants. Due to picloram's persistence it can control hardier invasive and undesirable plants species like leafy spurge (*Euphorbia esula*). Product mixtures of picloram and 2,4-D are effective at controlling invasive herbaceous weeds and woody species that encroach in tallgrass prairies and is used to preserve these natural areas.[9]

For additional information on the benefits of picloram, see the *Picloram (005101): Use, Usage, Benefits Information and Impacts from Potential Mitigation document.*

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

The Agency has reviewed the risks and benefits associated with the registered uses of picloram in developing this Proposed Interim Registration Review Decision. EPA has determined that there are no potential human health risks of concern.

The Agency identified potential risks to non-target terrestrial plants from spray drift, runoff, and from compost contamination. Potential chronic risks to birds were also identified which are

[7] United States Forest Service. 2011. Picloram Human Health and Ecological Risk Assessment: Final Report. Accessed 09/2020.
[8] United States Forest Service. 2020. Regional Office. Accessed 11/2020. https://www.fs.usda.gov/about-agency/contact-us/regional-offices
[9] Tu, M., Hurd C, and J.M. Randall. 2001. Weed Control Methods Handbook: Tools and Techniques for Use in Natural Areas. A publication by The Nature Conservancy. Accessed 09/2020. https://www.invasive.org/gist/products/handbook/methods-handbook.pdf

limited to the area of the application and nearby areas. The Agency is proposing mandatory spray drift management measures to reduce risks to non-target organisms and is proposing new compost labeling and stewardship measures to reduce the potential for compost contamination. EPA is also proposing herbicide resistance management labeling and other label updates including crop rotation instructions to bring all labels up to current standards.

1. Updated Gloves Statement

The Agency proposes to update the gloves statements on current labels to be consistent with Chapter 10 of the Label Review Manual. All statements that refer to the chemical resistance category selection chart are proposed to be removed from picloram labels, as they might cause confusion for users. Instead, the labels should list the appropriate chemical-resistant glove types to use. The proposed change does not fundamentally change the personal protective equipment that workers need to use, and therefore should impose no impacts on users.

2. Update Crop Rotation Instructions

Some picloram labels indicate that sorghum grain and rye may be rotated to picloram-treated soil without a soil bioassay. For example, some labels note the following instructions for sorghum: "Plant only a labeled crop such as pasture grasses, small grains (barley, oats, rye, or wheat), or after a rotation interval of 8 months, grain sorghum." However, these instructions are incorrect. Rye and grain sorghum are not registered uses, these crops do not have primary crop tolerances, and field trial data for similar crops (MRID 42641801 for corn and wheat) suggest residues would remain in the field beyond 12-months. There is potential for rye and grain sorghum to incur violative residues as a result of planting in picloram-treated soil without a proper bioassay.

All labels are proposed to be modified to exclude rye and grain sorghum when discussing rotation to labeled crops. In addition, the Agency proposes to clarify crop rotation instructions to note that non-labeled crops cannot be planted in picloram-treated soil until a minimum of 12 months after treatment. In addition, sensitive broadleaf crops should not be planted until after soil residues have declined to a safe level as indicated by an adequately sensitive bioassay. The requirement for a bioassay protects plants from the phytotoxic effects of picloram and obviates the need for tolerances for inadvertent residues.

Crop rotation instructions vary from label to label and are sometimes confusing and unclear. The Agency proposes to clarify crop rotation instructions to establish 12-month minimum plant back interval when treated fields are rotated to non-labeled crops. The proposed crop rotation instructions are as follows: "Treated fields may be rotated to labeled crops at any time. For fields being rotated to a non-labeled crop, picloram application must be made a minimum of 12 months prior to planting. Do not plant sensitive broadleaf crops until soil residues have declined to a safe level as indicated by an adequately sensitive bioassay using the intended broadleaf crop."

Registrants may choose plant back intervals that are even longer than the 12-month time frame being proposed (some picloram labels already note plant back intervals as long as 36 months), however registrants may not note a timeframe that is less than 12 months.

The proposed label clarifications are similar to plant back intervals and bioassay instructions already on the labels and so should not have significant impacts on users.

3. Measures to Address Potential Compost Contamination

a. Compost Prohibition, Notification, and Recordkeeping

The Agency is proposing label language to reduce the potential for picloram contamination of compost. As described in EPA's ecological risk assessment, picloram is persistent in compost and can potentially result in plant damage from use of composted material contaminated with picloram residues. The proposed compost prohibition[10] instructs users not to sell or transport treated plant materials or manure from animals that have grazed on treated forage off-site for compost distribution or for use as animal bedding/feed for 18 months after application.

Increasing the awareness of property owners/operators about the potential long-term impacts of picloram on their land may help increase the likelihood of compliance with the proposed off-site composting prohibition. Pasture is the picloram use site which is most likely to have treated materials entering the compost waste stream. Therefore, the Agency is proposing that applicators applying picloram to pasture sites notify property owners/operators in writing, that picloram is a persistent pesticide and that plant material and manure exposed to picloram is not allowed to be sold or transported off-site for compost distribution or for use as animal bedding/feed for 18 months after application. Information to be communicated to the property owner/operator, in writing, by applicators are as follows: the name of the applicator, the date of application, the area(s) treated, the name and EPA registration number of the product applied, information on the persistence of picloram, and information on any label restrictions affecting hay, manure, and plant materials that might be recycled into compost.

In addition, EPA is proposing recordkeeping where applicators applying picloram to pasture use sites must retain a record describing how the property owner/operator was notified of compost restrictions. The following information is to be retained as part of the recordkeeping requirement:

- the name of the applicator,
- the date of application,
- the area(s) treated,
- the EPA registration number of the product applied,
- a copy of the written notification provided to the property owner/operator, and
- the date that notification of the property owner/operator occurred.

These records should be retained by the applicator for two years. If these records are already being kept as part of state or local requirements, duplicate records are not necessary. Communication between the applicator and property owner/operator is important in case the manager of the land changes over time. It is important that the property owner/operator receive information on picloram applications in order to make informed decisions about the management of treated plant materials and manure on the affected land to prevent compost contamination.

[10] See text for compost prohibition on next page.

Applicators may provide notification to the property owner/operator via email, via mail, via paper handout, or by any other written communication method so long as notification occurs.

Applications to public land are exempt from the notification requirement because public lands are managed by federal, state, or local authorities or contractors hired by these authorities. Applications by property owners/operators on their own land are also exempt from this proposed notification requirement as all users/applicators are already required to follow any label requirements and it is impractical for land managers to notify themselves. Picloram is already classified as a restricted-use pesticide, and applications can only be made by certified applicators or workers under the direct supervision of the certified applicator. However, some land managers are certified applicators and may need the additional flexibility if making applications on their own land.

In addition to the measures noted previously, the Agency is requiring that animals that have been fed picloram-treated forage must be fed forage free of picloram for at least three days before movement to an area where manure may be collected, or sensitive crops are grown. This ensures that manure from animals that have recently grazed on treated forage stays on site. The three-day period is based on open literature data which indicates the retention time for feed particles is approximately 52 hours for cattle[11], 48 hours for horses[12], 45 hours for sheep, and 32 hours for goats.[13] A three-day clean out period will be protective of non-treated areas with susceptible plant species and non-treated areas where manure may be collected for compost based on this literature.

The label language for the compost mitigation, notification, and recordkeeping requirement are as follows:

- "This product is persistent and may be present in treated plant materials for months to years after application. Do not sell or transport treated plant materials or manure from animals that have grazed on treated plant materials off-site for compost distribution or for use as animal bedding/feed for 18 months after application."
- For products with pasture uses: "The applicator must document that they have notified property owners/operators, or customers, in writing, of the compost and animal bedding/feed prohibitions before application of the product occurs. Applicators must keep the records of notification for two years. This record must include date of application, the name of the applicator, the EPA registration number of the product applied, area(s) treated, and a copy of the written notification provided to the property owner/operator. Notification may be made via email, via mail, via paper handout, or by

[11] Mambrini M, Peyraud JL. Retention time of feed particles and liquids in the stomachs and intestines of dairy cows. Direct measurement and calculations based on faecal collection. Reprod Nutr Dev. 1997 Jul-Aug;37(4):427-42. doi: 10.1051/rnd:19970404. PMID: 9342792

[12] S. Van Weyenberg, J. Sales, G.P.J. Janssens. Passage rate of digesta through the equine gastrointestinal tract: A review. Livestock Science. 99. 3-12. https://doi.org/10.1016/j.livprodsci.2005.04.008.

[13] Tsiplakou, Eleni & Hadjigeorgiou, Ioannis & Sotirakoglou, K. & Zervas, George. (2011). Differences in mean retention time of sheep and goats undercontrolled feeding practices. Small Ruminant Research. 95. 48-53. 10.1016/j.smallrumres.2010.09.002.

any other written communication method. Records must be made available to State Pesticide Regulatory Official(s), and to EPA upon request. If this information is already being retained, duplicate records are not needed."

- "Applications by property owners/operators on their own property are exempt from this notification and recordkeeping requirement."
- "Applications to public land are exempt from this notification requirement."
- "Manure from animals that have grazed or eaten forage or hay harvested from treated areas within the previous three days may only be applied to the fields where the following crops will be grown: pasture grasses, grass grown for seed, wheat and corn."
- "Animals that have been fed picloram-treated forage must be fed forage free of picloram for at least 3 days before movement to an area where manure may be collected, or sensitive crops are grown."

Some potential impacts to picloram users from these measures include potential increased difficultly in disposing of plant material and excess manure; potential increases in the cost of plant and manure storage or disposal; potential additional costs associated with storage of compost materials. Additionally, livestock managers may have to treat only a portion of a site to have an adequate untreated area for livestock to graze during the 3-day clean out period or may not be able to restrict grazing or supply untreated forage for three days. The Agency acknowledges that the notification and recordkeeping measures impose an additional burden on the applicator and the property owner/operator. However, if a user was unable to comply with any mitigation for picloram, the user may apply another herbicide without compost restrictions, if available, which could be more costly and less efficacious.

b. Education Materials and Stewardship Plans

The Agency is proposing that educational materials on the compost issue should be developed by the registrants and provided to applicators property owners/operators, and potentially other affected stakeholders. These materials can help educate property owners/operators and livestock producers on ways to prevent picloram from entering the compost stream. Having targeted educational materials that applicators could provide directly to property owners/operators and livestock producers may help inform these stakeholders and prevent compost contamination. EPA also encourages educational materials to be developed for a wider audience including farmers, compost facilities, gardeners, and other stakeholders involved in the compost waste stream.

Elements that should be part of the educational materials include:

(1) information about picloram: how is it used, how residues arrive in compost, and crops that are particularly sensitive to exposure,

(2) information, including pictures, about the symptoms of herbicide damage (leaf cupping, stunting, swollen stems, leaf puckering, etc.),

(3) the persistence of picloram and information on how long it may last in compostable materials and manure,

(4) tips to prevent materials from entering the compost waste stream for hay producers, dealers, purchasers of hay/straw, livestock and horse owners, and farmers,

(5) methods for how farmers and gardeners using manure, compost, hay, and grass clippings can test for persistent herbicides with their own sample pot and field bioassays, and

(6) any compost/manure label restrictions.

The Agency is proposing that the educational materials be available for download via a link on the label, where applicators can download educational materials which can then be provided the to the proper owner/operator as part of the notification requirement.

In addition, EPA is proposing to require stewardship plans from registrants that include information on (1) how frequently educational materials will be updated with any new information, and (2) how these materials will be shared/distributed to applicators, land managers, livestock producers, and others involved in the compost supply chain, and (3) how picloram registrants may be coordinating efforts.

As part of discussions with the Agency on February 19, 2020 (for the registration review of clopyralid), Corteva Agriscience noted past stewardship efforts to educate stakeholders on the potential for compost contamination from use of aminopyralid (another pyridine herbicide with similar compost contamination issues). Corteva Agriscience currently has an internal stewardship program for aminopyralid and is working to develop a technical bulletin to inform applicators and growers about the importance of preventing compost contamination. EPA encourages registrants to leverage this existing program for picloram. The Agency can issue a DCI for stewardship plans to ensure that all technical registrants are involved (and can collaborate) in stewardship efforts.

EPA encourages the use of existing materials that meet the elements described above for applicators to share with property owners/operators and among the impacted compost and picloram applicator community. In addition, picloram registrants are encouraged to develop any other stewardship materials that may help in educating users and property owners/operators about the unique challenges of managing pesticides like picloram. Some state agricultural extension agencies have developed educational materials on picloram and strategies to prevent compost contamination which EPA encourages registrants to leverage.

c. Revision of Compost Pictogram

Some picloram labels have a pictogram to educate users on ways picloram residues can enter compost (Figure 1). For products that allow use on pasture, rangeland, conservation reserve land, and agricultural crops, EPA is proposing a revised pictogram on these labels where the primary focus is to communicate that manure and plant material exposed to picloram should not be moved offsite for composting and provide information for how to manage treated materials. In addition to the changes to the pictogram, a warning to limit the movement of manure and plant materials is proposed to accompany the pictogram. Corteva Agriscience has generated a new

pictogram (Figure 2) which it has agreed to add to product labels. Figure 2 is an example pictogram for a label with some affected use sites, registrants may customize the pictogram to fit registered use sites for picloram. While all registrants are not required to use Corteva's pictogram, the Agency requires that similar pictograms be developed if registrants opt not use Corteva's pictogram. Any proposed pictograms must be approved by the Agency before inclusion on the label.

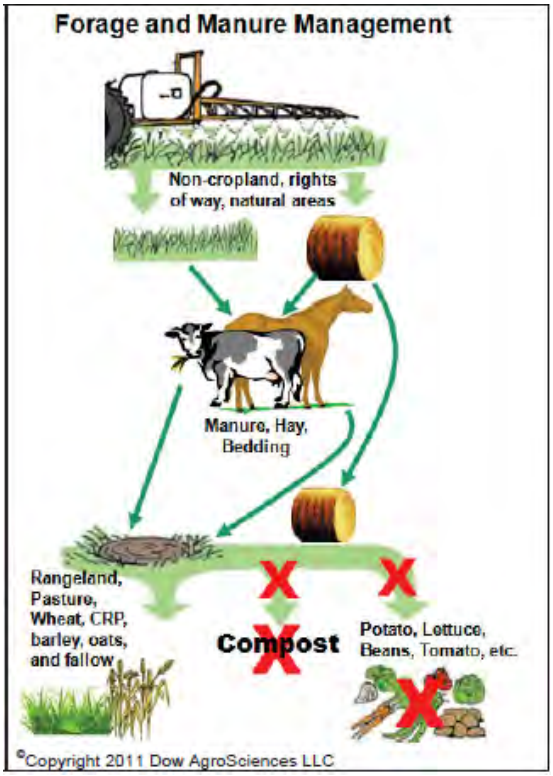

Figure 1: The current pictogram on some picloram labels showing pathways picloram can enter manure and compost.

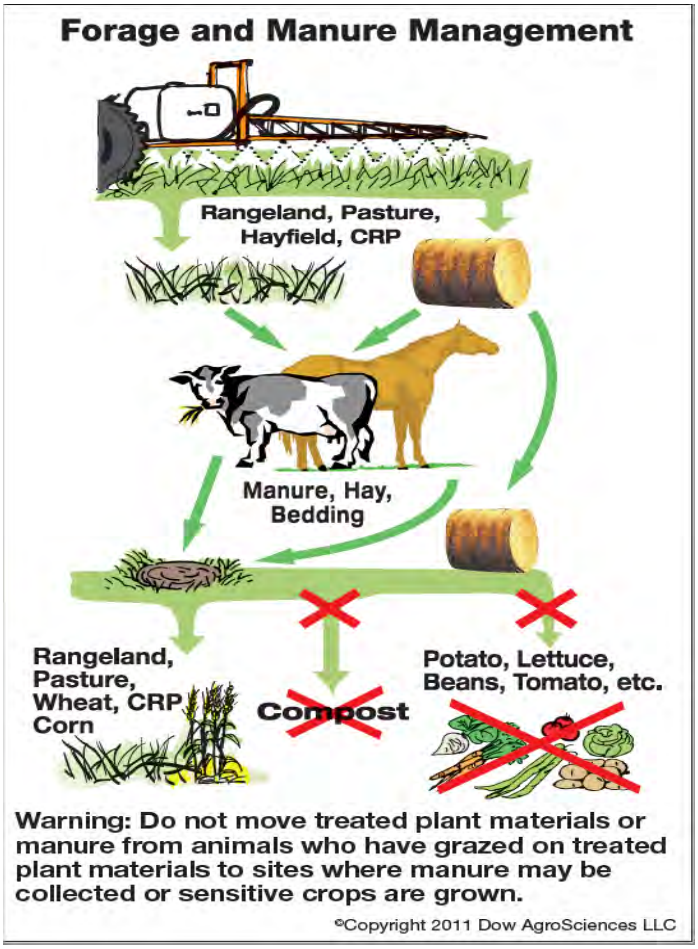

Figure 2: A proposed compost pictogram to replace current pictogram on picloram labels warning users of the compost/manure restrictions.

4. Spray Drift Management

The Agency is proposing label changes to reduce off-target spray drift due to risk of concerns being identified for off field non-target plants from both aerial and ground application. The proposed label changes will establish a baseline level of protection against spray drift that is consistent across all picloram 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 picloram.

The Agency is proposing the following spray drift mitigation language to be included on all picloram 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 also providing recommendations which allow picloram registrants to standardize all advisory language on picloram product labels. Registrants must ensure that any existing advisory

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, do not apply when wind speeds exceed 15 mph at the application site.
- For ground boom applications, apply with the release height no more than 3 feet above the ground or crop canopy unless making a turf, pasture, or rangeland application, in which case applicators may apply with a nozzle height no more than 4 feet above the ground.
- For ground boom-less applications, there is no mandatory release height restriction due to boom-less equipment having physical limitations for achieving a height of 3 to 4 feet. Advisory spray drift language informing applicators to set nozzles at the lowest effective height to help reduce the potential for spray drift is proposed. The droplet size for these applications are also typically coarser, thus reducing the risk of spray drift.
- For ground and aerial applications, applicators are to select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 and Standard 641 (ASABE S572 for ground application and ASABE S641 for aerial application).

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 courser droplet sizes (as defined by The American Society of Agricultural and Biological Engineers S572 and S641) specifically for picloram. However, because a medium to coarse droplet size is already required on several picloram labels and picloram is systemic, the Agency anticipates this requirement will have few impacts on picloram users. EPA encourages comments on any potential impacts to growers from specifying a mandatory minimum droplet size on picloram product labels.

The Agency is considering a mandated wind speed of 15 miles per hour (mph) or less for all use sites and across all application equipment. Currently, most picloram labels do not contain mandated wind restrictions; however, at least one label (i.e., EPA Reg. # 62719-17, 2009a) does

mandate a 2-10 mile per hour wind restrictions. A survey[14] of more than 2,000 certified pesticide applicators in Missouri found that most applicators are aware of wind speeds when making herbicide applications, and that most typically apply at wind speeds of 15 mph or lower. However, there are situations (e.g., when rain and other weather conditions are right for application, when pest pressure is high, etc.) when applicators will spray at wind speeds greater than 15 mph.

The Agency is considering a maximum spray release height of four feet for ground boom applications to turf, pastureland or rangeland; all other use sites may be restricted to a three-foot spray release height. Currently, labels to not contain a spray release height restriction. There is no release height required for rights of way including roadside applications; these applications are applied with a boom-less ground sprayer.

Spray release height is important to minimize overlap of spray from nozzles while maintaining proper coverage. Nozzles placed too low will not provide adequate coverage and could lead to portions of the field not receiving pesticide application. Untreated areas can harbor pests and could lead to re-infestation of treated areas and result in increased pesticide use. A review of manufacturer recommendations found that a maximum release height of 4-feet for pastureland or rangeland allows adequate coverage for most nozzles[15], and EPA expects no negative impact from this mitigation.

However, a three-foot spray release height for agricultural crops may impact growers that currently use picloram at a release height of more than three feet. In such a case, growers may have to purchase new nozzles to accommodate a three-foot spray height, adjust their boom, or apply a different chemical that does not have this requirement which could be more expensive and/or less efficacious.

The Agency has assessed the impact of the proposed spray drift management labeling and has concluded that the spray drift management measures proposed are not expected to substantially alter the way picloram is used.

In addition to including the spray drift restrictions and advisory language on picloram labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all picloram labels where such information currently appears. The proposed new language above, which cites ASABE S572 and S641, eliminates the need for VMD information.

[14] Bish, M. and K.W. Bradley. 2017. Survey of Missouri Pesticide Applicator Practices, Knowledge, and Perceptions. Weed Technology 31:165–177. Available at: https://weedscience.missouri.edu/Pesticide%20Applicator%20Knowledge_2017.pdf

[15] Tindall, K. and C. Hanson. 2018. Qualitative Benefits and Usage Assessment of Diflufenzopyr (PC Code 005108) and Diflufenzopyr-Sodium (PC Code 005107). Accessed 02/2020. https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0911-0022.

5. Non-target Organism Advisory

The Agency is also proposing the addition of a non-target organism advisory. The protection of pollinating organisms is a priority for the Agency. Use of picloram 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, EPA is proposing a non-target organism advisory to be placed on picloram labels to address this potential concern. The proposed advisory reads as follows:

"NON-TARGET ORGANISM ADVISORY: 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."

6. Proposed Water Advisories

In addition to spray drift and compost mitigation measures, EPA is proposing updated water advisories to address potential concerns with detections and persistence in surface and groundwater. The picloram RED previously required water advisories, which the Agency is now proposing to update as follows:

Surface Water Advisory

Picloram has been detected in surface water monitoring data. Picloram's fate properties suggest that it has a high potential to reach surface water. For this reason, the Agency is proposing a surface water advisory to be placed on all picloram labels to address this potential concern.

Non-agricultural labels are proposed to include the following 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 groundwater. This product is classified as having high potential for reaching both surface water and aquatic sediment via runoff for several months after application."

Agricultural labels are proposed to include the following 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 groundwater. This product is classified as having high potential for reaching both surface water and aquatic sediment via runoff for several months after application. 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 picloram 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

Picloram has been detected in groundwater monitoring data. In addition, picloram has environmental fate properties that indicate it has potential to persist in groundwater. For this reason, the Agency is proposing a groundwater advisory to be placed on all picloram labels to address this potential concern:

"Picloram and its associated salts is known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

Users are advised not to apply picloram where soils have a rapid to very rapid permeability (such as loamy sand to sand) and the water table of an underlying aquifer is shallow or to soils containing sinkholes over limestone bedrock, severely fractured surfaces, and substrates which would allow direct introduction into an aquifer. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater."

The Agency anticipates minimal impacts from requiring these statements on all picloram end-uses product labels as these measures are not expected to fundamentally affect how picloram is used and will promote good pesticide management practices.

Irrigation Water Statement

There have been incidents of damage to non-target plants caused by the use of irrigation water containing picloram residues. Due to the highly persistent nature of picloram in groundwater, using contaminated irrigation water also represents an exposure pathway for non-target terrestrial organisms. The Agency is proposing an irrigation water statement to be applied to all labels to address this potential risk:

"Do not contaminate water intended for irrigation or domestic purposes. To avoid injury to crops or other desirable plants, do not treat or allow spray drift or run-off to fall onto banks or bottoms of irrigation ditches, either dry or containing water, or other channels that carry water that may be used for irrigation or domestic purposes. Do not apply to snow or frozen ground."

7. Herbicide Resistance Management

On August 24, 2017, EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.[16] Consistent with the Notice, 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.

[16] 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

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.

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.

8. Tolerance Actions

EPA anticipates removing trailing zeros from several tolerances to conform to OECD guidelines. For additional details, refer to Section III.A.4. The Agency will use its FFDCA rulemaking authority to make the anticipated changes to the tolerances.

9. 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) and the Endangered Species Act (ESA) of this case, the Agency has made the following proposed interim decision: (1) additional data are proposed to be required at this time; and (2) changes to the affected registrations and their labeling are proposed 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 picloram, 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 picloram. The Agency's final registration review decision for picloram 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.

10. Data Requirements

The requirements of GDCI-005101-1396 have been satisfied, except the following: non-guideline honey bee adult chronic oral toxicity (MRID 50504401 is in review), non-guideline honey bee larval chronic oral toxicity (MRID 50504402 is in review), and non-guideline honey bee acute larval toxicity (a waiver request has been submitted in MRID 51298901). The GDCI noted that tier II and tier III pollinator studies may be required pending the results of the tier I pollinator studies. Agency will determine if additional Tier II pollinator studies are needed after the Tier I pollinator studies have been reviewed. The Agency will update the status of the GDCI when the new bee studies and the waiver request have been reviewed.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for picloram and will allow a 60-day comment period. 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, EPA may issue an interim registration review decision for picloram. However, a final decision for picloram may be issued without the Agency having previously issued an interim decision. A final decision on the picloram 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 picloram 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 Picloram

Registration Review Case #: 7212
PC Codes: 117401, 117403, 117404, & 117423
Chemical Type: Herbicide
Chemical Family: Pyridine carboxylic acid
Mechanism of Action: synthetic auxin--mimics naturally occurring plant hormones, thereby disrupting growth

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Birds	Application to crops, spray drift and runoff	Dietary	Chronic	Reduction in egg and hatchling size	Enforceable spray drift management measures
Terrestrial Plants	Spray Drift and Runoff	Foliar absorption	N/A	Growth, seedling emergence	Enforceable spray drift management measures Groundwater advisory Surface water advisory Irrigation statements
Terrestrial Plants	Contaminated Compost	Residues in compost	N/A	Growth, Seedling Emergence	Language prohibiting the off-site use of picloram-treated/exposed materials in compost and animal feed/bedding for 18 months after application Notification and record keeping requirement for applicators to inform land managers/operators of compost restrictions A clean-out period of 3 days for animals that have grazed on treated plant materials before being moved to an area where manure may be collected Updated compost pictogram to inform users on how to manage treated plant materials Registrant-generated stewardship and education measures

Appendix B: Proposed Labeling Changes for Picloram Products

<table>
<tr><th>Description</th><th>Proposed Label Language for Picloram Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>End Use Products</td><td></td></tr>
<tr><td>Mechanism of Action Group Number</td><td>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
Include the type of pesticide (i.e., HERBICIDE or FUNGICIDE or INSECTICIDE) in the fourth column.
<table><tr><td>Picloram</td><td>GROUP</td><td>4</td><td>HERBICIDE</td></tr></table></td><td>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.</td></tr>
<tr><td>HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management</td><td>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)</td><td>Directions for Use, prior to directions for specific crops under the heading “WEED RESISTANCE-MANAGEMENT”</td></tr>
<tr><td>Updated Gloves Statement</td><td>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.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</td></tr>
<tr><td>Non-target Organism Advisory</td><td>“NON-TARGET ORGANISM ADVISORY: 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.”</td><td>Environmental Hazards</td></tr>
</table>

Description	Proposed Label Language for Picloram Products	Placement on Label
Groundwater Advisory	"Picloram is known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow. Users are advised not to apply picloram where soils have a rapid to very rapid permeability (such as loamy sand to sand) and the water table of an underlying aquifer is shallow or to soils containing sinkholes over limestone bedrock, severely fractured surfaces, and substrates which would allow direct introduction into an aquifer. Your local agricultural agencies can provide further information on the type of soil in your area and the location of groundwater."	Environmental Hazards
Surface Water Advisory for products with no agricultural uses	"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 groundwater. This product is classified as having high potential for reaching both surface water and aquatic sediment via runoff for several months after application."	Environmental Hazards
Surface Water Advisory for products with agricultural uses	"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 groundwater. This product is classified as having high potential for reaching both surface water and aquatic sediment via runoff for several months after application. 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 picloram 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."	Environmental Hazards
Irrigation Water Statement	"Do not contaminate water intended for irrigation or domestic purposes. To avoid injury to corps crops or other desirable plants, do not treat or allow spray drift or run-off to fall onto banks or bottoms of irrigation ditches, either dry or containing water, or other channels that carry water that may be used for irrigation or domestic purposes. Do not apply to snow or frozen ground."	Environmental Hazards
Remove Rye and Grain Sorghum as Labeled Use Sites	References to rye and grain sorghum must be removed if listed as labeled use sites. For example, rye and grain sorghum must be removed from the following statement: "Plant only a labeled crop such as pasture grasses, small grains (barley, oats, rye, or wheat), or after a rotation interval of 8 months, grain sorghum."	Throughout Label
Updated Crop Rotation Instructions	"Treated fields may be rotated to labeled crops at any time. For fields being rotated to a non-labeled crop, picloram application must be made a minimum of 12 months prior to planting. Do not plant sensitive broadleaf crops until soil residues have declined to a safe level as indicated by an adequately sensitive bioassay using the intended broadleaf crop."	Directions for Use
Off-site Compost and Animal Feed/Bedding Restrictions	**For all products:** • "This product is persistent and may be present in treated plant materials for months to years after application. Do not sell or transport treated plant materials or manure from animals that have grazed on treated plant materials off-site for compost distribution or for use as animal bedding/feed for 18 months after application."	Directions for Use

Description	Proposed Label Language for Picloram Products	Placement on Label
	• "Manure from animals that have grazed or eaten forage or hay harvested from treated areas within the previous three days may only be applied to the fields where the following crops will be grown: pasture grasses, grass grown for seed, wheat and corn." • "Animals that have been fed picloram-treated forage must be fed forage free of picloram for at least 3 days before movement to an area where manure may be collected, or sensitive crops are grown." **Additional labeling for products with pasture uses:** • "The applicator must document that they have notified property owners/operators, or customers, in writing, of the compost and animal bedding/feed prohibitions before application of the product occurs. Applicators must keep the records of notification for two years. This record must include date of application, the name of the applicator, the EPA registration number of the product applied, the area(s) treated, and a copy of the written notification provided to the property owner/operator. Notification may be made via email, via mail, via paper handout, or by any other written communication method. Records must be made available to State Pesticide Regulatory Official(s), and to EPA upon request. If this information is already being retained, duplicate records are not needed." • "Applications by property owners/operators on their own property are exempt from this notification and record keeping requirement." • "Applications to public land are exempt from this notification requirement."	
Forage and Manure Management Pictogram	Include forage and manure management pictogram to communicate that treated plant materials and manure from animals that have grazed in treated areas cannot be sold or transported off-site for compost distribution and animal feed/bedding. In addition, this warning must be included in the pictogram: "Warning: Do not move treated plant materials or manure from animals who have grazed on treated plant materials to sites where manure may be collected or sensitive crops are grown."	Direction for Use
Link to educational materials	"For more information on how to manage picloram treated materials and to prevent picloram from contaminating compost please visit https://www.epa.gov/pesticide-reevaluation/registration-review-pyridine-and-pyrimidine-herbicides."	Directions for Use
Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	"**MANDATORY SPRAY DRIFT MANAGEMENT** **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 select a nozzle and pressure combination that delivers a medium or coarser droplet size (ASABE S641). • 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	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Aerial Applications"

Description	Proposed Label Language for Picloram Products	Placement on Label
	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. • 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 during temperature inversions."	
Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications	"**MANDATORY SPRAY DRIFT MANAGEMENT** • **Ground Boom Applications:** Apply with the release height no more than 3 feet above the ground or crop canopy unless making a turf, pasture, or rangeland application, in which case applicators may apply with a nozzle height no more than 4 feet above the ground. • Applicators are required to select a nozzle and pressure combination that delivers a medium or coarser droplet size (ASABE S572). • Do not apply when wind speeds exceed 15 mph at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are applied as liquids and allow boom-less ground sprayer applications (this includes application to roadsides and rights of ways)	**"MANDATORY SPRAY DRIFT MANAGEMENT** • **Boom-less Ground Sprayer Applications:** Applicators are required to select a nozzle and pressure combination that delivers a medium or coarser droplet size (ASABE S572) 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 Management" under the heading "Boom-less 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.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Picloram Products	Placement on Label
	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. **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.	

Description	Proposed Label Language for Picloram Products	Placement on Label
	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 ADVISORIES** **<u>Boom-less Ground Applications:</u>** 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 ADVISORIES** **<u>Handheld Technology Applications:</u>** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
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

Appendix C: Compost Incidents Reported to EPA for Picloram

Incident number	Year	State	Legality classification	Certainty index	Affected species	Incident Summary
I010624-001	2000	WA	Registered use	Probable	Unknown Plant	Home gardeners reported non-target plant injuries associated with the distribution of compost by Washington State University. Tordon™ 101 Mixture containing both picloram TIPA salt and 2,4-D was used on university fields and the resulting harvested hay was fed to cattle. Manure from the cattle contained picloram residues, and residues were also detected in soil samples from home gardens where the compost was applied. Excreta from the cattle contained Tordon™, and the subsequent concentration found in the home gardens was of the order of 0.01 ppb picloram. It was considered unlikely that damage to the non-target plants could be attributed to the 2,4-D use (no residues were found in the garden soil and 2,4-D is not known to be persistent in compost), but the certainty of injury being attributed to the nontarget plants as a result of picloram use was considered probable.
I018930-031)	2007	TX	Accidental Misuse	Possible	Cantaloupe, watermelon, onion, tomatoes and peppers	An incident was reported where Grazon™ (picloram TIPA salt and 2,4-D) allegedly caused injury to 2 acres of cantaloupe, watermelon, onion, tomatoes and peppers to the point where these crops could not produce fruits. Manure from horses fed hay previously treated with Grazon™ was composted and used for fertilizer in an organic production system. The manure was composted, applied to the field and incorporated with tillage equipment. The incident report indicated that label directions were not followed in this case. However, the incident report also stated that was apparently no way for the organic grower to know that Grazon™ had been used on the hay that was fed to the horses prior to the grower obtaining manure and composting.
I018677-001	2007	VA	Undetermined	Highly Probable	Tomato, potato and squash	An incident was reported where mulch containing picloram residues was applied to a field and resulted in damage to 10 acres of crops. Plant samples showed detections of the herbicide.
I025047	2013	TX	Undetermined	Possible	Unknown Plant	A grower applied three tons of cow manure from a local feeding operation and following application nothing grew on his land. The grower claimed manure may have been contaminated with picloram, clopyralid, and aminopyralid. The certainty that picloram use caused this incident was determined to be possible. The legality of the use was not determined.
I025960-001	2013	VT	Misuse	Highly Probable	Unknown Plant	Picloram along with aminopyralid and clopyralid residues were reportedly detected in compost from Green Mountain Compost. Picloram reportedly entered the manure from treated grass clippings.

Appendix D: Endangered Species Assessment

In 2013, 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. 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 picloram does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this PID, 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 picloram. This will allow 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 picloram as part of completing this registration review.

Appendix E: 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 picloram, 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), picloram 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 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,[17] 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. Picloram 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 EPA website.[18]

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

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