Memorandum Supporting Final Decision to Approve Registration for the New Active Ingredient of Trifludimoxazin

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I. SUMMARY

This memorandum presents the rationale to support the final decision of the U.S. Environmental Protection Agency (EPA or the Agency) to register under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the new active ingredient (ai), trifludimoxazin, for use on legume vegetable group 6; foliage of legume vegetable group 7; bearing and non-bearing tree crops: citrus fruit group 10-10, pome fruit group 11-10, tree nuts group 14-12; cereal grain group 15&16 (except rice); peanut; soybean; and post-harvest and fallow land use.

Trifludimoxazin (1,5-dimethyl-6-thioxo-3-[2,2,7-trifluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2-1,4-benzoazin-6-yl]-1,3,5-triazinane-2,4-dione; CAS Number: 1258836-72-4), is a new oxazine contact herbicide to control broadleaf and grass weed species. Both the Herbicide Resistance Action Committee (HRAC) and the Weed Science Society of America (WSSA) classify trifludimoxazin as a Group 14 (PPO inhibition) herbicide. The herbicidal action of trifludimoxazin is as a light-dependent peroxidizing herbicide (LDPH) that acts through inhibition of the protoporphyrinogen-IX-oxidase (PPO) enzyme, which is an important component of biosynthesis of chlorophyll in plants. PPO inhibition ultimately causes the cell membranes to leak, rapidly dry, and disintegrate. Trifludimoxazin is primarily a contact herbicide and is rapidly absorbed by roots and foliage. Susceptible emerging weed seedlings treated with trifludimoxazin absorb the chemical through roots and foliage and will usually die as they reach the soil surface or shortly after emergence. Trifludimoxazin will be an additional broad-spectrum weed control option in the labeled crops to control weeds, including weeds that are resistant to some PPO herbicides and other modes of action.

The Agency received an application from BASF Corporation (referred to hereafter as BASF) to register trifludimoxazin products. BASF's application includes a single technical product, Tirexor Herbicide Technical (EPA Reg. No. 7969-491; 99.2% Trifludimoxazin) as well as five end-use products, Tirexor Herbicide (EPA Reg. No. 7969-492; 41.53% Trifludimoxazin), Vulcarus Herbicide (EPA Reg. No. 7969-496; 41.53% trifludimoxazin), Rexovor Herbicide (EPA Reg. No. 7969-494; 41.53% Trifludimoxazin), Voraxor Herbicide (EPA Reg. No. 7969-495; 10.76% Trifludimoxazin, 21.51% Saflufenacil) and Antorix Herbicide (EPA Reg. No. 7969-493; 10.76% Trifludimoxazin, 21.51% Saflufenacil).

Tirexor (EPA Reg. No. 7969-492), Vulcarus (EPA Reg. No. 7969-496) and Rexovor (EPA Reg. No. 7969-494) are soluble concentrate liquid herbicides containing 4.17 pounds trifludimoxazin per gallon, that may be applied by ground (as a broadcast, banded or spot treatment) or by air. Voraxor (EPA Reg. No. 7969-495) and Antorix (EPA Reg. No. 7969-493) are also soluble concentrate liquid herbicides containing 1.04 pounds trifludimoxazin and 2.08 pounds saflufenacil per gallon and may be applied by ground (as a broadcast, banded or spot treatment) or by air.

II. REQUESTED ACTION

On April 28, 2022, the EPA received an application from BASF to register one technical product and five end-use products containing trifludimoxazin for use on cereal grains crop group 15 (except rice), forage/fodder/straw of cereal grains crop group 16 (except rice), legume vegetable group 6, foliage of legume vegetable group 7, soybean, citrus fruit crop group 10-10, peanut, pome fruit crop group 11-10, and tree nut crop group 14-12, postharvest and fallow land use.

Table 1. Overview of Registered Products

EPA File Symbols	Product Information
7969-491	Trifludimoxazin Technical (99.2%) – Tirexor Herbicide Technical
7969-496	7969-496 Trifludimoxazin 41.53% Liquid Herbicide – Vulcarus™
7969-492	7969-492 Trifludimoxazin 41.53% Liquid Herbicide- Tirexor™
7969-494	7969-494 Trifludimoxazin 41.53% Liquid Herbicide - Rexovor™
7969-495	7969-495 Trifludimoxazin 10.76% + Saflufenacil 21.51% - Voraxor™
7969-493	7969-493 Trifludimoxazin 10.76% + Saflufenacil 21.51% - Antorix™

Trifludimoxazin was previously registered as new herbicide by the Agency on May 17, 2021. Subsequently, BASF voluntarily withdrew the initial registrations after EPA was sued for allegedly failing to comply with the ESA when approving the previous registration. The tolerances that were established for the initial registration remain and BASF Corporation has not submitted a tolerance petition with this new application. Therefore, the Agency has not published a notice of filing in the Federal Register under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting the establishment of tolerance regulations for residues of trifludimoxazin on various commodities. EPA is moving forward with the previously assessed crop groups for trifludimoxazin per request of the registrant. EPA is not proposing to update the tolerances to reflect the newer crop groups.

In this application, BASF Corporation included proposed mitigations intended to reduce exposure to non-target organisms (including listed species). These proposed mitigations include removal of all previously approved non-agricultural use sites, prohibition of use in AK, HI, and US territories, prohibition of aerial application in peanuts and tree crops, and reduced maximum application rates in most field, row and tree crops.

Under FIFRA section 3(c)(4), EPA is required to notify the public when a request for registering a new active ingredient is made and allow a 30-day public comment period. The EPA published a notice of receipt in the Federal Register for an application requesting the registration of trifludimoxazin on March 27, 2023. One comment was received. This comment is discussed in Section V Public Comments.

III. USE PROFILE

Table 2 outlines the uses for trifludimoxazin. The trifludimoxazin end-use products Tirexor (7969-492 trifludimoxazin 41.53%), Vulcarus (7969-496 trifludimoxazin 41.53%), Rexovor (7969-494 trifludimoxazin 41.53%), Voraxor (7969-495 trifludimoxazin 10.76% + saflufenacil 21.51%) and

Antorix (7969-493 trifludimoxazin 10.76% + saflufenacil 21.51%) are formulated as a soluble concentrate. Trifludimoxazin may be applied by ground equipment (banded, broadcast, or spot treatment) or aircraft for pre- or post-emergent control of broadleaf and grass weeds. Trifludimoxazin may be applied with sprayable fluid nitrogen fertilizer solutions. Additionally, trifludimoxazin may be impregnated on and applied with dry bulk fertilizers. The label stipulates that applicators and other handlers must wear a long-sleeved shirt and long pants, chemical resistant gloves, shoes plus socks, and protective eye wear (such as face shield, goggles, or safety glasses). Depending on the use site, maximum single application rates range from 0.011 to 0.034 lb ai/A. The minimum re-treatment interval is 14 days, and the pre-harvest intervals for applicable use sites/patterns range from 0 to 7 days, in rotational crops a plant back interval (PBI) of 30 days is sufficient. The restricted-entry interval (REI) is 12 hours. The product label prohibits trifludimoxazin use on any non-agricultural use sites, including residential applications. The product label prohibits use in Alaska, Hawaii, United States (US) Territories, and New York (Nassau and Suffolk counties only). Spot treatments and applications with bulk fertilizers must not exceed the maximum labeled rate for the crop. Applications of trifludimoxazin to areas where domestic animals graze is prohibited.

Table 2. Final Use Patterns of Trifludimoxazin								
Crop Group/ Use Group	**Application Method [1]**	**Max Single Use Rate (lbs ai/A)**	**Max # Uses/ Year**	**Max Annual Use Rate (lbs ai/A/yr)**	**Minimum Retreatment Interval (d)**	**Preharvest Interval (d)**	**Aerial application restriction**	**Comments**
Citrus[2] Group 10-10	Ground	0.022	4	0.089	21	May be applied any time up to or on the day of harvest.	Do not apply aerially	--
Corn	Aerial, Ground	0.011	1	0.011	NA	NA		Do not apply after crop emergence
Legume Vegetable[3] Group 6 and 7	Aerial, Ground	0.011	1	0.011	NA	NA		
Peanut	Ground	0.034	1	0.034	NA	NA	Do not apply aerially	
Pome Fruit[4] Group 11-10	Ground	0.022	4	0.089	21	May be applied any time up to or on the day of harvest.	Do not apply aerially	-
Postharvest and Fallow[5]	Aerial, Ground	0.022	1	0.022	NA	NA		--
Cereal Grain[6]	Aerial, Ground	0.011	1	0.011	NA	NA		Do not apply after crop emergence
Sorghum	Aerial, Ground	0.011	1	0.011	NA	NA		
Soybean	Aerial, Ground	0.011	2	0.022	14	NA		
Tree Nut[7],[8]	Ground	0.022	4	0.089	21	7	Do not apply aerially	-

NA - Not applicable;

[1] Ground applications included banded, broadcast, or spot treatments.

[2] Citrus Crop Group 10-10 includes Australian desert lime, Australian finger lime, Australian round lime, Brown river finger lime, calamondin, citron, citrus hybrids, grapefruit, Japanese summer grapefruit, kumquat, lemon, lime, mediterranean mandarin, mount white lime, new guinea wild lime, orange (sour), orange (sweet), pummelo, Russell river lime, satsuma mandarin, sweet lime, tachibana orange, Tahiti lime, tangelo, tangerine (mandarin), tangor, trifoliate orange, uniq fruit.

[3] Legume vegetable Crop Groups 6 and 7 include edible beans, edible peas, and field peas.

[4] Pome fruits Crop Group 11-10 includes apple, azarole, crabapple, loquat, mayhaw, medlar, pear, Asian pear, quince, Chinese quince, Japanese quince, tejocote.

[5] May be applied after previous crop harvest, during a fallow period, preceding crop planting or after crop planting as pre-emergence treatment in field and row agricultural crops. that includes all labeled crops including canola, cotton, rice, sugar beet and sunflower.

[6] Cereal grains (Crop Groups 15 and 16 except rice) that includes sorghum, corn and small grains. Corn on the label refers to field corn (grain, seed, or silage), popcorn (grain, seed), and sweet corn (processing, fresh market, seed). Small grains as a labeled use refers to barley, millet (pearl and proso), oats, rye, triticale, and wheat (including durum, spring and winter).

[7] Tree nuts Crop Group 14-12 includes African nut-tree, almond, beech nut, Brazil nut, Brazilian pine, bunya, bur oak, butternut, cajou nut, candlenut, cashew, chestnut, chinquapin, coconut, coquito nut, dika nut, ginkgo, guiana chestnut hazelnut (filbert), heartnut, hickory nut, Japanese horse-chestnut, macadamia nut, mongongo nut, monkey-pot, monkey puzzle nut, okari nut, pachira nut, peach palm nut, pecan, pequi, pili nut, pine nut, pistachio, sapucaia nut, tropical almond, walnut (black/English), yellowhorn.

[8]Tree nut, Pome fruit & Citrus crop groups applications were updated in January 2025 from 4 to 3 annual applications for co-formulations of trifludimoxazin.

IV. EVALUATION

In evaluating a pesticide registration application, EPA assesses a wide variety of use information (i.e., where and how the pesticide is used) and environmental fate (i.e., persistence and mobility of the chemical in the environment) and toxicity (i.e., effects on humans and other non-target organisms) studies to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the use of the product. Risk assessments are developed to evaluate the environmental fate of the compound as well as how it might affect a wide range of non-target organisms including humans and terrestrial and aquatic wildlife (plants and animals). In addition, a benefits assessment may be conducted. Based on these assessments, the EPA evaluates benefits versus risks and approves language for each pesticide label to ensure the directions for use and safety measures are appropriate to mitigate any potential risk to meet the FIFRA standard of no unreasonable risks to humans or the environment. In this way, the pesticide label communicates essential limitations and mitigations that are necessary for public and environmental safety. It is a FIFRA violation to use a registered pesticide in a manner inconsistent with its labeling. Consistent with Endangered Species Act (ESA) Section 7(a)(2), EPA also assessed the potential effects of the use of trifludimoxazin on federally listed threatened or endangered (hereafter referred to as "listed") species and their designated critical habitats (CHs).

Please note that the sections below A-C are for assessment of risks to human health, assessment of environmental and ecological risks, ESA assessment, and benefits assessment.

A. Assessment of Risks to Human Health

The EPA requires a wide range of studies to assess a pesticide use scenario. For the proposed uses of trifludimoxazin, the database is complete.

The toxicology database is considered complete and is adequate. Acceptable guideline studies for developmental, reproductive toxicity, and neurotoxicity are available. The HASPOC recommended that the inhalation toxicity study be waived at this time (J. Camp, TXR# 0057977, 11/27/2019) and the study was waived based on this recommendation.

This section summarizes EPA's Human Health Risk Assessment for New Active Ingredient trifludimoxazin. The complete assessment can be found in docket ID number EPA-HQ-OPP-2022-0649 at www.regulations.gov.

1. Toxicology Profile

The available database of guideline studies for trifludimoxazin indicates that the primary target organs in mammals are the thyroid and liver. However, the hematological effects associated with the PPO inhibitor class of chemicals were observed but not considered adverse at the selected lowest-observable adverse-effects levels (LOAELs). Effects on the thyroid occurred in rats and consisted primarily of follicular cell hypertrophy/hyperplasia and altered colloid of the thyroid after subchronic and chronic exposure durations. Increased relative thyroid weights were also observed in male rats; however, thyroid hormones were not adversely affected after subchronic

exposure for males and females. Liver effects were also observed at the same dose as thyroid effects in male rats after subchronic and chronic exposure. Liver effects were also observed in mice after subchronic and chronic exposure. Effects on the reproductive system were observed as evidence of increased abnormal sperm in male rats in the extended one generation reproductive toxicity study (EOGRTS), and as effects to the epididymis in rats after subchronic and chronic exposure.

Trifludimoxazin did not demonstrate neurotoxic potential in either acute or subchronic neurotoxicity studies in rats. However, in the 90-day subchronic study, observations were suggestive of neurotoxicity, evidenced by functional observational battery (FOB) deficits as well as histopathological findings in the spinal cord and medulla oblongata. These effects were not observed in the chronic toxicity study, but the dosing was lower compared to the subchronic study and neurotoxicity may have occurred at higher doses than what were assessed.

There were no adverse maternal or developmental effects observed in the rat developmental toxicity study at the limit dose. However, in the rabbit developmental study, decreased fetal body weight was observed at a lower dose than maternal toxicity; thus, increased quantitative susceptibility was observed. The EOGRTS study demonstrated no increase in susceptibility as no effects were observed in the offspring while increased incidence and severity of follicular cell hypertrophy/hyperplasia and altered colloid in the thyroid was observed in the parental animals. Immunotoxicity was not observed throughout the toxicity database. Additionally, there were no effects in the dermal toxicity study.

In accordance with EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), the Cancer Assessment Review Committee (CARC) classified trifludimoxazin as "suggestive evidence of carcinogenic potential" (Wilson, M, TXR#0058028, 04/24/2020). The CARC determined that quantification of risk using a non-linear approach (i.e., chronic reference dose [cRfD]) will adequately account for all chronic toxicity, including carcinogenicity, that could potentially result from exposure to trifludimoxazin.

Trifludimoxazin was categorized as having low acute toxicity via the oral (toxicity category III), eye (toxicity category III), dermal (toxicity category IV), and inhalation (toxicity category IV) routes of exposure. It is non-irritating to skin, and not a dermal sensitizer. The signal word assigned for all routes of exposure is "Caution."

A summary of the points of departure (POD) selected for human health risk assessments can be found in **Tables 3** and **4**. No effects attributable to a single dose were observed in the database; therefore, an endpoint for acute dietary was not selected. The rat combined chronic/carcinogenicity study was selected to evaluate chronic dietary exposure. The EOGRTS was selected to evaluate short-term oral exposure in adults and short- and intermediate-term inhalation exposure scenarios. The co-critical 90-day and 1 year dog studies were selected to evaluate incidental oral exposure. Dermal exposure scenarios were not assessed because there was no dermal hazard identified. This section, *Assessment of Risks to Human Health,* is a summary of the agency's human health assessment of trifludimoxazin; the full Human Health Risk Assessment can be found in docket ID number EPA-HQ-OPP-2022-0649 at www.regulations.gov.

While there were adverse androgen and thyroid effects observed for trifludimoxazin, EPA has concluded that no additional estrogen, androgen, or thyroid data are needed at this time (see Section VI. B. below).

Table 3. Summary of Toxicological Doses and Endpoints for Trifludimoxazin for Use in Dietary and Non-Occupational Human Health Risk Assessments

Exposure/ Scenario	POD	Uncertainty/ FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	Not selected; no effects attributable to a single dose were observed in the database.			
Chronic Dietary (All Populations)	NOAEL = 10.7 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.11 mg/kg/day cPAD = 0.11 mg/kg/day	**Combined Chronic/Carcinogenicity study (Rat)** LOAEL = 33 mg/kg/day based on increased incidence of spermatogenic granuloma, altered colloid and follicular cell hyperplasia in the thyroid, and increased pigment, multinucleated hepatocytes and bile duct hyperplasia in the liver.
Incidental Oral (Children 1-2 yrs old) Short-term	NOAEL = 15 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	**Co-critical 90-day and 1 year** LOAEL = 50 mg/kg/day based on abnormal gait, paralysis, degeneration of the fasciculus gracilis and white material in the cervical cord, thoracic cord, medulla oblongata, and lumbar cord.
Adult Oral Short- and Intermediate- Term	Parental NOAEL = 6.4 mg/kg/day	UF_A = 3X UF_H = 10X FQPA SF = 1X	LOC for MOE = 30	**EOGRTS** Parental LOAEL = 22 mg/kg/day based on increased incidence and severity of follicular cell hypertrophy/hyperplasia and altered colloid in the thyroid.
Dermal Short-and Intermediate-Term (1-30 days)	Not selected. No toxicity was observed in a route-specific dermal study, including effects to the thyroid. The increased susceptibility observed in the database was not of concern because, using a 9% DAF, the dermal equivalent LOAEL of developmental effects of concern would be 2X the limit dose and not considered relevant to human health risk assessment.			
Inhalation Short- and Intermediate-Term (1-30 days)	Parental NOAEL = 6.4 mg/kg/day Oral toxicity assumed equal to inhalation toxicity	UF_A = 3X UF_H = 10X FQPA SF = 1X	LOC for MOE = 30	**EOGRTS** Parental LOAEL = 22 mg/kg/day based on increased incidence and severity of follicular cell hypertrophy/hyperplasia and altered colloid in the thyroid.

Table 3. Summary of Toxicological Doses and Endpoints for Trifludimoxazin for Use in Dietary and Non-Occupational Human Health Risk Assessments				
Exposure/ Scenario	**POD**	**Uncertainty/ FQPA Safety Factors**	**RfD, PAD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Cancer (oral, dermal, inhalation)	Classification: "Suggestive evidence of carcinogenic potential". The RfD approach is considered protective.			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UFA = extrapolation from animal to human (interspecies). UFH = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. EOGRTS = extended one generation toxicity study.

Table 4. Summary of Toxicological Doses and Endpoints for Trifludimoxazin for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	**POD**	**Uncertainty Factors**	**LOC for Risk Assessment**	**Study and Toxicological Effects**
Dermal Short- and Intermediate-Term (1-30 days)	No hazard identified.			
Inhalation Short- and Intermediate-Term (1-30 days)	Parental NOAEL = 6.4 mg/kg/day Oral toxicity assumed equal to inhalation toxicity	UF_A = 3X UF_H = 10X	LOC for MOE = 30	**EOGRTS** Parental LOAEL = 22 mg/kg/day based on increased incidence and severity of follicular cell hypertrophy/hyperplasia and altered colloid in the thyroid.
Cancer (oral, dermal, inhalation)	Classification: "Suggestive evidence of carcinogenic potential". The RfD approach is considered protective.			

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UFA = extrapolation from animal to human (interspecies). UFH = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. EOGRTS = extended one generation toxicity study.

2. Dietary (Food + Water) Risks

An acute dietary exposure analysis was not conducted for trifludimoxazin because no appropriate endpoint attributable to a single exposure was identified for the general U.S. population or any population subgroups. Therefore, based upon a qualitative analysis, the Agency concludes there are no acute dietary risks of concern for trifludimoxazin at this time.

Chronic dietary (food and drinking water) exposure and risk assessments were conducted using the Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). Residue input values are

based on tolerance-level residues for all proposed commodities. Because all residues were below the limit of quantitation (<LOQ), processing factors were not incorporated. EDWCs provided by EFED were incorporated directly into the assessments as point estimates. In conducting this assessment, HED assumed that 100% of all crops with trifludimoxazin uses were treated. The chronic risk estimates of food and drinking water found for trifludimoxazin are below the Agency's LOC at < 1% of the chronic population-adjusted dose (cPAD) for the U.S. population and all population subgroups. Therefore, the Agency concludes there are no chronic risks of concern for trifludimoxazin at this time.

The Agency has determined that quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to trifludimoxazin. Therefore, a separate cancer dietary risk assessment is not required, and the non-cancer chronic dietary assessment is protective of any dietary cancer risks (noted in the previous paragraph).

3. Occupational Handler Risks

Based on the anticipated use patterns and current labeling, and types of equipment and techniques that can potentially be used, short- and intermediate-term occupational and post-application handler exposure is expected from the uses of trifludimoxazin. Since no endpoints were identified for the dermal route of exposure, only inhalation exposure and risk estimates were calculated for occupational handlers. None of the short or intermediate-term occupational handler scenarios risk estimates (driven by inhalation since no dermal toxicity endpoints were identified) resulted in margin of exposures (MOEs) that are of concern (MOEs are all greater than 400 (LOC = 30)) with baseline attire (long-sleeve shirt, long pants, and shoes plus socks). No risks estimates of concern were identified for aerial applicators.

In accordance with the Agency's current practices, a quantitative non-cancer occupational post-application inhalation exposure assessment was not performed for trifludimoxazin. Any residues which become inhalable during post-application activities are expected to be lower in concentration than the residues assessed in the handler scenarios. Therefore, it is expected that handler inhalation exposure estimates, which were not of concern, would be protective of most occupational post-application inhalation exposure scenarios.

4. Residential Risks

Trifludimoxazin is not expected to result in any residential exposures, either for residential handlers, or residential post-application scenarios, since there are no proposed residential uses. Therefore, there are no residential MOEs for consideration in the aggregate risk assessment for trifludimoxazin.

5. Aggregate Risk

In accordance with the FQPA, HED must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative

estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure.

The aggregate risk estimates are equivalent to the dietary exposure assessment conclusions (food and drinking water only) because there are no residential exposures anticipated from the uses. The risk estimates are below the LOC for all dietary routes of exposure. An acute dietary exposure analysis was not conducted for trifludimoxazin because no appropriate endpoint attributable to a single exposure was identified for the general U.S. population or any population subgroups. As an acute dietary exposure analysis was not conducted for trifludimoxazin, there are no acute exposures that contribute to aggregate exposure or risk. Chronic aggregate risk is equal to chronic dietary exposure (food + drinking water) and is not of concern.

6. Non-Occupational Spray Drift Exposure and Risk Estimates

HED conducts human health spray drift assessments to determine potential risk from indirect exposure to pesticides that may drift during or immediately after an application. Pesticide applications made in the form of a spray and applied aerially or via airblast or groundboom may result in pesticide drift and deposition in non-target areas adjacent to the application site.

On July 15th, 2024, the Agency updated its practice on spray drift[1] to include chemical-specific spray drift assessments for proposed uses through Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration actions (e.g., Section 3 new active ingredient and/or new use registrations, label amendments, Section 18 emergency exemptions, etc).

Trifludimoxazin is proposed for registration as a new active ingredient. Therefore, EPA conducted a chemical-specific assessment of spray drift exposure. Because a dermal POD has not been established for trifludimoxazin, only incidental oral non-occupational spray drift exposure and risk estimates have been assessed.

There were no risks at the edge of the field and therefore no spray drift buffers are required to protect bystanders.

7. Cumulative Risk

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to trifludimoxazin and any other substances and trifludimoxazin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that trifludimoxazin has a common mechanism of toxicity with other substances.

B. Assessment of Environmental Fate and Ecological Risks

[1] *Implementing Chemical Specific Human Health Spray Drift Analysis for Pesticide Registration Action.* Available online: https://www.regulations.gov/document/EPA-HQ-OPP-2013-0676-0124.

The ecological risk assessment examines the potential for adverse effects to non-target organisms associated with proposed uses of trifludimoxazin and accounts for any mitigations on the proposed label as submitted by the registrant in their application. EPA also conducted an assessment that evaluates potential effects on listed species and includes EPA's predictions of potential likelihood of future jeopardy (J) for federally threatened or endangered (listed) species or adverse modification (AM) of designated critical habitats (CH). These assessments also considered potential effects to the co-formulated active ingredient saflufenacil in the proposed products. In addition to consideration of any mitigations included in the registrant's initial application, EPA's assessment also takes into account additional mitigations proposed by EPA and agreed to by the registrant subsequent to the original application with the goal of avoiding potential likelihood of future jeopardy or adverse modification (J/AM). Evaluated taxa include mammals, birds (which serve as surrogates for reptiles and terrestrial-phase amphibians), terrestrial invertebrates (*Apis* and non-*Apis*), fish (where freshwater fish serve as surrogates for aquatic-phase amphibians), aquatic invertebrates, and aquatic, terrestrial and wetland plants. Ecological risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects using a risk quotient (RQ) method. For this method, RQs are calculated by dividing point estimates of exposure (i.e., estimated environmental concentration [EEC]) by point estimates of toxicity (RQ = EEC/toxicity endpoint), for both acute and chronic effects. The RQs are then compared to EPA's acute and chronic risk Levels of Concern (LOC) for each taxon. The LOCs are well-established levels used by EPA to indicate potential risk to non-target organisms.

The LOC indicates whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. RQs below a LOC indicate there are no risks of concern for that taxon. If the RQ exceeds the LOC, then the EPA further characterizes and describes the associated risk of concern.

These findings also play a role in EPA's assessment of potential effects to listed species, as required by the Endangered Species Act (ESA). If the RQs representative of listed species exposure are below the listed species LOC for a particular taxon, EPA does not expect direct effects to listed species in that taxon. However, further refinement or analysis may be necessary to complete an effects determination for listed species within that taxon because there may be effects to a listed species from potential direct effects to another taxon on which the listed species depends for prey, pollination, habitat, and/or dispersal (referred to as "PPHD"). In making its effects determinations, EPA evaluates both potential direct and PPHD effects to listed species and designated critical habitats.

EPA has determined that all relevant data requirements specified in 40 CFR Part 158 based on the uses of trifludimoxazin have been satisfied (completed, waived, or not triggered). There are no data gaps for environmental fate or ecological effects studies of trifludimoxazin.

This section summarizes EPA's Environmental and Ecological Risk Assessment. The complete assessment can be found in docket ID number EPA-HQ-OPP-2022-0649 at www.regulations.gov.

1. Environmental Fate

The Residues of Concern (ROC) for assessing aquatic and terrestrial exposure are the parent compound plus major degradates M850H001, M850H002, M850H003, M850H004, M850H033, M850H0035 and M850H042, which are the seven degradates that form in environmentally relevant media.

Where alkaline conditions exist, the major environmental exposure route of degradation for trifludimoxazin is hydrolysis (half-life = 0.33 day at pH 9), while hydrolysis is slow under neutral conditions, and is stable at pHs 4 and 5. Also, trifludimoxazin degrades via soil photolysis (time to 50% degradation (DT_{50}) = 32 days). Where neutral or acidic conditions exist, the major environmental exposure route of degradation is aerobic soil metabolism. Under aerobic soil conditions, trifludimoxazin is non-persistent to slightly persistent (DT_{50} = 12-40 days). Trifludimoxazin ROC degrades in days to years under anaerobic aquatic conditions (DT_{50} = 8.8-817 days) and degrades under aerobic aquatic conditions similarly (DT_{50} = 19-224). Trifludimoxazin is classified as moderately water soluble and as moderately mobile in soil. Trifludimoxazin is not expected to volatilize under dry and wet field conditions. Terrestrial field dissipation of trifludimoxazin indicated dissipation half-lives from 2.9 to 12.5 days across six sites.

2. Environmental Effects

EPA took a comprehensive approach in evaluating potential risk concerns for all taxa (including freshwater and estuarine/marine fish and invertebrates, aquatic vascular and non-vascular plants, birds, mammals, terrestrial invertebrates (including honey bees), and terrestrial and wetland plants using available data. These studies include registrant-submitted acute and chronic toxicity data on trifludimoxazin. Since trifludimoxazin is a new pesticide that was only registered for use in the United States for a short time before the initial registration was canceled, there are no incident data to report for any taxon.

In the following sections, the toxicity of trifludimoxazin (and its co-formulated active ingredient saflufenacil, where relevant) to various taxonomic groups is summarized. Simultaneous exposure to both trifludimoxazin and saflufenacil as contained in co-formulated products (*i.e.,* Antorix and Voraxor) was considered in this assessment. After a comparison of the available toxicity data for both active ingredients, trifludimoxazin was determined to be the driver of toxicity for all taxa, except for terrestrial invertebrates, which were more sensitive to saflufenacil. Therefore, the risk conclusions for trifludimoxazin are inclusive of saflufenacil exposure across all taxa, except terrestrial invertebrates, where exposure to saflufenacil was quantitatively assessed due to the more sensitive endpoint. It is important to note that EPA determined there was no relevant evidence of greater-than-additive effects for trifludimoxazin and saflufenacil.[2]

As discussed above, EPA integrates toxicity data with exposure estimates (*i.e.*, estimated environmental concentrations (EEC)) to generate RQ values. **Table 5** summarizes RQs and LOC exceedances for listed and non-listed species associated with the uses of trifludimoxazin.

[2] USEPA. 2023. *Trifludimoxazin: Addendum to Patent Search Reviews*. March 16, 2023. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency (DP 467118).

Terrestrial Plants

Vegetative vigor endpoints represent the most sensitive growth stage for terrestrial plants. Trifludimoxazin was similarly toxic to both dicots (tomato IC_{25} of 0.00075 lbs a.i./A) and monocots (ryegrass IC_{25} of 0.0011 lbs a.i./A) in the available seedling emergence studies. A similar trend was observed in vegetative vigor studies, where dicot plants (IC_{25} of 0.0000438 lbs a.i./A; soybean) were slightly more sensitive to trifludimoxazin exposure than monocot plants (IC_{25} = 0.000193 lbs a.i./A; corn). While dicots are more sensitive than monocots, there are toxicity concerns for both. There were LOC exceedances for listed and non-listed terrestrial and wetland aquatic plants for all uses of trifludimoxazin. Therefore, direct risks of concern are expected for this taxon.

Aquatic Vascular and Non-vascular Plants

In general, vascular plants were more sensitive to trifludimoxazin than non-vascular plants. Five toxicity studies were conducted on the vascular aquatic plant, *Lemna gibba* with the technical grade active ingredient (TGAI, 98.5% a.i.), 3 major degradates M850H001, M850H002, M850H004, and a trifludimoxazin typical end-use product (TEP, BAS 850 00H (40.9% a.i.)). The major degradates were 24 to 150-fold less toxic to aquatic plants compared to the parent compound (EC_{50} = 0.115 µg a.i./L; LOAEC = 0.0305 µg a.i./L based on a 33% reduction in biomass). Vascular toxicity endpoints for the TEP (BAS 850 00H; NOAEC = 0.0139 µg a.i./L; EC_{50} = 0.116 µg a.i./L) were similar to that of the TGAI (NOAEC = 0.0143 µg a.i./L; EC_{50} = 0.115 µg a.i./L).

For nonvascular aquatic plants, the most sensitive EC_{50} was 0.200 µg a.i./L, for the TGAI based on a 35% reduction in freshwater diatom (*Navicula pelliculosa*) yield at the LOAEC of 0.134 µg a.i./L. The degradates were 5 to 20-fold less toxic to non-vascular aquatic plants compared to the parent compound. Nonvascular toxicity endpoints for the TEP (freshwater algae (*Pseudokirchneriella subcapitata*); NOAEC = 0.068 µg a.i./L; EC_{50} = 0.20 µg a.i./L) were similar to that of the TGAI (NOAEC = 0.108 µg a.i./L; EC_{50} = 0.356 µg a.i./L). There were LOC exceedances for listed and non-listed, vascular and non-vascular aquatic plants for all uses of trifludimoxazin. Therefore, direct risks of concern are expected for this taxon.

Aquatic Invertebrates

Trifludimoxazin is classified as moderately toxic to freshwater invertebrates (*Daphnia magna*) (1,950 µg a.i./L). There was no evidence that *Daphnia* were more sensitive to the metabolites M850H001 and M850H002 compared to TGAI. In a chronic exposure study conducted with daphnia, a 20% reduction in parental survival, 17% reduction in total living offspring, and 9% decrease in successful birth rate were observed at the LOAEC (20.4 µg a.i./L; NOAEC = 10.1 µg a.i./L). For estuarine/marine invertebrates, trifludimoxazin is classified as highly toxic to mysids (*Americamysis bahia*) on an acute exposure basis (371 µg a.i./L). There were no significant effects observed for mysids in the available chronic exposure study (NOAEC = 52.5 µg a.i./L) and, therefore, the corresponding LOAEC is non-definitive (*i.e.,* LOAEC > 52.5 µg a.i./L). There were no LOC exceedances for aquatic invertebrates. Therefore, there are not expected to be direct risks of concern from exposure to trifludimoxazin or the co-formulated active ingredient saflufenacil.

Aquatic Vertebrates

Trifludimoxazin is classified as practically non-toxic to freshwater and estuarine/marine fish on an acute exposure basis. On a chronic exposure basis, trifludimoxazin exhibits toxicity to both freshwater and estuarine/marine vertebrates with reported effects on survival and growth. In an early life-stage chronic for fathead minnow (*Pimphales promelas*), there was 11% reduction in number of live larvae at the LOAEC (18 µg a.i./L). In the sheepshead minnow chronic study, the most sensitive endpoints were wet weight and length with 16.3 % and 6.3% decreases, respectively, at the LOAEC (4.7 µg a.i./L).

Due to the potential for LDPH chemicals to cause enhanced toxicity to fish under UV light (*i.e.,* natural sunlight in clear, shallow pools), a chronic endpoint (NOAEC) for fish was estimated using a surrogate molar threshold following EPA guidance[3] (*i.e*., molecular weight of trifludimoxazin*0.002 µg-mol/L). Based on the molecular weight of trifludimoxazin of 412.3 g/mol, the NOAEC under UV light is 0.82 µg a.i./L. This molar equivalency fish chronic toxicity NOAEC is roughly 15 and 4x, respectively, less than the lowest empirical chronic toxicity NOAEC for freshwater fish (12 µg a.i./L) and for estuarine/marine fish (2.7 µg a.i./L). There were no LOC exceedances for aquatic vertebrates; therefore, there are not expected to be direct risks of concern from exposure to trifludimoxazin or the co-formulated active ingredient saflufenacil.

Birds, Reptiles, and Terrestrial-Phase Amphibians

Acute oral toxicity tests of TGAI with bobwhite quail (*Colinus virginianus*), mallard duck (*Anas platyrhynchos*), and canary (*Serinus canaria*) reported no effects from trifludimoxazin at concentrations > 2000 mg a.i./kg-bw. Based on these data, trifludimoxazin is classified as practically non-toxic to birds on an acute oral exposure basis. There were no mortalities or other sublethal effects reported in sub-acute dietary studies conducted with mallard ducks and bobwhite quail (LC_{50} = 2,841 and 2,222 mg a.i./kg-diet, respectively). In a chronic exposure study conducted with bobwhite quail, the LOAEC (285 mg a.i./kg-diet) was determined based on significant reproductive endpoint effects (viable embryos/eggs set, live embryos/eggs set, number of hatchlings/eggs set, 14-day hatchlings/eggs set, and no. of hatchlings/live embryos) (NOAEC 145 mg a.i./kg-diet). There were no LOC exceedances for birds (surrogates for reptiles and terrestrial-phase amphibians). Therefore, there are not expected to be direct risks of concern from exposure to trifludimoxazin or the co-formulated active ingredient saflufenacil.

[3] EPA LDPH guidance can be found here: https://www.epa.gov/sites/default/files/2016-06/documents/guidancelightdependentperoxidizingherbicides.pdf

Mammals

An acute oral toxicity study with rats (*Rattus norvegicus*) reported no chemical-related effects at the highest tested concentration (lethal dose to 50% of tested organisms, *i.e.* LD_{50} >2000 mg a.i./kg-bw). Therefore, trifludimoxazin is considered practically non-toxic to mammals on an acute oral exposure basis. Chronic exposure to trifludimoxazin resulted in a NOAEC of 750 mg/kg-diet (NOAEL = 64.4 and 68.1 mg a.i./kg-bw/day for males and females, respectively), based on no effects on survival, reproduction, or growth compared to the negative control. There were no LOC exceedances for any use pattern. Therefore, there are not expected to be direct risks of concern from exposure to trifludimoxazin or the co-formulated active ingredient saflufenacil.

Honey Bees (and Non-Apis Terrestrial Invertebrates)

Trifludimoxazin is classified as practically non-toxic to honey bees (*Apis mellifera)*, which serve as surrogates for both *Apis* and non-*Apis* bees, on both an acute contact and oral exposure basis. In addition, trifludimoxazin is classified as practically non-toxic to larval honey bees on an acute oral exposure basis. The chronic oral LOAEL (5.5 µg a.i./larva/day) for larval bees is based on a 17% reduction in adult bee emergence and is two times above the NOAEL (2.9 µg a.i./larva/day) used to calculate the RQs. There were no mortalities reported at any concentration (NOAEL = 9.6 µg a.i./bee/day) for adult honey bees on a chronic oral exposure basis. In the absence of more sensitive endpoints for non-*Apis* terrestrial invertebrates, the dietary endpoints for honey bees were used as surrogates to assess trifludimoxazin exposure to non-target, non-*Apis* terrestrial invertebrates.

Saflufenacil is a co-formulated active ingredient with trifludimoxazin in two TEPs proposed for registration (Antorix™ and Voraxor™). Based on the available toxicity data for saflufenacil, it has higher toxicity to honey bees compared to trifludimoxazin, and therefore is expected to be the driver for potential risks to terrestrial invertebrates. Exposure risks, from saflufenacil alone, are expected to be low for adult honey bees on an acute and chronic exposure basis and to larval honey bees on an acute exposure basis. The saflufenacil TGAI chronic oral LOAEL (0.49 µg a.i./larva/day) for larval bees is based on day-8 mortality and is three times above the NOAEL (0.15 µg a.i./larva/day). The chronic oral LOAEL (24.4 µg a.i./bee/day) for adult bees based on reductions in food consumption and is 1.8 times greater than the NOAEL (13.9 µg a.i./bee/day). In the absence of more sensitive endpoints for non-*Apis* terrestrial invertebrates, the dietary endpoints for honey bees were used as surrogates to assess saflufenacil exposure to non-target, non-*Apis* terrestrial invertebrates.

There are not expected to be risks of concern for honey bees or non-*Apis* terrestrial invertebrates from the uses of trifludimoxazin alone. However, there are on-field, direct risk concerns for honey bees and non-*Apis* terrestrial invertebrates based on exposure to the co-formulated active ingredient saflufenacil.

Table 5. Summary of Ecological Risk Conclusions for the Final Registration of the Herbicide Trifludimoxazin						
Taxa	**Exposure Duration or Pathway**	**Risk Quotient (RQ) Range[1]**	**Potential Risk to Non-listed Species?[3]**	**Additional Information/ Lines of Evidence**	**Do Potential Risks to Non-Listed Species Extend Beyond the Treated Field?**	**Potential Direct Effects to Listed Species?[4,5]**
Vascular and Non-Vascular Aquatic Plants	Wetland	Non-Listed 1.0 - 125 Listed 2.9 – 1007	Yes	Potential risk could occur for both vascular and non-vascular plants (wetland and non-wetland) based on assessment of wetland plant exposure zone (WPEZ) and aquatic plant exposure zone (APEZ) modeled estimated exposure concentrations (EECs).	Yes	Yes
	Non-Wetland	Non-Listed <0.1 – 10.2 Listed <0.1 – 82.1	Yes		Yes	Yes
Terrestrial Plants	Upland or Dry-Land	Non-Listed 0.7 – 148 Listed 0.1 – 1970	Yes	Multiple lines of evidence suggest potential risk for terrestrial and wetland plants from runoff and drift-based exposure.	Yes	Yes
	Wetlands, Riparian Areas	Non-Listed 0.1 - 187 Listed 0.1 - 2482	Yes		Yes	Yes
Aquatic Vertebrates (Surrogates for Aquatic phase Amphibians)	Acute	NC	No	RQs could not be calculated due to non-definitive endpoints. However, risk is expected to be low on an acute basis because EECs are at least 490x lower than the non-definitive endpoints.	No	No
	Chronic	Freshwater: <0.1 Estuarine/Marine: <0.1 – 0.4 LDPH-derived:	No	Based on the LDPH-derived endpoint, there were LOC exceedances for the uses of trifludimoxazin on tree crops, peanuts, and postharvest and fallow. However, risk to this taxon is considered to be low as there were no reported signs of hematological effects (from PPO-inhibition) in	No	No

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Taxa	**Exposure Duration or Pathway**	**Risk Quotient (RQ) Range[1]**	**Potential Risk to Non-listed Species?[3]**	**Additional Information/ Lines of Evidence**	**Do Potential Risks to Non-Listed Species Extend Beyond the Treated Field?**	**Potential Direct Effects to Listed Species?[4,5]**
		<0.1 – 1.4		the available aquatic vertebrate toxicity studies, no aquatic uses (including applications to rice and/or cranberry), and no LOC exceedances based on empirical toxicity data (non-adjusted). Therefore, risk is expected to be low from the uses of trifludimoxazin.		
Aquatic Water Column Invertebrates	Acute	Freshwater: NC Estuarine/Marine (Mysid): <0.01 Estuarine/Marine (Oyster): NC	No	RQs could not be calculated for freshwater invertebrates and oysters due to nondefinitive endpoints. However, both nondefinitive endpoints are nearly three orders of magnitude greater than the maximum EEC for trifludimoxazin exposure (1.26 µg a.i./L.; postharvest and fallow).	No	No
	Chronic	Freshwater: <0.1 - 0.1 Estuarine/Marine: <0.01 – 0.02	No	(No additional lines of evidence)	No	No
Aquatic Benthic Sediment Invertebrates	Acute	Freshwater: <0.01 Estuarine/Marine: <0.01	No	(No additional lines of evidence)	No	No
	Chronic	Freshwater Pore Water: <0.1 Sediment: <0.1	No	(No additional lines of evidence)	No	No

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		Estuarine/Marine Pore Water: <0.1 Sediment: <0.1				
Birds (Surrogates for Terrestrial-Phase Amphibians and Reptiles)	Acute	Dose-based NC Dietary-based <0.01	No	The maximum dose-based EEC (12.6 mg a.i./kg-bw) is 159x less than the nondefinitive dose-based endpoint for birds.	No	No
	Chronic	Dietary-based <0.1	No	(No additional lines of evidence)		
Mammals	Acute	Dose-based <0.1 Dietary-based NC	No	There is not acute dietary toxicity endpoint. However, risk is expected to be low based on risk quantitation for the available acute and chronic dose-based and chronic dietary-based toxicity endpoints.	No	No
	Chronic	Dose-based <0.1 Dietary-based <0.1	No	(No additional lines of evidence)		
Bees and Other Terrestrial Invertebrates	Acute Adult	NC	No	Both acute oral and contact endpoints for adults were non-definitive), with all available LD_{50} values >107 µg a.i./bee and at least three orders of magnitude the maximum dietary dose (0.0918 µg a.i./bee). Therefore, risk is expected to be low.	No	No
	Chronic Adult	0.1	No	(No additional lines of evidence)	No	No

Table 5. Summary of Ecological Risk Conclusions for the Final Registration of the Herbicide Trifludimoxazin						
Taxa	**Exposure Duration or Pathway**	**Risk Quotient (RQ) Range[1]**	**Potential Risk to Non-listed Species?[3]**	**Additional Information/ Lines of Evidence**	**Do Potential Risks to Non-Listed Species Extend Beyond the Treated Field?**	**Potential Direct Effects to Listed Species?[4,5]**
	Acute Larval	NC	No	The acute larval oral exposure endpoint was non-definitive. However, the non-definitive endpoint (LD_{50} > 105 µg a.i./larva) is an order of magnitude greater than the dietary EEC (0.46 µg a.i./larva). Therefore, risk is expected to be low.	No	No
	Chronic Larval	<0.1 – 3.1	Yes	There were larval honey bee and other terrestrial invertebrate chronic exceedances based on evaluation of the most sensitive endpoint for the co-formulated active ingredient saflufenacil. However, risk did not extend beyond the treated field.	No	Yes

C. Final Effects Determination under the Endangered Species Act

Consistent with ESA Section 7(a)(2), EPA assessed the potential effects of trifludimoxazin, and the co-formulated active ingredient saflufenacil, on listed species and designated critical habitats (CHs). The federal action area is the overall geographic extent or footprint of the federal action plus any additional areas where effects are reasonably expected to occur and is based on the registered uses of trifludimoxazin and the co-formulant saflufenacil. EPA conducted an overlap analysis to determine which listed species and designated CHs occur within this action area. EPA also considered life history (including factors such as diet and body weight), toxicity, and exposure information to determine whether trifludimoxazin will have No Effect (NE) or May Affect (MA) an individual of each listed species or its designated critical habitat.

Based on EPA's screening-level assessment, there are potential direct effects on listed bees and other terrestrial invertebrates (RQ range: 0.1-3.1), vascular and non-vascular aquatic plants (RQ range: <0.1-82), upland terrestrial plants (RQ range: 0.1-1970), and wetland plants (RQ range: 0.1-2482).

EPA's analysis identified 1,796 listed and proposed species and 921 designated CHs within the action area. EPA made NE determinations for 709 listed species and 499 designated CHs based on (1) low overlap; (2) the species or habitat is in an area where exposure is reasonably not expected to occur; (3) no direct toxicity to the taxon with no dependency on plants for PPHD; and/or (4) no plant-based physical and biological factors (PBFs). EPA made MA determinations for the remaining 1,087 listed species and 422 designated CHs.

For those listed species and designated CHs with MA determinations, EPA further distinguished whether trifludimoxazin is not likely to adversely affect (NLAA) or likely to adversely affect (LAA) an individual of the listed species or any designated CH. EPA made NLAA determinations for 203 listed species and 96 CHs. A majority of the NLAA determinations were based upon unlikely exposure due to habitat or when specific physical and biological factors for the designated CHs are not expected to be impacted by trifludimoxazin exposure. EPA made LAA determinations for 884 listed and proposed species and 326 CHs. These species were either listed or proposed terrestrial, wetland or aquatic plants or terrestrial invertebrates that may be directly affected by the proposed uses, or listed animals that depend upon plants for PPHD. For all designated CHs with proposed LAA determinations, the primary factor leading to the determination was potential effects on plant-based PBFs where plants serve as PPHD for the listed species. Table 6 summarizes the effects determinations by taxon for listed species and for designated CHs.

EPA further evaluated the LAA species and CHs and made predictions about the potential likelihood of future jeopardy to any listed species or potential likelihood of adverse modification of any designated CH from the use of trifludimoxazin (and the co-formulated active ingredient saflufenacil) after implementation of mitigations agreed upon by the registrant (as described in Sections VI.D. below). EPA originally predicted a potential likelihood of future J/AM for fourteen (14) listed terrestrial plant species and two (2) designated critical habitats, prior to the consideration of proposed mitigations that are expected to avoid the potential likelihood of future J/AM. These mitigations for the uses of trifludimoxazin are also expected to reduce incidental

take and adverse effects to plants which are likely to result from this action without these mitigations.

Table 6. Number of Listed and Proposed Species and Designated Critical Habitat Effects Determinations and EPA's Predictions of Potential Likelihood of Future Jeopardy or Adverse Modification by Taxon Following Commitment to EPA-Proposed Mitigations.[1]

Taxon	Number of Species/CH[2]	NE	NLAA	LAA, No J/AM	LAA, J/AM
Amphibians[2]	42	5	11	26	0
Aquatic Invertebrates	194	13	15	166	0
Birds	111	61	13	37	0
Fish	180	17	11	152	0
Mammals	104	18	34	52	0
Plants	950	501	81	368	0
Reptiles[3]	55	10	16	29	0
Terrestrial Invertebrates[4]	161	84	22	54	0
Total Listed and Proposed Species	1796	709	203	884	0
Designated and Proposed Critical Habitat	921	499	96	326	0

[1] CH = critical habitat; NE = no effect; NLAA = not likely to adversely affect; LAA = likely to adversely affect; J = potential likelihood of future jeopardy; AM = potential likelihood of future adverse modification

[2] Reflects the species and critical habitats listed or proposed as of February 16th, 2022 due to availability of overlap and life history data from the Services.

[3] "Amphibians" and "Reptiles" includes species that have both a terrestrial and aquatic phase.

[4] Terrestrial Invertebrates" includes damselflies which have both a terrestrial and aquatic phase

C. Benefits Assessment

Trifludimoxazin is a LDPH and PPO inhibitor, classified by the Weed Science Society of America (WSSA) as Group 14 herbicide, which is proposed for preemergence and/or postemergence (burndown) control of a variety of problematic annual broadleaf weed species and some annual grass weed species. Based on usage information, for agricultural use sites, the five most commonly used herbicides in terms of acres treated for control of trifludimoxazin target weeds are glyphosate, atrazine, mesotrione, S-metolachlor, and fomesafen.

Field trials indicate that trifludimoxazin could provide comparable control of major weed pests such as waterhemp and Palmer amaranth, including some PPO-resistant biotypes, to herbicides such as flumioxazin, saflufenacil, and sulfentrazone that are currently registered and used by growers. Trifludimoxazin would be an additional broad-spectrum weed control option in the registered crops and may control some PPO-resistant weeds depending on the mechanism of resistance.

For more detailed information on benefits for trifludimoxazin refer to the following document in the docket EPA-HQ-OPP-2022-0649 "Revised Benefits Review for a New Active Ingredient Registration of Trifludimoxazin for Preemergence and/or Postemergence Control of Annual Broadleaf and Grass Weeds in Various Agricultural Use Sites".

D. Synergy

Some chemical companies have made claims in patents that certain combined mixtures of pesticides elicit synergistic effects, meaning that when the chemicals are mixed the combined effect is greater than the sum of the individual effects of each chemical. But upon inspection of these patents for trifludimoxazin, the underlying raw data of three patents are cumulative of data disclosed in the patent specification and are not replicated; therefore, they are relevant but not suitable for quantitative use in the ecological risk assessment. More details on the synergy patent search review are in the document entitled Trifludimoxazin: Review of U.S. Patent Search Submission in docket ID number EPA-HQ-OPP-2022-0649.

V. PUBLIC COMMENTS

On March 27, 2023, the EPA published a Notice of Receipt (NOR) in the Federal Register (EPA-HQ-OPP-2022-0649) notifying that EPA was in receipt of an application to register pesticide products containing an active ingredient not included in any currently registered pesticide products (trifludimoxazin) and announced a public comment period of 30 days. EPA received one comment on the NOR from the Center for Food Safety (CFS). CSF's comment summarized the history of the previous registration action, as well as detailed the risks, benefits, and mitigations previously proposed. CSF emphasized the need of EPA to meet FIFRA and ESA obligations. The comment can be found in docket ID number EPA-HQ-OPP-2022-0649 at www.regulations.gov.

Trifludimoxazin was previously registered with the Agency, and the registrant, BASF corporation, subsequently voluntarily withdrew the initial registration. This is a second application to register

this chemical with the Agency, and BASF Corporation has not submitted any tolerance petition with this new application as tolerances were already established in relation to the previous trifludimoxazin registration application. Therefore, the Agency has not published a notice of filing (NOF) in the Federal Register under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting the establishment of tolerance regulations for residues of trifludimoxazin on various commodities.

The comments are addressed in the Response to Public Comments (RTC) document published to the docket alongside this Final Decision Memo. The Memorandum Supporting Proposed Decision to approve registration for the new active ingredient of trifludimoxazin was available for 45-day public comment on June 11, 2025, closing on July 26, 2025. The Agency received 22 comments to the docket. The agency responded to the comments received on the NOR, and proposed decision document in the RTC and can be found in docket ID number EPA-HQ-OPP-2022-0649 at www.regulations.gov. None of the comments received changed the Agency's final regulatory decision to approve the registration.

VI. FINAL REGULATORY DECISION

In accordance with FIFRA, EPA registers a pesticide unconditionally when it determines that it will not cause unreasonable adverse effects on humans or the environment, while taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. Under FIFRA, EPA is charged with balancing risks posed by the use of a pesticide against its benefits. EPA must determine if the benefits in light of its use outweigh the risks for EPA to register the pesticide.

FIFRA 3(c)(5) requires EPA to approve registration if the Agency determines that:

(a) its composition is such as to warrant the proposed claims for it;
(b) its labeling and other material required to be submitted comply with the requirements of this subchapter;
(c) it will perform its intended function without unreasonable adverse effects on the environment; and
(d) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

A. Rationale and Risk Mitigation

EPA is proposing to issue unconditional registrations under FIFRA section 3(c)(5) for the following products for use on conventional varieties of legume vegetable group 6 & 7; citrus fruit group 10-10; pome fruit group 11-10; tree nuts group 14-12; cereal grain group 15 & 16 (except rice); peanut; and soybean.

- Tirexor Herbicide Technical (EPA File Symbol 7969-491) as a TGAI.
- Tirexor Herbicide (EPA File Symbol 7969-492) as an end-use product.
- Vulcarus Herbicide (EPA File Symbol 7969-496) as an end-use product.
- Rexovor Herbicide (EPA File Symbol 7969-494) as an end-use product.

- Voraxor Herbicide (EPA File Symbol 7969-495) as an end-use product.
- Antorix Herbicide (EPA File Symbol 7969-493) as an end-use product.

To determine whether the products will cause unreasonable adverse effects under FIFRA, EPA is charged with considering the economic, social, and environmental costs and benefits of the use of the pesticide. To determine the risks and benefits, the Agency reviewed a large body of information based on how these products will be used according to the final labeling. EPA determines whether a product will generally cause unreasonable adverse effects by considering whether the benefits of the product outweigh any potential risks of concern or adverse impacts from its use.

EPA has determined that the database is complete for assessment of risks to human health and the environment for the trifludimoxazin agricultural crop uses. Based on these data, EPA has not identified any dietary or aggregate risks of concern for human health. Additionally, EPA has not identified any direct risks of concern for listed or non-listed freshwater or estuarine/marine invertebrates, fish, aquatic-phase amphibians, mammals, or birds (surrogates for terrestrial-phase amphibians and reptiles) on an acute or chronic exposure basis. In addition, there were no acute direct risks to bees. However, EPA identified potential direct risks of concern for terrestrial, wetland, and aquatic plants, as well as chronic risk to bees and non-*Apis* terrestrial invertebrates that may forage on fields that have been treated with trifludimoxazin products containing the co-formulant saflufenacil. The Agency believes the proposed mitigations to reduce runoff and spray drift described in the ESA section below will avoid the potential likelihood of future jeopardy for listed species and/or adverse modification of designated critical habitat. These mitigations will also reduce the likelihood of adverse effects to individual listed and non-listed species including bees.

Trifludimoxazin is a non-selective protoporphyrinogen oxidase (PPO) inhibitor in the n-phenyl-imide chemical family. It is for pre- and post-emergence control of annual and perennial grass and broadleaf weeds. Trifludimoxazin products could be used in existing weed control programs, or as an additional rotation or tank-mix PPO partner, including as a part of Herbicide Resistance Management (HRM) and Integrated Pest Management (IPM) programs.

The Agency finds the benefit of having a broad spectrum, non-selective foliarly applied herbicide for control of broadleaf weeds and grasses, as a rotational tool, partnered with the mitigation measures for any environmental risks. EPA reviewed the compositions of the products and determined that the claims made are warranted as the data and product label support the approval of the registrations. The final labeling, which has been revised to include additional mitigation measures to address ecological risks, contains all the necessary requirements and restrictions, and complies with the requirements of FIFRA.

Therefore, considering the assessed risk to human health and the environment, consistent with the requirements of FIFRA section 3(c)(5), EPA has determined that trifludimoxazin meets the regulatory standard under FIFRA and concludes that registering the products and the use of trifludimoxazin as a non-selective foliar herbicide for weed control in conventional varieties of legume vegetable group 6 &7; citrus fruit group 10-10; pome fruit group 11-10; tree nuts group 14-12; cereal grain group 15 & 16 (except rice); peanut; and soybean, would not cause unreasonable adverse effects on human health or the environment when the herbicides are used in accordance with the labels, and widespread and commonly recognized practice.

B. Endocrine Disruptor Screening Program

The Federal Food Drug and Cosmetic Act (FFDCA) §408(p) requires EPA to develop a screening program to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." (21 U.S.C. 346a(p)). In carrying out the Endocrine Disruptor Screening Program (EDSP), FFDCA section 408(p)(3) requires that EPA "provide for the testing of all pesticide chemicals," which includes "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." (21 U.S.C. 231(q)(1) and 346a(p)(3)). However, FFDCA section 408(p)(4) authorizes EPA to, by order, exempt a substance from the EDSP if the EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." (21 U.S.C. 346a(p)(4)).

The EDSP initiatives developed by EPA in 1998 includes human and wildlife testing for estrogen, androgen, and thyroid pathway activity and employs a two-tiered approach. 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 pathways. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any adverse estrogen, androgen, or thyroid effect. If EPA finds, based on that data, that the pesticide has an adverse endocrine-related effect on humans, FFDCA § 408(p)(6) also requires EPA, "… as appropriate, [to] take action under such statutory authority as is available to the Administrator … as is necessary to ensure the protection of public health." (21 U.S.C. 346a(p)(6)).

Between October 2009 and February 2010, EPA issued Tier 1 test orders/data call-ins (DCIs) for its first list of chemicals ("List 1 chemicals") for EDSP screening and subsequently required submission of EDSP Tier 1 data for a refined list of these chemicals. EPA received data for 52 List 1 chemicals (50 pesticide active ingredients and 2 inert ingredients). EPA scientists performed weight-of-evidence (WoE) analyses of the submitted EDSP Tier 1 data and other scientifically relevant information (OSRI) for potential interaction with the estrogen, androgen, and/or thyroid signaling pathways for humans and wildlife.

In addition, for FIFRA registration, registration review, and tolerance-related purposes, EPA collects and reviews numerous studies to assess potential adverse outcomes, including potential outcomes to endocrine systems, from exposure to pesticide active ingredients. Although EPA has been collecting and reviewing such data, EPA has not been explicit about how its review of required and submitted data for these purposes also informs EPA's obligations and commitments under FFDCA section 408(p). Consequently, on October 27, 2023, EPA issued a Federal Register Notice (FRN) providing clarity on the applicability of these data to FFDCA section 408(p) requirements and near-term strategies for EPA to further its compliance with FFDCA section 408(p). This FRN, entitled Endocrine Disruptor Screening Program (EDSP): Near-Term Strategies for Implementation' Notice of Availability and Request for Comment (88 FR 73841) is referred to here as EPA's EDSP Strategies Notice. EPA also published three documents supporting the strategies described in the Notice:

- Use of Existing Mammalian Data to Address Data Needs and Decisions for Endocrine Disruptor Screening Program (EDSP) for Humans under FFDCA Section 408(p);
- List of Conventional Registration Review Chemicals for Which an FFDCA Section 408(p)(6) Determination is Needed; and,
- Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions (referred to here as List 1 Screening Conclusions).

The EDSP Strategies Notice and the support documents are available on www.regulations.gov in docket number EPA-HQ-OPP-2023-0474. As explained in these documents, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans, focusing first on conventional active ingredients. Although EPA voluntarily expanded the scope of the EDSP to screening for potential impacts to the estrogen, androgen, and thyroid systems in wildlife, EPA announced that it is not addressing this discretionary component of the EDSP at this time, considering its current focus on developing a comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan and November 2022 ESA Workplan Update). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE memoranda indicate that available data were sufficient for FFDCA section 408(p) assessment and review for potential adverse effects to the estrogen, androgen, or thyroid pathways for wildlife. For the remaining 17 List 1 chemicals, Tier 1 WoE memoranda made recommendations for additional testing. EPA expects to further address these issues taking into account future scientific work.

As discussed in EPA's EDSP Strategies Notice and supporting documents, EPA will be using all available data to determine whether additional data are needed to meet EPA's obligations and discretionary commitments under FFDCA section 408(p). For some conventional pesticide active ingredients, the toxicological databases may already provide sufficient evaluation of the chemical's potential to interact with estrogen, androgen, and/or thyroid pathways and EPA will generally not need to obtain any additional data to reevaluate those pathways, if in registration review, or to provide an initial evaluation for new active ingredient applications. For instance, EPA has endocrine-related data for numerous conventional pesticide active ingredients through either a two-generation reproduction toxicity study performed in accordance with the current guideline (referred to here as the updated two-generation reproduction toxicity study; OCSPP 870.3800 - Reproduction and Fertility Effects) or an extended one-generation reproductive toxicity (EOGRT) study (OECD Test Guideline 443 - Extended One-Generation Reproductive Toxicity Study). In these cases, EPA expects to make FFDCA 408(p)(6) decisions for humans without seeking further estrogen or androgen data. However, as also explained in the EPA's EDSP Strategies Notice, where these data do not exist, EPA will reevaluate the available data for the conventional active ingredient during registration review to determine what additional data, if any, might be needed to confirm EPA's assessment of the potential for impacts to estrogen, androgen, and/or thyroid pathways in humans. For more details on EPA's approach for assessing these endpoints, see EPA's EDSP Strategies Notice and related support documents.

Also described in the EPA's EDSP Strategies Notice is a framework that represents an initial approach by EPA to organize and prioritize the large number of conventional pesticides in registration review. For conventional pesticides with a two-generation reproduction toxicity study performed under a previous guideline (i.e., an updated two-generation reproduction toxicity study

or an EOGRT is not available), EPA has used data from the Estrogen Receptor Pathway and/or Androgen Receptor Pathway Models to identify a group of chemicals with the highest priority for potential data collection (described in EPA's EDSP Strategies Notice as Group 1 active ingredients). For these cases, although EPA has not reevaluated the existing endocrine-related data, EPA has sought additional data and information in response to the issuance of EPA's EDSP Strategies Notice to better understand the positive findings in the ToxCast™ data for the Pathway Models and committed to issuing DCIs to require additional EDSP Tier 1 data to confirm the sufficiency of data to support EPA's assessment of potential adverse effects to the estrogen, androgen, and/or thyroid pathways in humans and to inform FFDCA 408(p) data decisions. For the remaining conventional pesticides (described in EPA's EDSP Strategies Notice as Group 2 and 3 conventional active ingredients), EPA committed to reevaluating the available data to determine what additional studies, if any, might be needed to confirm EPA's assessment of the potential for impacts to endocrine pathways in humans. Since the release of the EDSP Strategies Notice, EPA has updated these groups for conventional pesticides. As further information is received, these groups may be updated in the future as needed.

As noted in EPA's EDSP Strategies Notice and summarized above, where EPA has received endocrine-related data through an updated two-generation reproduction toxicity study or EOGRT study, EPA will generally not need to obtain any additional data, including EDSP Tier 1 data, to confirm its assessment of the potential for adverse effects to the estrogen and androgen pathways in humans. In the case of trifludimoxazin, an EOGRT study has been submitted and no additional data are needed, at this time, to support EPA's assessment of the potential for adverse estrogen and androgen effects in humans.

An EOGRT study that evaluates lifestage sensitivity to thyroid effects is available and the results have been incorporated into the human health risk assessment for trifludimoxazin. Therefore, EPA has concluded, at this time, that the points of departure for human health risk assessment to evaluate the proposed uses of trifludimoxazin are protective of potential adverse estrogen, androgen, and thyroid effects in humans.

The current PODs for human health risk assessment for trifludimoxazin are based on potential adverse androgen and thyroid effects. Since the human health risk assessment did not identify any risks of concern, EPA has completed its FFDCA section 408(p)(6)-related commitments and obligations "to ensure the protection of public health" at this time.

C. Endangered Species Assessment (ESA)

ESA section 7(a)(2) provides that "*[e]ach Federal agency shall, in consultation with [FWS] ensure that any action authorized, funded, or carried out by such agency. . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species. . . .*"
EPA completed effects determinations for federally listed threatened and endangered species (listed species) for the registered uses of trifludimoxazin in the areas where it may be applied. EPA evaluated whether the registration of this active ingredient poses any reasonable expectation of discernible effects to listed species and designated critical habitats within the action area in the listed

species effects determination. The ESA effects determination makes use of the best available scientific and commercially available information and considered both direct and PPHD effects. The term "direct effects" refers to decreases in the survival, growth, or reproduction of individuals of a listed species due to exposure to trifludimoxazin. The term "PPHD effects" refers to impacts on individuals of a listed species that may be the result of the effects of trifludimoxazin to organisms on which the listed species depends upon for prey, pollination, habitat, and/or dispersal.

In the *Final* effects determinations (*Trifludimoxazin: Ecological Risk Assessment and Biological Evaluation for the Proposed Section 3 New Chemical Registration*), EPA concluded that the use of the registered trifludimoxazin products may affect, and are LAA, multiple listed species and designated critical habitats. When considering an action (*e.g.*, the registration of a pesticide product), the ESA directs federal agencies to avoid jeopardizing listed species or adversely modifying their designated critical habitats. An LAA determination is not equivalent to a jeopardy determination; however, EPA can predict the potential likelihood for future J/AM to help inform the formal consultation with the Services and resulting Biological Opinions developed by the Services (*See 50 C.F.R. 402.40(b)(1)*). The purpose of the EPA evaluation of the potential likelihood of future J/AM is to inform mitigations to avoid and minimize exposures to listed species earlier in the consultation process. Therefore, for those species and critical habitats with preliminary LAA determinations, EPA further assessed the potential likelihood that the registered trifludimoxazin products would lead to future J/AM determinations. The Services though will make the final determination as to any jeopardy to listed species and any adverse modification to designated critical habitats.

In the effects determination, EPA originally predicted a potential likelihood of future J/AM for fourteen (14) listed terrestrial plant species and two (2) designated critical habitats, prior to the consideration of proposed mitigations that are expected to avoid the potential likelihood of future J/AM. For one species Spring Creek Bladderpod (*Lesquerella perforata*), the prediction of jeopardy was based on the assumption that this species is found on the treated agricultural field and the overlap at 0 m (i.e., on-field). EPA predicted a potential likelihood of future jeopardy for the remaining thirteen plant species outlined in the EPA's 2024 Vulnerable Species Action Plan and are found in close proximity (>1% overlap at 30 m or less for any associated UDL) to trifludimoxazin use sites. The main risk concern for trifludimoxazin is direct effects (via spray drift and runoff) to listed and non-listed terrestrial and wetland aquatic plants and PPHD effects to listed animals that rely on terrestrial plants and/or vascular and non-vascular aquatic plants. To address the predicted potential likelihood of future jeopardy of listed species and adverse modification of designated critical habitat, EPA used the Herbicide Strategy (HS) framework to inform the level of mitigations necessary to reduce spray drift/runoff.

Overall, EPA identified six points of spray drift/runoff mitigation as sufficient to make population- and community-level effects to listed species not likely from the registered uses of trifludimoxazin. Users must select mitigations that total six points from the website (https://www.epa.gov/pesticides/mitigation-menu). The mitigations identified for the product label, which include national alignment with the HS and committed to by the registrant, include 15- and 110- ft ground and aerial spray drift buffers, respectively, between the application area and closest downwind edge of non-target aquatic and terrestrial habitat, and 6 mitigation points for all uses, and establishment of a Pesticide Use Limitation Areas (PULA) for one species (Spring Creek

Bladderpod). In addition, these mitigations include a reduction in number of applications to tree crops (4 to 3 maximum annual applications) for co-formulated products containing saflufenacil to mitigate risk to terrestrial invertebrates. These mitigations eliminated the predicted potential likelihood of future jeopardy for all but one listed species (Spring Creek Bladderpod). For this species, geographically-specific mitigations as mandated by species-specific PULA, that will be implemented through Bulletins Live! Two (BLT), are expected to reduce exposures so that there is no predicted potential likelihood of future J/AM for any listed/proposed species or designated/proposed critical habitat. Through this mitigation spray applications are prohibited in specific areas between September 15th and May 15.th

EPA predicts that the mitigation measures on these labels reduce the potential likelihood of adverse effects on listed species and their designated critical habitats to the extent that the registration of products containing trifludimoxazin (and the co-formulated active ingredient saflufenacil) would not result in predictions of a potential likelihood of future jeopardy for any listed species or potential likelihood of future adverse modification for any designated CHs. However, the Services have the sole authority to make a final determination of whether these registration actions will likely cause jeopardy of any listed species or adverse modification of any designated CHs. The Services provide their determinations in their biological opinions and may determine that additional mitigations are necessary.

When EPA determines that initiating formal consultation is appropriate on a FIFRA action, the Agency may still be able to proceed with the action before completing consultation if it determines that doing so will not result in "any irreversible or irretrievable commitment of resources . . . [that] has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate [ESA section 7(a)(2)]." See 16 U.S.C. § 1536(d). As stated above, EPA initiated formal consultation with the Services. EPA will work with the Services to complete the consultation process as expeditiously as possible. Acknowledging that the final determination on jeopardy and adverse modification is made by the Services and that either (or both) of the Services may not fully adopt EPA's prediction that this action will avoid jeopardy and adverse modification, the registration includes a term to allow EPA to address any further mitigation determined to be necessary following consultation. The Agency has also concluded that granting the registrations for diflufenican prior to the completion of formal consultation with the Services will not result in any irreversible or irretrievable commitment of resources that would have the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures, in accordance with ESA section 7(d)[4].

D. Label Requirements

The following statements are included on the final end-use product labels.

The following label mitigations have been added to the final product labels (EPA File Symbol 7969-492, 7969-496, 7969-494, 7969-495 and 7969-493) to mitigate environmental risks:

[4] Endangered Species Act Section 7(d) Consistency Determination with Respect to the Application for the Registration of Products Containing the New Active Ingredient Trifludimoxazin.

1. For all use sites:

    a. DO NOT apply the product through any type of irrigation system (e.g. chemigation)
    b. DO NOT contaminate water used for irrigation or domestic purposes
    c. DO NOT sell, distribute, or use in Alaska, Hawaii, US Territories (including American Samoa, Guam, Puerto Rico, Mariana Islands, US Virgin Islands), and in Nassau and Suffolk counties in New York State.

2. The following statements are the use directions in the crop-specific information section of the product label:

    For citrus crop group 10-10, tree nuts crop group 14-12, and pome fruits crop group 11-10:

    a. DO NOT apply aerially in bearing or non-bearing fruit and nut trees
    b. DO NOT apply more than 0.022 lbs a.i. per acre in a single application to citrus, tree nuts, and pome fruits.
    c. DO NOT apply more than 0.089 lbs a.i. per acre per year in citrus, tree nuts, and pome fruits.

    For legume vegetables crop groups 6 & 7, small cereal grain crop groups 15 &16 (except rice), and corn:

    a. DO NOT apply more than 0.011 lbs a.i. per acre in a single application to legume vegetables, small cereal grains (except rice), and corn.
    b. DO NOT apply more than 0.011 lbs a.i. per acre per year to legume vegetables, small cereal grain (except rice) and corn.

    For soybean:

    a. DO NOT apply more than 0.011 lbs a.i. per acre in a single application to soybean.
    b. DO NOT apply more than 0.022 lbs a.i. per acre per year to soybean.

    For peanut:

    a. DO NOT apply aerially in peanut, apply only by ground application equipment
    b. DO NOT apply more than 0.034 lbs a.i. per acre in a single application.
    c. DO NOT apply more than 0.034 lbs a.i. per acre per year.

    Post-harvest and fallow application:

    a. DO NOT apply more than 0.022 lbs a.i. per acre in a single application for post-harvest and fallow application.
    b. DO NOT apply more than 0.022 lbs a.i. per acre per year for post-harvest and fallow application.

3. The following statements are the use directions in the crop-specific information section of the product label for co-formulated products (Voraxor, 7969-495 and Antorix, 7969-493):

    a. DO NOT apply more than 8.25 fl ozs per acre (0.134 lbs a.i. per acre saflufenacil + 0.067 lbs a.i. per acre trifludimoxazin) as a maximum cumulative amount from sequential applications per year.
    b. DO NOT apply more than 3 applications per year.

4. The following Pollinator Advisory statement is included in the "Environmental Hazards" section of the co-formulated products (Voraxor, 7969-495L and Antorix, 7969-493):

    a. **Pollinator Advisory statement:** This product is potentially toxic to bee larvae. Avoid application of this product to crops in bloom or if bees are actively collecting pollen or nectar from the treatment area.

5. To address direct effects to listed plants that establish off-site and prey, pollination, habitat, and dispersal (PPHD) effects to listed animal species that rely on plants, the following applies to all use sites:

- The following language is included in the "**Mandatory Spray Drift Management**" section:

  For aerial and ground applications, maintain a wind-directional (downwind) buffer distance (for aerial - 110 feet and for ground - 15 feet) from the edge of the treated area. The buffer footage distance may include the following managed areas, provided that people are not present within the application exclusion zone during the application, and they will not be contacted by the pesticide, either directly or through drift (see 40 CFR 170.405(a) and 40 CFR 170.505(a)):

    a. Buffer Restrictions for Ground and Aerial Applications:
        - Ground – 15 ft buffer between application area and closest downwind edge of non-target aquatic AND terrestrial habitat
        - Aerial – 110 ft buffer between the application area and closest downwind edge of non-target aquatic AND terrestrial habitat

MANDATORY SPRAY DRIFT MANAGEMENT

Ground Boom Applications:

- During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 15 miles per hour.
- Wind speed and direction must be measured on location using a windsock or anemometer (including systems to measure wind speed or velocity using application equipment).

- Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.
- Do not release spray at a height greater than 2 feet above the ground or crop canopy.
- Applicators must select nozzle and pressure that deliver coarse to very coarse droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASAE S572).
- DO NOT apply during temperature inversions.

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 must select nozzle and pressure that deliver very coarse or coarser droplets in accordance with the most current version of the American Society of Agricultural & Biological Engineers Standard 641 (ASABE S641).

- During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes) must register between 3 and 15 miles per hour.

- Wind speed and direction must be measured on location using a windsock, an anemometer (including systems to measure wind speed or velocity on an aircraft), or an aircraft smoke system.

- Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.

- If the wind speed is 10 miles per hour or less, applicators must use a minimum of ½ swath displacement upwind at the downwind edge of the field. When the wind speed is between 11-15 miles per hour, applicators must use a minimum of ¾ swath displacement upwind at the downwind edge of the field.

- When the wind speed is between 11-15 miles per hour, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.

- DO NOT apply during temperature inversions.

Mandatory Ecological Spray Drift Buffer Requirements:
Ecological spray drift buffers are required for this product for aerial, ground boom to field crops unless the application is occurring as a specialized application (e.g., soil injection, tree injection, spot treatment, small treatment area less than 1/10th of an acre). Access EPA's Mitigation Menu Website at www.epa.gov/pesticides/mitigation-menu for the full list of parameters to evaluate whether your field is subject to the required spray drift buffer.

Applicators must access and search Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins within six months prior to or on the day of the application to determine whether the application site falls within a Pesticide Use Limitation Area (PULA). If you are located inside a PULA, follow the instructions in the BLT bulletin. If the application site falls outside of a PULA, follow the instructions in the "Outside a PULA" section below. Additional restrictions may be present in bulletins—always follow the most restrictive bulletin instructions.

Outside PULAs:
If you are located outside of a PULA, a minimum down-wind spray drift buffer must be maintained between the application area and any unmanaged areas for applications to field crops. Unmanaged areas are defined in comparison to managed areas--anything that is not a managed area is an unmanaged area. Refer to the "Managed Areas Definition" section of this label for information on managed areas.

Mandatory Spray Drift Buffers

For aerial and ground applications, maintain a wind- directional (downwind) buffer distance from the edge of the treated area as follows:

Application Method	Minimum Required Buffer Distance
Aerial	110 feet
Ground	15 feet

Reduction Options for All Ecological Drift Buffers:
Wind-Directional
The applicator may choose among the ecological drift buffer reduction options on EPA's Mitigation Menu Website (https://www.epa.gov/pesticides/mitigation-menu) to reduce the wind-directional buffer distance before applying this product. All buffer reduction options selected must align with the minimum droplet size and release height requirements on this label.

Examples of buffer reduction options include: using larger droplets, lowering the boom height, reducing the maximum single application rate, reducing the number of passes across the field, maintaining a windbreak or hedgerow, or using directed sprayers.

The buffer reduction options must be employed in accordance with the instructions and descriptions on EPA's Mitigation Menu Website. When using more than one option during the application, the percent reduction in the buffer distances may be added together. The maximum buffer reduction that can be achieved by a combination of buffer reduction options is 100% (i.e., no drift buffer).

Additional restrictions may be present in bulletins—always follow the most restrictive bulletin instructions. If you are located in an area where PULAs overlap, follow the most restrictive requirements across all bulletins. When tank mixing, the most restrictive of the products' label or bulletin requirements must be followed (e.g., drift buffers that are not wind-directional, Application Exclusion Zone drift requirements, drift buffers to residences, schools, and parks where people could be present, use prohibitions, timing restrictions, and application method prohibitions).

SPRAY DRIFT ADVISORIES:

THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. Be aware of nearby non-target sites and environmental conditions.

IMPORTANCE OF DROPLET SIZE

An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions.

Controlling Droplet Size – Ground boom

- 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:

- 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

For ground equipment, the boom should remain level with the crop and have minimal bounce. Automated boom height controllers are recommended with large booms to better maintain optimum nozzle to canopy height. Excessive boom height will increase the potential for spray drift.

HOODED (OR SHIELDED) SPRAYERS

Shielding the boom or individual nozzles can reduce spray drift. Consider using hooded 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.
Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.

MEASURING WIND SPEED AND WIND DIRECTION

Best Management Practices for measuring wind speed and wind direction:

- Applicators should check and acquire the predicted wind speed and direction for the application site within 12 hours prior to conducting applications to determine the time periods wind speed is likely to fall outside the applicable thresholds.
- Applicators should reassess wind speed and direction at the application site at least every hour while applications are in progress.
- Measuring wind speed and direction can be done by:
    - Relying on equipment on the application equipment that measures wind speed (e.g., aerial equipment).
    - Using a tower anemometer with telemetry or handheld anemometer. Users should read user manual on how to calibrate, operate and interpret the output from an anemometer. Ground applicators should stop at least every hour to take a reading with a tower anemometer with telemetry or handheld anemometer. Some anemometers may have software that would allow users to view wind measurements in real time while making an application, and, those cases, applicators would not have to stop to take measurements.
    - Using a windsock. Wind can be estimated with a windsock using the strips on a windsock. The applicator should consult the user manual for the windsock on wind speed estimation and direction of wind. Applicators should look at the sock at least every hour to estimate wind speed and direction.
    - Using an aircraft smoke system. Laying down several puffs of smoke along different lines using an aircraft smoke system can provide an accurate view of what the wind speed and direction for the application.
    - Checking behind the spray rig at least every hour to see if the spray has changed direction from when the application started.

- To minimize runoff from use sites the following language is required in the "**application instructions**" section. Please note that the EPA's mitigation menu website noted below should be utilized.
    - DO NOT apply during rain.
    - DO NOT apply this product when soil is saturated or at field capacity, or when a storm event likely to produce runoff from the treated area is expected to occur within 24 hours following application.

- Within 24 hours after application, DO NOT irrigate the treatment area to the point of runoff.

MANAGEMENT OF RUNOFF/EROSION: A variety of factors including soil type, slope, and weather conditions (e.g., rainfall) can influence volume and intensity of water running off the treated field. The applicator should evaluate factors and make appropriate adjustments when applying this product. Land management, agronomic practices, field conditions, and application measures that reduce, to the maximum extent practicable, runoff from treated fields, should be implemented by land managers/users of this product.

MANDATORY RUNOFF MITIGATION:

Applicators must access and search Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins within six months prior to or on the day of the application to determine whether the application site falls within a Pesticide Use Limitation Area (PULA). If you are located inside a PULA, follow the instructions in the BLT bulletin. If the application site falls outside of a PULA, follow the instructions in the section below.

- **6** mitigation points are required for all field crops listed on this label. Follow the steps below to achieve points.

Step 1. To achieve the mitigation points specified above, visit EPA's mitigation menu website (www.epa.gov/pesticides/mitigation-menu) for a full list of mitigation and mitigation relief options.

Step 2. Determine if you are eligible for mitigation relief. Runoff/erosion mitigation is NOT required if certain field/application parameters are present at the time of application (*e.g.*, subsurface or tile drains with controlled outlet, perimeter berm systems, irrigation tailwater return systems, spot treatment, etc).

Step 3. If the application site does not meet the field/application parameters specified on EPA's mitigation menu website, choose among the mitigation and/or mitigation relief options on EPA's mitigation menu website to meet or exceed the required points noted here before applying this product.

Step 4. To achieve mitigation points for the application, the mitigation and mitigation relief measures must be:

- Employed in accordance with the instructions and descriptions on EPA's Mitigation Menu Website.
- In place during the application unless a different timing (such as before or after application) is specifically provided in the measure's description on EPA's Mitigation Menu Website. EPA may periodically update the Mitigation Menu Website, for example, by adding new mitigation measures or updating a mitigation measure description.

Step 5. Additional restrictions may be present in bulletins—always follow the most restrictive bulletin instructions. If you are located in an area where PULAs overlap, follow the most

restrictive requirements across all bulletins. When tank mixing, the most restrictive requirements must be followed between the products' labels and bulletins.

6. To address on-field effects to non-target species, specifically the listed plant species Spring Creek Bladderpod, included in the "Bulletins Live! Two" web-based system (BLT), the end-use product directs all users to access the BLT prior to application, according to the label statement below:

   ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email *ESPP@epa.gov*."

7. REPORTING ECOLOGICAL INCIDENTS: For guidance on reporting ecological incidents, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticideincidents.

VII. SUPPORTING DOCUMENTS

All supporting documents can be found in docket ID number EPA-HQ-OPP-2022-0649 at regulations.gov.