Department of Pesticide Regulation



Gavin Newsom

Governor

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MEMORANDUM

TO: Minh Pham, Chief

Environmental Monitoring Branch

VIA: Shelley DuTeaux, PhD MPH, Chief

Human Health Assessment Branch

FROM: Qiaoxiang Dong, PhD, Staff Toxicologist

Risk Assessment Section

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Risk Assessment Section

DATE: June 7, 2024

SUBJECT: HUMAN HEALTH REFERENCE LEVEL REQUEST FOR AZOXYSTROBIN IN

DRINKING WATER

On November 16, 2020, DPR's Pesticide Registration Branch asked the Human Health Assessment Branch (HHA) to provide Human Health Reference Levels (HHRLs) for DPR's Surface Water Protection Program (SWPP) for azoxystrobin for screening detected or modelestimated concentrations of its residues in drinking water (DPR, 2021a). This request was in response to a request by the Sacramento River Source Water Protection Program (SRSWPP) to evaluate the impact of azoxystrobin use in rice fields north (upstream) of the greater Sacramento area. The updated DPR HHRLs in this memo supersede the corresponding HHRL for azoxystrobin established in 2021 (DPR, 2021a). Since the completion of the 2021 evaluation, HHA has revised its approach and now establishes separate HHRLs for maximum and average residue levels in surface water.

Conclusions and Recommendations:

- 1. HHA calculated Human Health Reference Levels (HHRLs) to be used for detected or model-estimated residues of azoxystrobin in surface water using (1) acute and chronic consumption rates for drinking water from the National Health and Nutrition Examination Survey (NHANES) 2005–2010 database; and (2) toxicological endpoints established by the United States Environmental Protection Agency (US EPA).
- 2. The DPR Acute Surface Water HHRL of 3526 ppb for azoxystrobin applies to the evaluation of **maximum** residue levels in drinking water from surface water sources. Azoxystrobin maximum residue concentrations equal to or less than DPR HHRL are not

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Minh Pham June 7, 2024 Page 2

expected to pose a risk to human health, including for sensitive subpopulations. This DPR Acute Surface Water HHRL supersedes the corresponding HHRL (1808 ppb) previously issued in 2021 (DPR, 2021a).

3. The DPR Chronic Surface Water HHRL of 360 ppb for azoxystrobin applies to the evaluation of **average** residue concentrations in drinking water from surface water sources. Average residue concentrations of azoxystrobin equal to or less than the DPR Chronic Surface Water HHRL are not expected to pose a chronic risk to human health, including for sensitive subpopulations.

Background

Technical Name: Azoxystrobin

Chemical Name: Methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yl]oxyphenyl]-3-

methoxyprop-2-enoate

Chemical Abstracts Service Registry Number (CAS #): 131860-33-8

Molecular Weight: 403.4 g/mol (NCBI, 2023)

Chemical Structure:

Azoxystrobin is a β-methacrylate compound that is structurally similar to naturally occurring strobilurins and is used as a systemic, broad-spectrum fungicide to inhibit spore germination. It is used on almonds, rice, pistachios, wine grapes, raisins, garlic, cereals, potatoes, apples, bananas, citrus, tomatoes and other crops. Azoxystrobin was first registered by US and California in 1997 (USEPA, 1997). As of June 2024, there are 94 active registrations in California (DPR, 2024a). According to the most recent available data from the DPR's Pesticide Use Reporting (PUR) database, 243,983 pounds of azoxystrobin active ingredient were used in 31,652 California agricultural applications in 2021 (DPR, 2021b).

Review of Regulatory Documents and Databases

A review of pertinent regulatory documents was performed to ensure that the most scientifically supportable toxicological data were used for this evaluation (summarized in Table 1, below). A comprehensive systematic review was beyond the scope of the request.

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)	
USEPA	1997	Pesticide Fact Sheet-Azoxystrobin	USEPA (1997)	
NRA	1999	Public release summary on evaluation of the new active azoxystrobin in the product AMISTAR WG FUNGICIDE.	NRA (1999)	
USEPA	2000	Azoxystrobin. Human Health Risk Assessment for Residues in/on Barley, Bulb Vegetables, Cilantro, Citrus Fruits, Corn, Cotton, Leafy Vegetables (except Brassica), Leaves of Root and Tuber Vegetables, Peanuts, Root and Tuber Vegetables, Soybeans, and Wild Rice; Higher Tolerances for the Fat and Meat Byproducts of Cattle, Goats, Horses, and Sheep; and Apples (Inadvertent Residues).	USEPA (2000a)	
USEPA	2000	Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health	USEPA (2000b)	
FSC	2006	Evaluation Report Azoxystrobin.	FSC (2006)	
USEPA	2006	Azoxystrobin. Human Health Risk Assessment for New Uses on Foliage of Legume Vegetables, Group 7; Fruiting Vegetables, Group 8 (Except Tomato); Pea and Bean, Succulent and Dried Shelled (Except Soybeans), Subgroups 6B and 6C; Nongrass Animal Feeds, Group 18; and Citrus; and Section 18 Requests for Groups 6 and 7 to Control Soybean Rust.	USEPA (2006a)	
USEPA	2006	Azoxystrobin. Human Health Risk Assessment for New Uses on Dill, Chive, Sunflowers, and Canola.	USEPA (2006b)	
FAO	2008	Azoxystrobin. Evaluation of Data for Acceptable Daily Intake and Acute Dietary Intake for Humans, Maximum Residue Levels and Supervised Trial Median Residue Values.	FAO (2008)	
USEPA	2008	Azoxystrobin. Human Health Risk Assessment for a Section 3 New/Amended Uses on Non-grass Animal Feeds (Crop Group 18), Sorghum, Wheat, Cotton and Wild Rice.	USEPA (2008)	
USEPA	2009	Azoxystrobin. Human Health Risk Assessment for a Section 3 Amendment to Reduce the Preharvest Interval for Barley Grain and Straw and to Add Seed Treatment Uses on Head and Stem Brassica Vegetables (Subgroup 5A) and Sorghum, Grain.	USEPA (2009a)	
USEPA	2009	Azoxystrobin. Human Health Assessment Scoping Document in Support of Registration Review.	USEPA (2009b)	
USEPA	2012	Azoxystrobin: Human Health Risk Assessment for the Proposed Use on Sugarcane.	USEPA (2012a)	
USEPA	2012	Azoxystrobin: Revision to the Human Health Risk Assessment for the Proposed Use on Sugarcane.	USEPA (2012d)	

Table 1. Review of Regulatory Documents and Databases

Regulatory	Year	Title	Reference(s)
Agency			
USEPA	2012	Azoxystrobin: Human Health Risk Assessment for Proposed Uses	USEPA (2012b)
		on Dragon Fruit, Wasabi, and Tuberous and Corm Vegetables	
		(Subgroup 1C), and from the Revisions to Various Crop Groups	
		(Onion Subgroups 3-07 A, B; Fruiting Vegetable Subgroups 8-10	
		A,B; Small Fruit and Berry Subgroups 13-07 A, B, F, G, Oilseeds	
		Subgroups A, B, C; and Citrus Fruit Group 10-10).	
USEPA	2012	Azoxystrobin: Human Health Risk Assessment for Use on Ginseng	USEPA (2012c)
		(Import), Rye, and Oats and Section 3 Amendments to Revise the	
		Established Tolerances on Cereal Grains (Barley and Wheat) Due	
		to Changes of Pre-Harvest Intervals.	
USEPA	2013	Azoxystrobin: Revised Human Health Risk Assessment for Use on	USEPA (2013)
		Ginseng (Import), Rye, and Oats, and Section 3 Amendments to	· · ·
		Revise the Established Tolerances on Cereal Grains (Barley and	
		Wheat) Due to Changes of Pre-Harvest Intervals.	
FAO/WHO	2013	Pesticide Residues in food 2012.	FAO/WHO
			(2013)
DPR	2015	Azoxystrobin: Summary of Toxicology Data	DPR (2015)
USEPA	2015	Azoxystrobin. Human Health Aggregate Risk Assessment for	USEPA (2015a)
		Permanent Tolerances on Imported Asian Pear, Imported Tea, and	, ,
		Imported Coffee; Establishment of Permanent Tolerances on Ti	
		Palm and for Crop Group Conversions for Stone Fruits Group 12-	
		12 and Tree Nut Group 14-12 Crop Groups.	
USEPA	2015	Azoxystrobin: Human Health Draft Risk Assessment for	USEPA (2015c)
		Registration Review.	
USEPA	2015	Azoxystrobin: Revised Addendum to Human Health Aggregate	USEPA (2015d)
		Risk Assessment D423691 and D418374, Dated 4/17/2015, to	
		Support a New Use on Quinoa.	
USEPA	2016	Azoxystrobin Proposed Interim Registration Review Decision Case	USEPA (2016)
		Number 7020.	
USEPA	2018	Azoxystrobin Interim Registration Review Decision Case Number	USEPA (2018a)
		7020.	
USEPA	2018	Azoxystrobin; Pesticide Tolerances.	USEPA (2018b)
USEPA	2018	Azoxystrobin: Revised Human Health Draft Risk Assessment for	USEPA (2018c)
		Registration Review	
USEPA	2018	2018 Edition of the Drinking Water Standards and Health	USEPA (2018d)
		Advisories Tables.	
USGS	2018	Health-Based Screening Levels for evaluating water-quality data	USGS (2018)
		(2d ed.)	_
USEPA	2021	Human Health Benchmarks for Pesticides.	USEPA (2021b)
USEPA	2021	Technical Support Document for the Draft Fifth Contaminant	USEPA (2021a)
		Candidate List (CCL5)-Contaminant Information Sheets.	
USEPA	2022	Technical Support Document for the Final Fifth Contaminant	USEPA (2022)
		Candidate List (CCL 5) -Contaminant Information Sheets.	

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
USEPA	2023	Azoxystrobin. Human Health Risk Assessment for the Establishment of Tolerances for Residues in/on Mango and Papaya and Establishment of a Tolerance for Residues in/on Impolied Palm Oil.	USEPA (2023)
PMRA	2023	Proposed Maximum Residue Limit PMRL2023-38, Azoxystrobin	PMRA (2023b)
PMRA	2023	Proposed Re-evaluation Decision PRVD2023-02, Azoxystrobin and Its Associated End-use Products.	PMRA (2023a)

FAO: Food and Agriculture Organization of the United Nations; FSA: Food Safety Commission of Japan; NRA: National Registration Authority for Agricultural and Veterinary Chemicals in Australia; PMRA: Pest Management Regulatory Agency Health Canada; USEPA: United States Environmental Protection Agency; USGS: U.S. Geological Survey; WHO: World Health Organization.

Summary of Toxicology

Azoxystrobin was placed in Toxicity Category^a value of IV for oral and III for dermal and inhalation hazards based on median lethal doses. It is not a skin sensitizer or a skin or eye irritant (Toxicity Categories IV & III) (USEPA, 2018c). US EPA classified azoxystrobin as "not likely to be carcinogenic to humans" based on carcinogenicity studies in rats and mice (USEPA, 2018c).

Azoxystrobin is not included on the Proposition 65 (the California Safe Drinking Water and Toxic Enforcement Act of 1986) list for chemicals known to cause cancer, reproductive toxicity, or developmental toxicity (OEHHA, 2023).

Liver and biliary effects, increased liver weights, gross and histopathological lesions of the bile duct and liver, and clinical chemistry alterations were common in rats and dogs exposed to azoxystrobin by the oral route (USEPA, 2018c). Decreased body weights or body weight gains were also consistent effects across studies and species. No developmental effects or reproductive/offspring effects or neurotoxicity were seen in rat/rabbit developmental toxicity or rat reproduction and neurotoxicity studies (USEPA, 2018c).

DPR's Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries reported in California from 1992 to 2019 (the most recent data available). There were forty-two reported cases involving exposure to azoxystrobin in combination with other active ingredients and nine cases for azoxystrobin alone. In these nine cases, most individuals experienced itchiness, headaches, stomachaches, and nausea. Some also experienced

^a Acute Toxicity Categories. US EPA Label Review Manual Chapter 7: Precautionary Statements. US Environmental Protection Agency, Office of Pesticide Programs, Registration Division. Revised March 2018. Available at https://www.epa.gov/sites/default/files/2018-04/documents/chap-07-mar-2018.pdf (USEPA 2018c).

Minh Pham June 7, 2024 Page 6

diarrhea, slightly burning eyes, stinging of cheeks, dry skin, a slippery sensation and bad taste in the mouth (DPR, 2024b).

HHA has evaluated all required toxicity data submitted for azoxystrobin as part of registration in California but has not conducted a human health risk assessment (DPR, 2015). For purposes of this evaluation, HHA reviewed relevant regulatory documents (Table 1) and adopted toxicological endpoints and points of departure (PODs) established by US EPA for azoxystrobin.

US EPA's acute POD was an estimated-no-effect-level (ENEL) of 67 mg/kg/day based on increased incidences of diarrhea at the lowest-observed-adverse-effect-level (LOAEL) of 200 mg/kg/day in an acute neurotoxicity study in rats. As the LOAEL was the lowest dose tested, it divided by a dose extrapolation factor of 3 (Food Quality Protection Act safety factor, FQPA) to calculate the ENEL (USEPA, 2018c). The ENEL of 67 mg/kg/day was then divided by a total uncertainty factor (UF_{TOTAL}) of 100 to derive an acute reference dose (aRfDb) of 0.67 mg/kg/day. The UF_{TOTAL} included a 10x for interspecies extrapolation (UFA) and 10x for intraspecies variability (UFH) (USEPA, 2018c). The chronic POD was a NOAEL of 18 mg/kg/day (males) based on reduced body weights in both sexes and bile duct lesions in males at the LOAEL of 82.4 mg/kg/day from a combined chronic toxicity/carcinogenicity feeding study in rats (USEPA, 2018c). The chronic RfD (cRfD) of 0.18 mg/kg/day was calculated by dividing the NOAEL by the UF_{TOTAL} of 100 as described above.

Calculation of Human Health Reference Levels

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. HHRLs for azoxystrobin were calculated using their respective acute and chronic RfDs as the maximum safe exposure and the acute (95th percentile) and chronic (mean) drinking water intake rates for non-nursing infants as the maximum water intake. Non-nursing infants are the population identified as having the highest consumption of drinking water per kilogram of bodyweight among the standard populations that HHA evaluates, including the general US population and other sensitive subpopulations such as children 1–2 years of age and women of childbearing age (13–49 years). The water consumption rates were extracted from the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 05-10-c) and the What We Eat in America (WWEIA) database. WWEIA is the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES). It is a collection of two-day dietary survey data (including drinking water consumption) from 2005 to 2010 for the US population and select subgroups (USEPA, 2014). HHA uses the 95th percentile of the exposure levels for each population

^b An RfD is an estimate of a daily oral exposure for specific duration (acute or chronic) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Available at https://www.epa.gov/iris/iris-glossary

subgroup as the default upper bound for acute exposures, while two-day nonconsecutive food intake is used as a surrogate for chronic consumption patterns (DPR, 2009).

Formulas Used to Calculate Acute and Chronic Surface Water HHRLs

Acute Surface Water HHRL (ppb) =
$$\frac{aRfD}{acute DWI} \times 1000$$

Chronic Surface Water HHRL (ppb) =
$$\frac{\text{cRfD}}{\text{Chronic DWI}} \times 1000 \times \text{RSC}$$

Drinking Water Intake (DWI) is 95th percentile (acute) or mean (chronic) water consumption rates for non-nursing infants. Acute and chronic water consumption data were extracted using the DEEM-FCID (version 4.02, 05-10-c). A residue concentration of 1 ppm consumption defaults to the consumption rates by dimensional analysis (acute = 0.194566 L water/kg BW and chronic = 0.099559 L water/kg BW). The values were then rounded to two decimal points for the calculation of corresponding HHRLs (0.19 and 0.10 L water/kg BW).

DPR Chronic Surface Water HHRLs incorporate a relative source contribution (RSC) factor of 0.2. The RSC factor accounts for the possibility that exposure to a pesticide residue may come from sources other than drinking water (*i.e.*, food and air). A default RSC of 0.2 assumes that the exposure from water sources will be 20% of the total exposure while other intakes will make up the remainder (80%). This RSC factor is routinely used by regulatory agencies for deriving chronic screening concentrations of drinking water (USEPA, 2000b; USEPA, 2015b).

DPR Acute Surface Water HHRL for Azoxystrobin

DPR Acute Surface Water HHRLs are for screening maximum pesticide residue concentrations in drinking water. Maximum residue concentrations of azoxystrobin in drinking water equal to or less than the DPR Acute Surface Water HHRL (3,526 ppb, Table 2) are not expected to pose a risk to human health including for sensitive subpopulations. This DPR Acute Surface Water HHRL supersedes the corresponding HHRL (1808 ppb) previously issued in 2021 (DPR, 2021a).

DPR Chronic Surface Water HHRL for Azoxystrobin

DPR Chronic Surface Water HHRLs are for screening average pesticide residue concentrations in drinking water from a surface water body. Average residue concentrations of azoxystrobin in drinking water equal to or less than DPR Chronic Surface Water HHRL (360 ppb, Table 2) are not expected to pose a risk to human health including for sensitive subpopulations. DPR Chronic

Minh Pham June 7, 2024 Page 8

Surface Water HHRLs that incorporate RSCs are only appropriate for the evaluation of averaged (i.e., mean) residue concentrations in surface water.

Other Reference or Regulatory Levels for Azoxystrobin in Drinking Water

DPR considers other reference and regulatory levels for drinking water in the development of HHRLs, especially with regards to best practices in dietary and drinking water exposure assessment. Common federal regulatory levels for drinking water include US EPA enforceable Maximum Contaminant Levels (MCLs^c), non-legally enforceable Health Advisories (HAs^d), and Human Health Benchmark for Pesticides (HHBP^e), and United States Geological Survey (USGS) Health-Based Screening Levels (HBSLs^f) (USEPA, 2018d; USEPA, 2021b; USGS, 2018). For azoxystrobin, USGS listed a 2017 chronic HHBP of 1200 ppb in its 2018 HBSL database (USGS, 2018); in 2021 US EPA issued an acute HHBP of 4500 ppb for children and a chronic HHBP of 1070 ppb for general population (USEPA, 2021b). Although US EPA chronic HHBP and DPR Chronic Surface Water HHRL for azoxystrobin are both based on the same chronic PODs, these two values differ because they were calculated using different water consumption rates.

^c Maximum Contaminant Levels (MCLs) are used for the protection of public drinking water systems and do not apply to privately owned wells or any other individual water system. Available at https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf

^d Health Advisories (HAs) are estimated acceptable drinking water levels for chemicals based on information of adverse health effects and are not legally enforceable Federal standards, but rather serve as technical references to be used by federal, state, and local officials. Available at https://www.epa.gov/system/files/documents/2022-01/dwtable2018.pdf

^e The 2021 US EPA Human Health Benchmark for Pesticides (HHBPs) contain 430 pesticides that currently have no federal drinking water standards. HHBPs are not legally enforceable, but rather are provided by US EPA for pesticides that have no drinking water standards or health advisory (HA). Available at https://www.epa.gov/system/files/documents/2021-07/hh-benchmarks-technical-document-2021.pdf

f USGS Health-Based Screening Levels (HBSLs) are "non-enforceable water-quality benchmarks" that were developed using (1) the latest US EPA Office of Water methods for establishing drinking-water guidelines and (2) the most recent US EPA peer-reviewed publicly available toxicity information. Available at https://water.usgs.gov/water-resources/hbsl/

Table 2. DPR Acute and Chronic Surface Water HHRLs for Azoxystrobin

Residue	Acute or Chronic	Water Consumption Rates for Non-Nursing Infants (L water/kg BW)	RfD ^a (mg/kg/day)	HHRL (ppb)	US EPA HHBP ^b (ppb)
Azoxystrobin	Acute (Maximum Residues)	0.19	0.67	3,526	4500 (Children)
	Chronic (Average Residues)	0.10	0.18	360	1070 (General Population)

BW: bodyweight; DPR: Department of Pesticide Regulation; HHBP: Human Health Benchmark for Pesticides; HHRL: Human Health Reference Level; L: liter; RfD: reference dose; ppb: parts-per-billion.

^a Acute and chronic RfDs for azoxystrobin were based on toxicological endpoints established by US EPA as described in text (USEPA, 2018c)

 $[^]b$ In 2021, US EPA provided Human Health Benchmark for Pesticides (HHBPs) containing 430 pesticides that currently have no federal drinking water standards. HHBPs are not legally enforceable, but rather are provided by US EPA for pesticides that have no drinking water standards or health advisories (USEPA, 2021b). An Acute HHBP for Children (ppb) = [acute RfD (mg/kg/day) x 1000 (µg/mg)]/[0.15 (L/kg/day) DWI-BW ratio; A Chronic HHBP for General Population (ppb) = [chronic RfD (mg/kg/day) x 1000 x 0.2 RSC] / 0.0338 (L/kg/day) DWI-BW ratio. DWI: drinking water intakes.

Conclusions

HHA calculated Human Health Reference Levels (HHRLs) to be used for azoxystrobin in drinking water from surface water resources. Maximum residue concentrations of azoxystrobin equal to or less than the DPR Acute Surface Water HHRL of 3526 ppb in drinking water, or average residue concentrations equal to or less than the DPR Chronic Surface Water HHRL of 360 ppb, are not expected to pose a risk to human health, including for sensitive subpopulations. The DPR Acute Surface Water HHRL of 3,526 ppb supersedes the corresponding HHRL (1808 ppb) previously issued in 2021 (DPR, 2021a).

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