



Department of Pesticide Regulation

Gravin Newsom
Governor

Yana Garcia
Secretary for
Environmental Protection

Julie Henderson
Director

MEMORANDUM

TO: Minh Pham
Environmental Program Manager II
Environmental Monitoring Branch

VIA: Shelley DuTeaux, PhD MPH, Chief
Human Health Assessment Branch

FROM: Chunbo Zhang, PhD, Associate Toxicologist
Pete Lohstroh, PhD, Senior Toxicologist
Toxicology and Dose Response Assessment Section

Svetlana Koshlukova, PhD, Senior Toxicologist
Risk Assessment Section

DATE: December 14, 2022

SUBJECT: RISKS FROM HUMAN EXPOSURE TO FLUTRIAFOL RESIDUES IN
GROUNDWATER

On August 10, 2022, the Department of Pesticide Regulation's (DPR) Human Health Assessment Branch (HHA) was notified by the Environmental Monitoring Branch (EMB) that routine monitoring conducted by the Groundwater Protection Program (GWPP) detected flutriafol in California's groundwater, with the highest concentration of 0.226 ppb. EMB requested that HHA determine if the highest concentration detected poses health concerns for individuals using the groundwater as a source of drinking water and provide a Human Health Reference Level (HHRL) for screening detections of flutriafol in groundwater (see request, Appendix 1). This memorandum is in response to that request.

Conclusions and Recommendations:

1. HHA calculated Human Health Reference Levels (HHRLs) to be used when flutriafol residues are detected in groundwater or drinking water using (1) acute and chronic dietary exposure estimates based on 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. Residue levels of flutriafol equal to, or less than, the DPR HHRL of 395 ppb in drinking water are not expected to pose a risk to human health, including for sensitive subpopulations. Thus, the highest detected flutriafol residues in California groundwater (0.226 ppb) should not be considered an acute or chronic health concern.

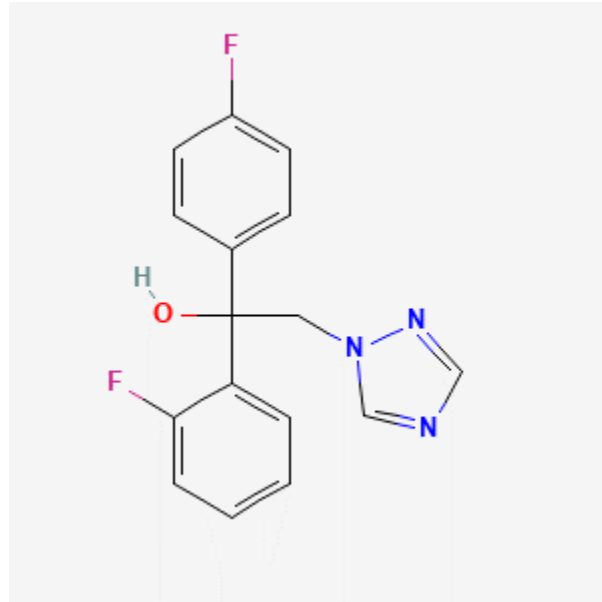
Background

Technical Name: Flutriafol

Chemical Name: 1-(2-fluorophenyl)-1-(4-fluorophenyl)-2-(1,2,4-triazol-1-yl)ethanol

Chemical Abstracts Service Registry Number (CAS): 76674-21-0 (NIH, 2022)

Chemical Structure:



(NIH, 2022)

Flutriafol is a contact and systemic triazole fungicide that acts by blocking the formation of ergosterol from lanosterol during demethylation, which interferes with the synthesis of fungal cell membranes.(US EPA, 2010b; US EPA, 2011a; US EPA, 2019). Flutriafol is registered for use on a variety of crops including alfalfa, barley, beets, coffee, corn and popcorn, cotton, fruits, grain sorghum, peanuts, oats, ornamentals, rice, rye, teosinte, tree nuts, turf, various vegetables, and wheats/triticale (US EPA, 2011a; US EPA, 2014d; US EPA, 2014c; US EPA, 2018b; US EPA, 2019). Products containing flutriafol were first registered in California in 2017 and currently there are two products with active registrations (DPR, 2022d). According to the latest data available from the DPR Pesticide Use Reporting (PUR) database, 10,954 pounds of flutriafol were used in 3816 California agricultural applications in 2018 (DPR, 2018).

DPR Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries reported in California from 1992 to 2018 (the most recent available data). There were no reported cases involving exposure to flutriafol alone or in combination with other active ingredients (DPR, 2022b).

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)
DPR	2009	Guidance for Dietary Exposure Assessment.	DPR, 2009a
DPR	2009	Summary of Toxicology Data; Flutriafol	DPR, 2009b
EFSA	2010	Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Flutriafol	EFSA, 2010
US EPA	2010	Pesticide Product Registrations; Conditional Approvals	US EPA, 2010a
US EPA	2010	Revised Baseline Ecological Risk Assessment for the Registration of Flutriafol	US EPA, 2010b
US EPA	2011	Flutriafol: Human Health Risk Assessment for Proposed Uses on Corn, Grapes, Peanuts, Pome Fruit (Crop Group 11), Stone Fruit (Crop Group 12), Sugar Beets, Wheat, Barley, Triticale, Buckwheat, Oats, Rye, Teosinte, and Imported Bananas	US EPA, 2011a
US EPA	2011	Integrated Risk Information System (IRIS) Glossary	US EPA, 2011b
US EPA	2013	Flutriafol Human Health Risk Assessment Import Tolerance on Coffee	US EPA, 2013
US EPA	2014	Dietary Exposure Evaluation Model User's Guide	US EPA, 2014a
US EPA	2014	Drinking Water Assessment for Proposed New Uses (R190, PP# 3F8199) of Flutriafol on Leafy Vegetables (Group 4), Brassica (Cole) Leafy Vegetables (Group 5), Grain Sorghum, and Cotton and (R190, PP# 3F8174) for Cucurbit Vegetables, Fruiting Vegetables, Strawberries, Tree Nuts, and Wheat Uses	US EPA, 2014b
US EPA	2014	Flutriafol Acute and Chronic Dietary Exposure and Risk Assessment in Support of Tolerances for Residues in/on Field Corn, Popcorn, Peanut, Wheat, Strawberries, Cucurbit Vegetables, Fruiting Vegetables, and Tree Nuts	US EPA, 2014c
US EPA	2014	Flutriafol Human-Health Risk Assessment for Tolerances for Residues in/on Field Corn, Popcorn, Peanut, Wheat, Strawberries, Cucurbit Vegetables, Fruiting Vegetables, and Tree Nuts	US EPA, 2014d
US EPA	2014	Flutriafol Occupational and Residential Exposure Assessment for Proposed Uses on Cucurbit Vegetables, Fruiting Vegetables, Strawberries, Tree Nuts, Wheat/Triticale, Brassica (cole) Leafy Vegetables, Celery, Leafy Vegetables, Cotton, and Sorghum	US EPA, 2014e
US EPA	2014	Flutriafol: Human Health Risk Assessment in Support of Tolerance for Residues in/on Cotton; Grain Sorghum; Leafy Vegetables, Except Brassica, Crop Group 4; and Brassica Leafy Vegetables Crop Group 5	US EPA, 2014f
DPR	2018	2018 Annual Statewide Pesticide Use Report Chemical Totals	DPR, 2018
US EPA	2018	2018 Edition of the Drinking Water Standards and Health Advisories Tables	US EPA, 2018a
US EPA	2018	Drinking Water Exposure Assessment for Proposed New Uses for Flutriafol in Alfalfa, Barley, Sweet Corn, Turf, and Ornamentals	US EPA, 2018b

Table 1. Review of Regulatory Documents and Databases

Regulatory Agency	Year	Title	Reference(s)
US EPA	2018	Label Review Manual, Chapter 7: Precautionary Statements	US EPA, 2018c
USGS	2018	Health-Based Screening Levels for Evaluating Water-Quality Data	USGS, 2018a
USGS	2018	Health-Based Screening Levels: Updated 2018 Technical Information	USGS, 2018b
US EPA	2019	Flutriafol: Human Health Risk Assessment in Support of a Section 3 Registration for Application to Alfalfa, Barley, Sweet Com, Rice (as a Rotated Crop), Turf, and Ornamentals	US EPA, 2019
US EPA	2021	2021 Human Health Benchmarks for Pesticides	US EPA, 2021a
US EPA	2021	Human Health Benchmarks for Pesticides: Updated 2021 Technical Document	US EPA, 2021b
DPR	2022	California Code of Regulations (Title 3. Food and Agriculture) Division 6. Pesticides and Pest Control Operations	DPR, 2022a
DPR	2022	California Pesticide Illness Query (CalPIQ)	DPR, 2022b
DPR	2022	Pesticide Residue Monitoring Program.	DPR, 2022c
DPR	2022	Welcome to California Product/Label Database Application	DPR, 2022d
NIH	2022	PubChem Compound Summary for CID 91727	NIH, 2022
OEHHA	2022	The Proposition 65 List	OEHHA, 2022
US EPA	2022	CompTox Chemicals Dashboard: Flutriafol	US EPA, 2022a
US EPA	2022	National Primary Drinking Water Regulations	US EPA, 2022b
DPR: Department of Pesticide Regulation; EFSA: European Food Safety Authority; NIH: National Institute of Health; US EPA: United States Environmental Protection Agency; USGS: United States Geological Survey; OEHHA: Office of Environmental Health Hazard Assessment			

Summary of Toxicology

Flutriafol has an acute Toxicity Category¹ value of II for oral toxicity, III for dermal toxicity, and IV for inhalation toxicity based on their median lethal doses. It is a Category III eye irritant and a Category IV skin irritant. Flutriafol is not a skin sensitizer (US EPA, 2013; US EPA, 2019). US EPA classified flutriafol as “Not likely to be Carcinogenic to Humans” based on chronic toxicity studies in rats and mice (US EPA, 2019).

Flutriafol is not included on the Proposition 65 (the California Safe Drinking Water and Toxic Enforcement Act of 1986) list of chemicals known to cause cancer, reproductive toxicity, or developmental toxicity (OEHHA, 2022).

Flutriafol causes liver toxicity in mammals following repeated oral exposures, a common signature of triazole fungicides. Increased levels of liver enzymes in the serum, increased liver weights and liver histopathology occurred at similar dose levels and durations of exposure in all

¹ 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> (US EPA, 2018c).

tested species (dogs, rats, and mice) (US EPA, 2011a). Flutriafol causes developmental toxicity in rats and rabbits and affects the hematopoietic system in rats, mice and dogs (US EPA, 2011a; US EPA, 2019).

HHA has evaluated all required toxicity data submitted as part of registration in California but has not conducted a human health risk assessment for flutriafol. For purpose of this evaluation, HHA adopted the critical acute point of departure (POD) established by US EPA for females 13–49 years of age (US EPA, 2011a; US EPA, 2019). The acute POD was a no observed adverse effect level (NOAEL) of 7.5 mg/kg/day based on decreased number of live fetuses, complete litter resorptions and increased post-implantation loss at the lowest observed adverse effect level (LOAEL) (15 mg/kg/day) in a developmental study in rabbits (US EPA, 2019). This NOAEL was divided by a total uncertainty factor (UF_{TOTAL}) of 100 to calculate an acute reference dose ($aRfD^2$) of 0.075 mg/kg/day. The UF_{TOTAL} included a 10x for interspecies extrapolation (UF_A), 10x for intraspecies variation (UF_H), and an 1x for Food Quality Protection Act (FQPA) Safety Factor (US EPA, 2019). HHA also uses this $aRfD$ for evaluating risk from illegal flutriafol residues detected on fresh produce for the California Pesticide Residue Monitoring Program (CPRMP) (DPR, 2022c). The chronic POD was a NOAEL of 5 mg/kg/day based on toxicity to the liver, spleen, and adrenal glands, anemia, and bodyweight and bodyweight gain decrements observed at the LOAEL (20 mg/kg/day) in a one-year chronic toxicity study in dogs (US EPA, 2011a; US EPA, 2019). The chronic RfD ($cRfD$) of 0.05 mg/kg/day (all populations) was calculated by dividing the NOAEL by the UF_{TOTAL} of 100 (10x each for interspecies and intraspecies extrapolation, and 1x for FQPA) (US EPA, 2019).

Calculation of DPR Human Health Reference Levels for Flutriafol

HHA calculated acute and chronic screening levels (Human Health Reference Levels or HHRLs) for flutriafol and proposes that the lower of the two values (the acute HHRL of 395 ppb) be used by GWPP as a guide when flutriafol residues are detected in groundwater or drinking water. This HHRL should be used for screening maximum detected flutriafol residue levels in drinking water.

An HHRL is the threshold pesticide residue for a maximum water intake that results in the maximum safe oral exposure. HHRLs were calculated using the acute and chronic $RfDs$ for flutriafol 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 body weight among the standard populations that HHA evaluates, including the

² 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> (US EPA, 2011b).

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 (US EPA, 2014a). HHA uses the 95th percentile of the exposure levels for each population 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, 2009a).

The HHRLs for flutriafol in groundwater or drinking water are summarized in Table 2. The lower reference value, the acute HHRL level of 395 ppb, was selected as the HHRL for residues of flutriafol in drinking water and is intended to be used for screening maximum detected residue levels.

Other Reference or Regulatory Levels

Flutriafol does not have an enforceable US EPA Maximum Contaminant Level (MCL³) or US EPA Health Advisories (HAs⁴) (US EPA, 2018a; US EPA, 2022b). It does have acute and chronic Human Health Benchmark for Pesticides (HHBPs⁵) of 2100 ppb and 300 ppb, respectively (Table 2). The chronic HHBP was also adopted by the US Geological Survey (USGS) as a Health-Based Screening Level (HBSLs⁶) (USGS, 2018a; US EPA, 2021a). Both HHBPs are based on the same acute and chronic PODs used in this document to calculate HHRLs. The DPR HHRLs and US EPA HHBPs differ because they were calculated using different parameters and/or assumptions (*e.g.*, consumption rates and relative source contribution (RSC) factors). The DPR HHRL of 395 ppb is the only reference level that is specifically intended to be used for screening maximum detected residue levels of flutriafol in groundwater.

³ 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/ground-water-and-drinking-water/national-primary-drinking-water-regulations> (US EPA, 2022b).

⁴ HAs are estimated acceptable drinking water levels for chemicals based on information of adverse health effects and are not a 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> (US EPA, 2018a).

⁵ The 2021 HHBPs contained 430 pesticides that currently have no federal drinking water standards. The HHBPs are not legally enforceable federal standards but rather provided by US EPA for pesticides that have no drinking water standards or health advisories (HAs). Available at <https://www.epa.gov/system/files/documents/2021-07/hh-benchmarks-technical-document-2021.pdf> (US EPA, 2021b).

⁶ 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/> (USGS, 2018a).

Table 2. Acute and Chronic DPR HHRLs for Flutriafol in Groundwater

Residue	Acute or Chronic	Water Consumption Rates for Non-Nursing Infants ^a (L water/kg BW)	RfD ^b (mg/kg/day)	HHRL ^c (ppb)	US EPA HHBP ^d (ppb)
Flutriafol	Acute	0.19	0.075	395	2100 (Females 13–49 years)
	Chronic	0.10	0.05	500	300 (General Population)

^a 95th percentile water consumption rates for non-nursing infants from NHANES database (2005–2010). Acute and chronic water consumption data were extracted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 05-10-c); A residue level 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 rounded to two decimal points for the calculation of HHRLs.

^b RfD: reference dose. Acute and chronic RfDs for flutriafol were established by US EPA (US EPA, 2019).

^c HHRL: human health reference level. $HHRL (ppb) = [RfD (mg/kg/day) \times 1000 (\mu g/mg)] / \text{Daily water intake (L/kg/day)}$. Daily water intake is 95th percentile for acute or chronic (mean) water consumption rates for non-nursing infants.

^d HHBP: human health benchmark for pesticides. Acute HHBP (ppb) for females 13–49 years = $[acute RfD (mg/kg/day) \times 1000 (\mu g/mg)] / 0.0354 (L/kg/day) \text{ Drinking Water Intake-Body Weight (DWI-BW) ratio}$. HHBP (ppb) for chronic exposure in general population = $[chronic RfD (mg/kg bw/day) \times 1000 (\mu g/mg) \times 0.2 RSC] / 0.0338 (L/kg/day) \text{ DWI-BW ratio}$. RSC: relative source contribution, assumed as 20% (US EPA, 2021a).

The recommended HHRL for screening flutriafol residues in drinking water is **bolded**.

Conclusions

HHA calculated Human Health Reference Levels (HHRLs) to be used when flutriafol residues are detected in groundwater or drinking water. Residue levels of flutriafol equal to, or less than, the DPR HHRL of **395 ppb** are not expected to pose a risk to human health, including for sensitive subpopulations, if ingested in drinking water. Thus, the highest detected flutriafol residues in California groundwater (0.226 ppb) should not be considered an acute or chronic health concern.

Chunbo Zhang

Chunbo Zhang, PhD
Associate Toxicologist, Toxicology and Dose Response Assessment Section

Svetlana Koshlukova

Svetlana Koshlukova, PhD
Senior Toxicologist, Risk Assessment Section

Peter Lohstroh

Peter N. Lohstroh, PhD
Senior Toxicologist, Toxicology and Dose Response Assessment Section

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Wheat/Triticale, Brassica (cole) Leafy Vegetables, Celery, Leafy Vegetables, Cotton, and Sorghum. Office Of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency. <https://www.regulations.gov/document/EPA-HQ-OPP-2013-0654-0006>.

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Minh Pham
December 14, 2022
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**Appendix 1: DPR Memo: Potential Health Effects of Flutriafol in
Groundwater 10 August 2022 (1 page)**



Julie Henderson
Director

MEMORANDUM

Jared Blumenfeld
Secretary for
Environmental Protection

TO: Shelley DuTeaux
Environmental Program Manager II
Human Health Assessment Branch

VIA: Minh Pham
Environmental Program Manager II
Environmental Monitoring Branch

Original Signed By 8/11/22

FROM: Joy Dias
Environmental Program Manager I
Environmental Monitoring Branch

Original Signed By 8/11/22

DATE: August 10, 2022

SUBJECT: POTENTIAL HEALTH EFFECTS OF FLUTRIAFOL IN GROUNDWATER

The Environmental Monitoring Branch (EMB) monitors the environment to determine the fate of pesticides, protecting the public and the environment from pesticide contamination through analyzing hazards and developing pollution prevention strategies. Consistent with EMB’s mission, the Groundwater Protection Program (GWPP) requested additional pesticides be added to analytical methods used to monitor for pesticides with the potential to contaminate groundwater.

During routine monitoring with the updated analytical method, the GWPP detected flutriafol in groundwater. To date, the highest concentration detected was 0.226 ppb (Table 1). The GWPP is currently conducting focused groundwater monitoring in high-use areas of this pesticide.

EMB requests the assistance of the Human Health Assessment Branch in determining whether the highest detection poses a significant risk to human health and to provide a human health reference level for flutriafol to use for screening detections.

Table 1. Summary of highest detection of flutriafol in California groundwater.

Chemical	DPR Chemical Code	CAS Number	Maximum Concentration Detected (ppb)	Year
Flutriafol	5971	95-76-1	0.226	2021

cc: Carissa Ganapathy, Senior Environmental Scientist (Supervisory)