



Karen Morrison, PhD  
Acting Chief Deputy Director  
California Department of Pesticide Regulation  
1001 I Street  
Sacramento, CA 95812-4015



Feb. 18, 2022

Danyel L. Ward  
US State Regulatory Affairs Lead

Bayer CropScience LP

800 N. Lindbergh Blvd  
St. Louis, MO  
63167 USA

Tel. +1 919 549 2303  
danyel.ward@bayer.com

**Re: Imidacloprid Registrants' Report to the DPR in Response to DPR's letter dated 23-Sept-2021; Notice of DPR's Determination of Imidacloprid Detections in California Groundwater**

Dr. Morrison,

Bayer CropScience LP and Bayer Environmental Science herein referred to as Bayer submits this attached report pursuant to Food and Agricultural Code (FAC) section 13150(a), that states registrants must submit a report and documented evidence that demonstrate both of the following:

- (1) That the presence in the soil of any active ingredient, other specified ingredient, or degradation product does not threaten to pollute the groundwater of the state in any region within the state in which the pesticide may be used according to the terms under which it is registered.
- (2) That any active ingredient, other specified ingredient, or degradation product that has been found in groundwater has not polluted, and does not threaten to pollute, the groundwater of the state in any region within the state in which the pesticide may be used according to the terms under which it is registered.

The following imidacloprid registrants are in agreement and support the scientific findings presented in this report (prepared by Bayer) covering products subject and noticed by DPR under this PCPA review:

- Nufarm Americas Inc.
- Helena Agri-Enterprises, LLC
- Ensystem III, Inc.
- UPL NA Inc. (on behalf of UPL Delaware, Inc.)
- Makhteshim Agan of North America, Inc. (d/b/a ADAMA)
- Albaugh, LLC
- Sharda



- Sulfur Mills
- Willowood LLC, C/O Generic Crop Science LLC
- Loveland Products Inc.
- OHP
- SiteOne / Lesco, Inc.
- Arborjet, Inc.,
- Arborsystems, Inc. (d/b/a/ ArborSystems)
- Everiss NA, Inc (a subregistrant of Albaugh)
- Koppers Performance Chemicals, Inc.
- Rainbow Treecare Scientific Advancements
- Invictis Crop Care, LLC
- Rockwell Labs Ltd d/b/a Maggie's Farms Ltd.

These supporting companies including Bayer hereafter are referenced as the “Respondents”. The Respondents have requested a public hearing and appreciate the opportunity to submit this report to DPR on the Pesticide Contamination Prevention Act review of imidacloprid.

As detailed in the Respondent’s Report, imidacloprid is a critical tool in integrated pest management and invasive pest control programs in the agricultural, forestry and lawn and landscape sectors. Protection of California groundwater resources, as well as continued access to imidacloprid, a critical tool, is important to the agricultural community.

The DPR Human Health Assessment Branch evaluated the human health risk associated with the maximum level of imidacloprid measured in well water (5.97 parts per billion (ppb)) following detection of imidacloprid in 15 of 309 monitored wells (detection at levels ranging from 0.051 to 5.97 ppb). DPR calculated an acute Human Health Reference Level (HHRL) of 283 ppb imidacloprid to be used as a guide for future human health evaluations. Residue levels above this reference level of 283 ppb may pose a human health concern. As discussed in the Respondent’s Report, the highest reported detection from the imidacloprid sampling (5.97 ppb) is nearly 50-fold lower than the value DPR’s scientists identified as protective of public health. Further, sampling from DPR (and other sources) indicates that the presence of imidacloprid in wells is not widespread, and there is no indication that levels of imidacloprid are increasing or will increase over time. Therefore, based on all empirical analysis, imidacloprid has not polluted and does not threaten to pollute groundwater in California.



As requested by DPR, we are self-certifying that this report is in compliance with Web Content Accessibility Guidelines (WCAG) 2.1, or a subsequent version, published by the Web Accessibility Initiative of the World Wide Web Consortium (W3C) at a minimum Level AA success criterion.

If you or the Advisory Team have any questions or comments, please contact Nasser Dean, US State Regulatory Engagement Manager at 916-205-9481 or at [nasser.dean@bayer.com](mailto:nasser.dean@bayer.com)

Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink that reads "Danyel L. Ward". The signature is fluid and cursive, with the first name being the most prominent.

Danyel L. Ward  
US State Regulatory Affairs Lead  
Bayer CropScience LP

**Title**

Imidacloprid Registrants' Report to  
the California Department of Pesticide Regulation (DPR)

Response to DPR's letter dated 23-Sept-2021; Notice of DPR's Determination of Imidacloprid  
Detections in California Groundwater

**Authors**

Dan Dyer, PhD

Mitchell Kurtzweil, PhD

Larry Sheets, PhD, DABT

Dave Sturdivant

David Wilson, PhD

*David Wilson*

---

Signature

**Report Number**

US0866

**Completed on**

18 February 2022

**Submitted By**

Bayer Crop Science LP  
800 Lindbergh Blvd.  
St. Louis, MO 63167, USA

## 1.0 Introduction

Protection of California groundwater resources as well as continued access to imidacloprid, a critical tool, is important to the agricultural community. Since the introduction of neonicotinoid insecticides in the 1990s, U.S. farmers, including those in California, have consistently and safely adopted these tools and as such neonicotinoids are the most commonly used insecticide class in the U.S. This wide-spread adoption of neonicotinoids speaks to the value of these tools in protecting farm yields. Imidacloprid is a critical tool in integrated pest management (IPM) and invasive pest control programs in the agricultural, forestry and lawn and landscape sectors. For the agricultural and forestry programs, imidacloprid controls the Asian citrus psyllid, Colorado potato beetle, glassy-winged sharpshooter, vine mealybug, whitefly and citrus leafminer among others. For landscape ornamental (non-agricultural) uses, imidacloprid controls mealybugs, whiteflies, adelgids (Hemlock Woolly Adelgid), flatheaded borers (Emerald Ash Borer), roundheaded borers, Japanese Beetles, aphids, and soft scale insects. In turf, imidacloprid is a critical tool used to control white grubs, billbugs, and cutworms. The properties of imidacloprid allow for foliar, soil, tree injection or seed treatment applications, enabling applicators to tailor the use to target the intended pest most effectively, while minimizing the environmental risk. Seed treatment applications, which protect the seed at its most vulnerable developmental stage can, depending on the crop, allow for lower planting rates, earlier planting dates and adoption of practices including no-till and use of cover crops.

On 23-Sept-2021, the California Department of Pesticide Regulation (“DPR”) notified Bayer Cropscience and other imidacloprid registrants that DPR is initiating the Pesticide Contamination Prevention Act (PCPA) review for imidacloprid following detection of imidacloprid residues in 15 groundwater wells above the reporting threshold of 0.05 parts per billion (ppb). DPR provided imidacloprid registrants the opportunity to request a hearing on this topic. The following imidacloprid registrants support this report prepared by Bayer: Nufarm Americas Inc., Helena Agri-Enterprises, LLC, Ensystem III, Inc., UPL NA Inc. (on behalf of UPL Delaware, Inc.), Makhteshim Agan of North America, Inc. (d/b/a ADAMA), Albaugh, LLC, Everiss NA, Inc (a sub registrant of Albaugh), Sharda, Sulfur Mills, Willowood LLC, C/O Generic Crop Science LLC, Loveland Products Inc., OHP, SiteOne / Lesco, Inc., Arborjet, Inc., Arborsystems, Inc. (d/b/a/ ArborSystems), Koppers Performance Chemicals, Inc., Rainbow Treecare Scientific Advancements, Innvictis Crop Care, LLC, and Rockwell Labs Ltd d/b/a Maggie's Farms Ltd. hereafter referenced as the “Respondents”. The Respondents have requested a public hearing and appreciate the opportunity to submit this report to DPR on the PCPA review of imidacloprid.

The Respondents look forward to working with California DPR in the PCPA review process regarding imidacloprid. The Respondents have prepared this summary to report on the lack of risk to human health from detections of imidacloprid in well water and the low threat of imidacloprid polluting groundwater in California.

## **1.1 Detections of Imidacloprid Residues in Well Water are Considerably Below Levels Found to be Protective of Human Health**

As indicated in the Department of Pesticide Regulation (DPR) Memorandum dated April 13, 2021 (Subject: Updated Risks from Human Exposure To Imidacloprid Residues in Well Water), the DPR Human Health Assessment (HHA) Branch was notified by the Environmental Monitoring Branch that imidacloprid was detected in the water of 15 of 309 total wells that were monitored. The detection levels ranged from 0.051 to 5.97 parts per billion (ppb). The Environmental Monitoring Branch then requested that HHA determine if there is a health concern for individuals using these wells as a source of drinking water.

In response, HHA evaluated the human health risk associated with the maximum level of imidacloprid measured in well water (5.97 ppb) by conducting acute and chronic drinking water exposure analyses using the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID, version 4.02, 5-10c), the drinking water consumption rates based on the National Health and Nutrition Examination Survey (NHANES) 2005-2010 database and the toxicological endpoints (no-observed-adverse-effect-levels (NOAEL)) previously established by DPR.

The assessment employed by HHA is an established, and accepted process for determining potential human health risk associated with exposure to residues of plant protection products. The details and conclusions of that evaluation are presented in the April 13, 2021 DPR Memorandum. The DPR Memorandum confirms that the imidacloprid levels detected in ground water pose no concern to human health.

This risk assessment calculates acute and chronic Margins of Exposure (MOE). These MOEs are based on the known hazard (toxicity endpoints) and the known level of exposure associated with imidacloprid (i.e., residues in well water). The calculated MOEs can then be compared to a target MOE to determine if there is a health concern risk associated with a given exposure level. The target MOE is 100 based on the conservative assumption that humans are 10 times more sensitive than rats and that there is a 10-fold variation in the sensitivity of humans. Thus, a calculated MOE lower than the target MOE (100) indicates a potential health concern.

Using the maximum residues of imidacloprid found in the well water (5.97 ppb), the acute risk assessment resulted in MOEs greater than 4,700 (4,735 to 20,247) for the US population and all population subgroups including those for nursing and non-nursing infants and children 1 through 12 years of age. The lowest acute MOE was for the subpopulation of non-nursing infants.

Chronic MOEs were greater than 9,000 (9,254 to 69,394) for the total US population and all population subgroups including those for nursing and non-nursing infants and children

1 through 12 years of age. The lowest chronic MOE was also for the subpopulation of non-nursing infants.

Again, these calculated MOEs demonstrate that the imidacloprid levels detected in ground water are well below any level that may be considered a human health concern.

DPR then calculated acute and chronic Human Health Reference Levels (HHRL) for imidacloprid to be used by Environmental Monitoring Branch as a guide when requesting future human health evaluations for imidacloprid residues detected in ground water. Residue levels exceeding this reference level may pose a health concern.

The reference level is simply determined by multiplying the level of imidacloprid residue measured in well water (5.97 ppb) by the ratio of the calculated MOE to the target MOE.

Acute HHRL:  $(4,735/100) \times (5.97 \text{ ppb}) = 283 \text{ ppb}$

Chronic HHRL:  $(9,254/100) \times (5.97 \text{ ppb}) = 552 \text{ ppb}$

If imidacloprid residue levels equal to these values are used in the acute and chronic drinking water exposure analyses, the calculated MOEs would be 100 for non-nursing infants (the population with the highest consumption of drinking water). This means that any level of imidacloprid residues found in well water greater than 283 ppb would result in calculated MOEs less than 100 and may pose a health concern.

While both reference levels are based on the subpopulation with the highest estimated risk (non-nursing infants), DPR determined that the acute reference level (283 ppb) based on the acute calculated MOE is the most appropriate for use in screening for human health concerns because it was the lowest and therefore protective of acute and chronic exposures.

The Respondents conclude the risk assessment methodology employed by DPR is appropriate for this evaluation. The Respondents also believe the HHRL of 283 ppb is an appropriate and sufficiently protective reference level to be used by the Environmental Monitoring Branch when considering potential future requests for human health evaluations. Moreover, the Respondents concur with DPR's conclusions which state that the imidacloprid levels detected in ground water wells fall considerably below the health protective drinking water level of 283 ppb derived by DPR HHA.<sup>1,2</sup> Indeed, the highest

---

<sup>1</sup> [DPR. 2018. Evaluation of the Potential Human Health Effects from Drinking Well Water Containing Imidacloprid.](#)

<sup>2</sup> This conclusion is also consistent with guidance from the US EPA. In particular, the detected imidacloprid levels are well below the acute and chronic human health benchmarks for pesticides (HHBPs) (930 ppb and 360 ppb, respectively) established by the US EPA. These are levels of imidacloprid in water that are considered to be the maximum, safe, exposure levels.

reported detection from the imidacloprid sampling (5.97 ppb) is nearly 50-fold lower than the value DPR's scientists identified as protective of public health.

## **1.2 Imidacloprid Concentrations in Groundwater are very low and not likely to increase; therefore, Imidacloprid does not threaten to pollute California Groundwater**

Detections of imidacloprid in wells in CA above DPR's reporting limit (RL) of 0.05 ppb were confined to a small percentage of the total number of samples analyzed by DPR in the 2003-2020 timeframe. This indicates that the presence of imidacloprid in wells is not widespread. Of the detections, there is only one value that exceeds 1 ppb and this value, 5.97 ppb, is nearly 50-times below the HHA value of 283 ppb. Furthermore, analysis of detections over time shows no trend toward increasing levels. Therefore, imidacloprid does not threaten to pollute California groundwater.

Well monitoring data available from the [DPR website](#)<sup>3</sup> was evaluated for sampling locations and frequency of imidacloprid detections by DPR. A total of 658 individual samples were obtained from 365 wells in 20 different counties in California. Although sampling data is reported as early as 2003, most sampling occurred in the 2014-2020 timeframe.

A total of 627 samples gave imidacloprid concentrations below DPR's 0.05 ppb reporting limit (RL), which is equivalent to the limit of detection (LOD) for the analytical method used by DPR. Only 30 samples from 15 wells in three counties gave detectable levels above 0.05 ppb, while one sample was at the RL. The values ranged from 0.051-5.97 ppb, constituting only 4.6% of the total number of samples. Twenty-seven of these detections were from wells in Fresno Co., while the other three were in Santa Barbara and Tulare counties.

The well monitoring data from the DPR website also contains results from sampling conducted by the United States Geological Survey (USGS) and the California State Water Resources Control Board (CSWRCB). A total of 1075 samples were obtained from 1021 wells across 45 counties in the 2004-2020 timeframe. Of these, only two samples, which were from Fresno Co., contained imidacloprid above 0.05 ppb at levels of 0.056 ppb and 0.091 ppb. Inclusion of these detections along with those obtained by DPR results in 1.8% detections across the state from 2003-2020. A summary of the combined data from DPR, USGS, and CSWRCB is provided in Appendix A.

Further assessment of the DPR, USGS, and CSWRCB data shows no indication that levels of imidacloprid increase over time, even after multiple years of potential use. Figure 1 (Appendix A) shows the levels of imidacloprid found in the 17 wells in which it was detected relative to the HHA value of 283 ppb. Figure 2 (Appendix A) shows no trend toward increasing levels of imidacloprid.

---

<sup>3</sup> [https://www.cdpr.ca.gov/docs/emon/grndwtr/well\\_inventory\\_database/index.htm](https://www.cdpr.ca.gov/docs/emon/grndwtr/well_inventory_database/index.htm)



In summary, only a small percentage (<5%) of groundwater samples contained any imidacloprid and there was no indication of increasing concentrations in groundwater. The highest amount detected was nearly 50 times less than the concentration that DPR considers protective of human health (the “HHRL”).

## **2.0 Conclusion**

DPR conducted a thorough and robust human health risk assessment to determine safe reference levels for imidacloprid in water. Based on this assessment, DPR recommended that imidacloprid detections in California wells be compared to a reference level of 283 ppb, which is the level of detected imidacloprid residues in water at or below which health concerns are not anticipated. The highest reported detection from the imidacloprid sampling (5.97 ppb) is nearly 50-fold lower than the value DPR’s scientists identified as protective of public health. Further, sampling from DPR (and other sources) indicates that 1) the presence of imidacloprid in wells is not widespread, and 2) there is no indication that levels of imidacloprid are increasing or will increase over time. Therefore, based on all empirical analysis, imidacloprid has not polluted and does not threaten to pollute groundwater in California.

## APPENDIX A

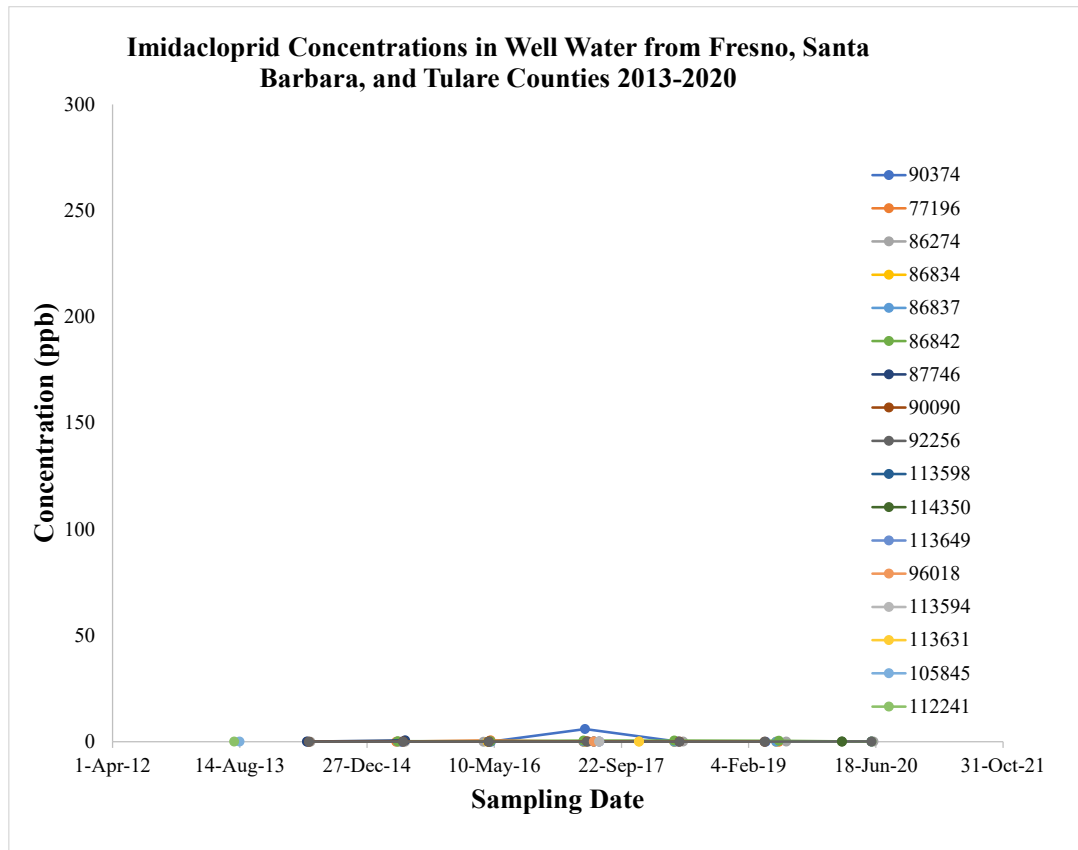
### Summary of Results from Analysis of Well Water Samples in CA by DPR, USGS, and CSWRCB

Total Number of Samples:	1733
No. Samples < 0.05 ppb <sup>1</sup> :	1701
No. Samples > 0.05 ppb:	32
Percent Detections:	1.8%
Range of Detections > 0.05 ppb	0.051-5.97 ppb
Mean of Detections > 0.05 ppb <sup>2</sup>	0.352 ppb
Median of Detections > 0.05 ppb <sup>2</sup>	0.091 ppb

<sup>1</sup> Includes the single value at 0.05 ppb.

<sup>2</sup> Eight of the samples were reanalyzed using a second method. The two values obtained were averaged to give a single value prior to determination of the mean and median.

**Figure 1. Imidacloprid Concentrations Relative to the HHA Value**



**Figure 2. Imidacloprid Concentrations Indicating Lack of Trend Toward Increasing Levels**

