




Julie Henderson
Director

Jared Blumenfeld
Secretary for
Environmental Protection

MEMORANDUM

TO: Karen Morrison
Acting Chief Deputy Director

FROM: Julie Henderson 
Director
(916) 445-4000

DATE: June 16, 2022

SUBJECT: DIRECTOR'S DECISION IN RESPONSE TO THE PESTICIDE REGISTRATION
AND EVALUATION COMMITTEE'S SUBCOMMITTEE FINDINGS AND
RECOMMENDATIONS REGARDING IMIDACLOPRID IN GROUNDWATER

Attached is my decision in response to the findings and recommendations of the Pesticide Registration and Evaluation Committee's subcommittee concerning groundwater detections of imidacloprid. My response has been made in accordance with all authorities and requirements in section 13150 of the Food and Agricultural Code which mandates this process of review for these detections. The subcommittee's findings and recommendations were transmitted to me on May 18, 2022; therefore, this response has been made within the 30 days statutory deadline. I thank you and all the members of the subcommittee for carrying out this important task.

Attachment

cc: Rich Breuer, State Water Resources Control Board (w/Attachment)
Dr. Lori Lim, Office of Environmental Health Hazard Assessment (w/Attachment)
Ann Prichard, Department of Pesticide Regulation (w/Attachment)



DIRECTOR'S DECISION IN RESPONSE TO THE PESTICIDE REGISTRATION AND EVALUATION COMMITTEE'S SUBCOMMITTEE FINDINGS AND RECOMMENDATIONS REGARDING IMIDACLOPRID IN GROUNDWATER

Between 2003 and 2021, the Department of Pesticide Regulation (DPR) conducted statewide groundwater sampling for imidacloprid. DPR's Groundwater Protection Program (GWPP) analyzed more than 700 groundwater samples from over 400 wells for detections of imidacloprid. Between 2014 and 2021, DPR's GWPP detected imidacloprid in Fresno, Santa Barbara, and Tulare counties in 16 unique wells at trace levels¹ and in 16 unique wells above the reporting limit (0.05 ppb between 2014 and 2020, and 0.02 ppb in 2021), with detections ranging from 0.022 to 5.97 ppb. The highest concentration (5.97 ppb) was detected in 2017 in Well 29 of DPR's Well Monitoring Network, which at the time served a vacant home. DPR also analyzed 144 well samples for imidacloprid degradates and identified no degradate detections. Where a pesticide is detected in groundwaters of the state and the detection is determined to be the result of legal agricultural use of the pesticide, a hearing before the Pesticide Registration and Evaluation Committee subcommittee (subcommittee), consisting of one member each from DPR, the Office of Environmental Health Hazard Assessment (OEHHA) and the State Water Resources Control Board, is held upon request to determine if the pesticide pollutes or threatens to pollute groundwater. (Food & Agr. Code, §§ 13149; 13150.)

After evaluating the imidacloprid detections, GWPP determined that they resulted from legal agricultural uses of imidacloprid. On September 21, 2021, DPR issued California Notice 2021-08 notifying registrants of agricultural use imidacloprid products of the legal agricultural use determination and the opportunity to request a hearing. After receiving hearing requests from imidacloprid agricultural use product registrants, the subcommittee held a public hearing pursuant to Food and Agricultural Code section 13149(c) on March 22-23, April 19, and May 17, 2022. The purpose of these hearings was to determine if agricultural use of imidacloprid pollutes or threatens to pollute groundwaters of the state. At the March 22-23 hearing, DPR's Human Health Assessment Branch (HHA) and GWPP, OEHHA, and imidacloprid agricultural use product registrants presented reports to the subcommittee regarding whether continued agricultural use of imidacloprid would pollute or threaten to pollute groundwaters of the state. The April 19 hearing was limited to receiving rebuttal evidence. During the course of the hearing process, the subcommittee received nearly 4,000 public comments (26 unique comments and 3,869 email form comments) from a range of environmental, public health, and agricultural stakeholders.

¹ "Trace concentration" refers to detections found between the method detection limit (0.01 ppb between 2014 and 2020, and 0.003 ppb in 2021) and the reporting limit (0.05 ppb between 2014 and 2020, and 0.02 ppb in 2021) for imidacloprid.

At the May 17, 2022 hearing, the subcommittee publicly deliberated, voted, and unanimously adopted findings and recommendations, entitled “Imidacloprid: Subcommittee Findings and Recommendations” (findings and recommendations) for transmittal to the DPR Director. After consideration of the evidence presented by hearing participants and through public comment, the subcommittee found that the presence of imidacloprid in the groundwaters of the state has not polluted and does not threaten to pollute the state’s groundwaters within the meaning of “pollute” as defined under Food and Agricultural Code section 13142: “... to introduce a pesticide product into the groundwaters of the state resulting in an active ingredient, other specified ingredient, or a degradation product of a pesticide above a level that does not cause adverse health effects, accounting for an adequate margin of safety.” While the subcommittee found that imidacloprid does not currently pollute or threaten to pollute groundwater, it recommended continued groundwater monitoring by GWPP and a human health toxicologic assessment by HHA.

In making its no pollution finding, the subcommittee compared GWPP sampling analyses with health screening levels (referred to as “public health protective concentrations” (PHC) by OEHHA and as “human health reference levels” (HHRL) by DPR) for imidacloprid in drinking water. All GWPP detections, except for the single 5.97 ppb detection, were within a range of 0.022 to 0.665 ppb. The subcommittee findings noted irregularities with the 5.97 ppb detection and expressed concern about basing potential regulatory action solely on this sample. The subcommittee noted that the 5.97 ppb detection: (1) was much higher in magnitude than all other imidacloprid detections in the same well, and the drop in magnitude of subsequent imidacloprid concentrations from the same well was considered unusual; (2) was far greater than imidacloprid detections in any other well, and was almost 10-fold higher than the next highest GWPP detection of 0.665ppb; and (3) was sampled from a well where the well water exhibited an unusual degree of murkiness. For these reasons, the subcommittee opposed basing a pollution finding on the 5.97 ppb detection. Even if the subcommittee had found the 5.97 ppb detection to be reliable, it still would have made a ‘no pollution’ finding because the 5.97 ppb detection was below the most conservative health-protective level that the subcommittee found to be supportable. (*See* subcommittee Finding 3.).

The subcommittee provided a range of scientifically supported imidacloprid health-protective values, rather than selecting a specific value. This was done in deference to the pending HHA risk assessment, which will be peer-reviewed by OEHHA, for final selection of the appropriate health-protective level. The numerous potential PHC/HHRLs provided by the subcommittee ranged from 10 to 283 ppb, based on various points of departure and study endpoints. The 10 ppb PHC—the most conservative health-protective level—was proposed by OEHHA in its report to the subcommittee. OEHHA based the 10 ppb level on a 0.8 mg/kg/day point of departure using an immunotoxicity endpoint derived from a study conducted in mice. It included several health-based default assumptions, including: (1) humans are 10-fold more sensitive than mice; (2) there is a 30-fold variation in sensitivity within the human population; and (3) 20% of the total imidacloprid consumption in humans would originate from drinking water (the remaining 80% would derive from other sources, including food and air).

The subcommittee declined to rely on several other potential points of departure, citing experiment design, reporting, or statistical flaws associated with the underlying studies. These are summarized below and described in HHA rebuttal testimony:

- *Bal et al. (2012a)*, *Bal et al. (2012b)*, and *Kara et al. (2015)*: No information was provided on the purity of the imidacloprid preparation being tested.
- *Khalil et al. (2017)* and *Zhao et al. (2021)*: Solvents inappropriate for toxicity testing were introduced to dissolve or suspend imidacloprid.
- *Abdel-Rahman Mohamed et al. (2017)*: The study was based on use of a single dose, thus lacking corroboration from other doses.
- *Sun et al. (2016)*, and *Sun et al. (2017)*: These studies had confounding experimental conditions, including the introduction of altered dietary fat content. For the diet with normal fat content, these studies lacked either a statistically significant dose response (Sun et al., 2016) or no effect of dosing was discernable (Sun et al., 2017).

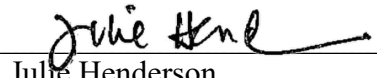
Director's Decision

On May 18, 2022, the subcommittee transmitted its unanimous findings and recommendations to the DPR Director. Food and Agricultural Code section 13150 requires the DPR Director to respond to the subcommittee concerning the detection of imidacloprid in groundwater within 30 days of the subcommittee's issuance of its findings and recommendations.

Every person in the state has a right to safe drinking water. Ensuring that agricultural pesticide use does not pollute and threaten equitable access to safe drinking water is critical to DPR's mission to protect human health and the environment for all Californians. Based on the evidence presented in this proceeding, as well as the reasons outlined above, the Director concurs with the subcommittee's unanimous finding that imidacloprid currently does not pollute and does not threaten to pollute the state's groundwaters. Importantly, imidacloprid will remain subject to groundwater monitoring requirements and DPR's program of continuous evaluation:

1. Pursuant to Food and Agricultural Code section 13152(a)(1), DPR shall continue to conduct groundwater monitoring for imidacloprid in DPR's Well Monitoring Network, which is located in areas vulnerable to pesticide leaching and runoff and has been shown to be sensitive to detections of imidacloprid. DPR shall continuously review new science and data that could impact the validity of the subcommittee's finding that imidacloprid does not pollute or threaten to pollute groundwater. The Director concurs with the subcommittee recommendation for GWPP to consider incorporating, to the extent feasible, pounds of active ingredient of imidacloprid applied to soil used per section, combined with an assessment of depth to groundwater and vulnerable soil types, to determine priority monitoring wells.
2. Where future developments in science or data impact the validity of the subcommittee findings, DPR will act pursuant to Food and Agricultural Code section 13152(a)(2) to mitigate or re-review the threat of pollution to groundwater presented by imidacloprid.

3. A statewide health-protective level should be established for imidacloprid as part of HHA's pending risk assessment to evaluate the potential pollution threat of any future detection.

Approved By:  Date: June 16, 2022
Julie Henderson
Director

Attachment: Imidacloprid: Subcommittee Findings and Recommendations

Subcommittee of the Pesticide Registration and
Evaluation Committee

Implementation of the Pesticide Contamination
Prevention Act

Imidacloprid: Subcommittee Findings and Recommendations
May 17, 2022

The California Department of Pesticide Regulation (DPR) conducted groundwater sampling studies between 2003 and 2021 in different areas of the state where agricultural products containing the active ingredient imidacloprid were legally used. Laboratory analyses confirmed detections of imidacloprid in samples collected in several counties.

According to DPR's "Legal Agricultural Use Determination for Imidacloprid Detections in California" (September 2021) and "Evidence Requested by the Subcommittee for Phase 2 of the Hearing on Imidacloprid Detections in Groundwater," (April 2022),¹ DPR's Groundwater Protection Program (GWPP) analyzed more than 700 groundwater samples from over 400 wells for imidacloprid. Some wells were sampled multiple times while other wells were sampled once. Some samples were analyzed using an imidacloprid-specific method while others used a multianalyte method, and some samples were analyzed using both methodologies. Between 2014 and 2021, DPR's GWPP detected imidacloprid above the reporting limit in 16 wells in Fresno, Santa Barbara, and Tulare counties, with concentrations ranging from 0.022 to 5.97 ppb. The highest concentration (5.97 ppb) was detected in 2017 in Well 29, which at the time served a vacant home. DPR evaluated these detections and determined them to have resulted from legal agricultural uses of imidacloprid. DPR also analyzed 144 well samples for imidacloprid degradates, but there were no detections.

In compliance with Food and Agricultural Code section 13149(c) and pursuant to California Notice 2022-03 "*Notice of Public Hearing Pertaining to Imidacloprid Product Residue Detections in Groundwater*" this subcommittee held hearings on March 22-23, 2022. During this Phase 1 hearing, state agencies and implicated registrants presented evidence regarding the continued agricultural use of imidacloprid for the subcommittee to determine if agricultural use of imidacloprid can continue, and if so, under what conditions. The public also had an opportunity to submit comments. Pursuant to California Notice 2022-04 "*Notice of Agenda for Phase 2(a) of Public Hearing Pertaining to Imidacloprid Product Residue Detections in Groundwater*" this subcommittee held a rebuttal hearing on April 19, 2022. The Phase 2(a) hearing was limited to receiving rebuttal evidence from hearing participants and receiving comments from the public.

¹ DPR's *Legal Agricultural Use Determination for Imidacloprid Detections in California* (September 2021) is available at: https://www.cdpr.ca.gov/docs/emon/grndwtr/imidacloprid/imidacloprid_lau.pdf and Errata available at: https://www.cdpr.ca.gov/docs/emon/grndwtr/imidacloprid/imidacloprid_lau_errata.pdf. DPR HHA's *Evidence Requested by the Subcommittee for Phase 2 of the Hearing on Imidacloprid Detections in Groundwater* (April 2022) available at: https://www.cdpr.ca.gov/docs/emon/grndwtr/imidacloprid/evidence_requested_phase2.pdf.

DISCUSSION

While the detections of imidacloprid in California groundwater are sufficient to conclude that they were the result of legal agricultural use of imidacloprid, the subcommittee has concerns about relying on the single detection point of 5.97 ppb in Well 29 as the basis for regulatory action. This is due to the anomalous nature of this detection in relation to all other detections, both within the same well and within all other wells with imidacloprid detections. First, the 5.97 ppb detection is much higher in magnitude compared to all other imidacloprid detections in this same well. Imidacloprid residues in Well 29 ranged from “non-detect” in 2014, “trace” in 2015, “non-detect” in 2016, 5.97 ppb in 2017, 0.095 ppb in 2018, “trace” in 2019, 0.053 ppb in 2020, and 0.045 ppb in 2021. The imidacloprid detection in 2017 (5.97 ppb) dropped to less than 2% of that level in 2018 (0.095 ppb) and to less than 1% of that level in 2019 (trace), 2020 (0.053 ppb), and 2021 (0.045 ppb). The magnitude of this drop is not consistent compared to the remaining reported imidacloprid detections. Second, the detection of 5.97 ppb in Well 29 is far greater than imidacloprid detections in any other wells. The detection in Well 29 is almost 10-fold higher than the second highest imidacloprid detection of 0.665 ppb in 2015 in Well 18. The 0.665 ppb detection is also more consistent in magnitude with the next highest detections of imidacloprid in other wells, including 0.644 ppb in 2016 (Well 47) and 0.536 ppb in 2018 (Well 23). Finally, DPR’s GWPP noted in its September 2021 Legal Agricultural Use Determination for Imidacloprid Detections in California (LAU), “[t]he highest concentration of 5.97 ppb was detected in a well that serves a vacant home. The sampled water from this well appeared murky and may not reflect the detectable residues in active domestic wells.” (LAU, p. 6.) Murkiness was not a characteristic of any other well samples.

At both Phase 1 and Phase 2(a) hearings, DPR’s Human Health Assessment Branch (HHA)² and the Office of Environmental Health Hazard Assessment (OEHHA)³ provided testimony regarding a range of health screening levels for imidacloprid in drinking water. DPR’s HHA testified that it evaluated a total of 3,499 published toxicity studies, including the eleven studies cited by OEHHA in their February 16, 2022, document entitled, “OEHHA’s Findings on the Health Effects of Imidacloprid Relevant to Its Identification as a Potential Groundwater Contaminant.” DPR’s HHA testified that it determined that several of the studies cited by OEHHA had experimental design, reporting, or statistical issues that precluded their use as the basis for a regulatory action. Based on a review of the remaining studies, health screening levels (Public Health Protective Concentration [PHC]/Human Health Reference Level [HHRL]) for imidacloprid in groundwater ranged between 10 ppb and 283 ppb.

² DPR HHA’s *Updated Risks from Human Exposure to Imidacloprid Residues in Well Water* (April 2021) is available at: https://www.cdpr.ca.gov/docs/emon/grndwtr/imidacloprid/imidacloprid_risks_memo.pdf. See also Footnote 1, above, for citation to DPR HHA’s *Evidence Requested by the Subcommittee for Phase 2 of the Hearing on Imidacloprid Detections in Groundwater* (April 2022).

³ OEHHA’s *Findings on the Health Effects of Imidacloprid Relevant to Its Identification as a Potential Groundwater Contaminant* (February 2022) available at: https://www.cdpr.ca.gov/docs/emon/grndwtr/imidacloprid/oehha_findings_health_effects.pdf.

FINDINGS

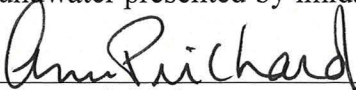
After considering the evidence and public comments presented in the March 22-23 and April 19 hearings, the subcommittee determined at the Phase 2(b) public hearing on May 17, 2022, that the presence of imidacloprid in the groundwater of the state has not polluted and does not threaten to pollute based on the definition of “pollute” in the law (Food and Agricultural Code, § 13150, subd. (c)(1)). The law defines “pollute” as “... to introduce a pesticide product into the groundwaters of the state resulting in an active ingredient, other specified ingredient, or a degradation product of a pesticide above a level that does not cause adverse health effects, accounting for an adequate margin of safety.” (Food and Agricultural Code, § 13142, subd. (j).

The subcommittee based their finding on the following information:

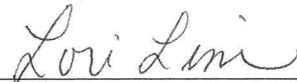
1. The highest concentration of imidacloprid detected in California groundwater was 5.97 ppb reported in 2017 in Well 29. However, as discussed above, the subcommittee has concerns about relying on this single concentration as the basis for regulatory action due to the anomalous nature of this concentration in comparison to others for this well and with all other concentrations from sampled wells. The second highest concentration of imidacloprid detected in groundwater was 0.665 ppb, which is consistent in magnitude with maximum concentrations of imidacloprid in other wells.
2. Calculation of health screening levels (PHC/HHRL) for imidacloprid in drinking water derived from available toxicological information using established approaches results in a range between 10 ppb and 283 ppb. Establishment of an updated health screening level for imidacloprid in drinking water will await publication of DPR’s revised imidacloprid risk characterization document, which is subject to peer review by OEHHA pursuant to Food and Agricultural Code section 11454.1.
3. Since all imidacloprid detections in groundwater fall below the range of health screening drinking water levels derived from available toxicological information using established approaches, the subcommittee concludes that imidacloprid has not polluted groundwater.
4. Although there has been use and detections of imidacloprid in some of the most vulnerable groundwater areas in the state (i.e., Fresno and Tulare counties), the subcommittee concludes that imidacloprid does not threaten to pollute the groundwater of the state under current labeled use conditions.

RECOMMENDATIONS

Based on the above findings, the subcommittee recommends that the Director allow the continued registration, sale, and agricultural use of imidacloprid products. As required by Food and Agricultural Code section 13152(a)(1), DPR will continue to conduct ongoing groundwater monitoring for imidacloprid in DPR's Well Network, which focuses monitoring in vulnerable areas, and continuously review new science and data that could impact the validity of the subcommittee's findings. The subcommittee recommends that DPR considers study designs for groundwater monitoring for imidacloprid to incorporate pounds of active ingredient applied to soil used per section, combined with an assessment of depth to groundwater and vulnerable soil types to determine priority monitoring wells. If DPR determines that there is new science or data that could impact the validity of the above findings, the Director will act as provided in Food and Agricultural Code section 13152(a)(2) to mitigate or re-review the threat of pollution to groundwater presented by imidacloprid use based on the new data.



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