

Department of Pesticide Regulation

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Yana Garcia Secretary for Environmental Protection

California Notice 2023-07

TO: Pesticide Registrants and Other Stakeholders

SUBJECT: PESTICIDE REGISTRATION PROGRAM ANNUAL PROCESSING TIMELINES

Pursuant to the Food and Agricultural Code (FAC) section 12811, Title 3 California Code of Regulations (3 CCR) section 6170, and to fulfill the Department of Pesticide Regulation's (DPR) mission of protecting human health and the environment, a pesticide must be registered (licensed) with the state before it can be used, possessed, or offered for sale in California. The Pesticide Registration Branch (PRB) is responsible for pesticide registration and coordinates the required data evaluation process among scientific evaluation programs within DPR's Pesticide Programs Division (PPD) and other state agencies. PRB serves as the primary point of contact for registrants on all pesticide activities. It prepares public notices and corresponds with registrants regarding data requirements, determinations of the human health and environmental effects of pesticides, and final actions on registrations. PRB also manages all data received, coordinates the continuous evaluation of pesticide products and data call-ins, maintains pesticide product label files and scientific data submitted to support pesticide registration, and provides information on registered pesticides and label instructions to pesticide enforcement agencies and the public.

Before a pesticide product is registered or amended in California, it must meet all applicable U.S. Environmental Protection Agency (U.S. EPA) and DPR data requirements for the pesticide product type. In order to meet these requirements, registrants may submit the data themselves or refer to appropriate data previously submitted to DPR for a similar pesticide product(s) registered by DPR subject to the same data requirements. Therefore, a pesticide product submission may not be routed to a particular scientific evaluation program within PPD based on current data requirements and/or previously evaluated data submitted to DPR.

To improve transparency for stakeholders, PRB publishes an annual report summarizing the past five years of registration and post-registration actions. The number of pesticide product registration and amendment submissions received and processed, and average number of days to complete different types of registration submissions are provided. New to the notice for 2023, PRB is providing information on the time spent in each of the scientific evaluation programs for currently registered active ingredients. Program-specific information for new active ingredient products is not collected in the same way in our legacy database and is thus not available. DPR is currently developing a new electronic tracking database for pesticide registration. Once implemented, the California Pesticide Electronic Submission Tracking system (CalPEST) will allow for more refined tracking and assessment of registration timelines, including new active ingredients.

As shown in the tables that follow, the past two years have seen increases in the average processing time for registration submissions overall, and in certain individual evaluation stations. There are two primary factors that have contributed to these increases: staffing, and consultation. First, DPR is understaffed relative to the registration workload and more applications for registration are received each year than can be processed. This creates backlogs in the number of registration items pending in all areas of the program. While staff are reallocated between different evaluation stations to address existing backlogs, this creates delays in other stations. Second, product amendments may or may not need to be routed to evaluation stations for formal scientific evaluation depending on the specific nature of the change (e.g., confirming substantively similar products or previously evaluated data). Unnecessary routing can lead to increased timelines for these products. To address this concern, DPR has implemented a prerouting consultation process that allows for an initial review to determine if formal scientific evaluation is needed. In the immediate term, this has added to overall staff workload and contributed to increasing timelines; however, in the long run, this will reduce the workload of evaluation station formal scientific review and should improve timelines overall.

In addition to the challenges described above, aspects of the registration program have been subject to an increased workload that reflects changes made in response to ongoing departmental evaluations focusing on ensuring compliance with various California Environmental Quality Act (CEQA) requirements. These changes include additional public reporting, enhanced data reviews by DPR evaluation program stations (e.g., DPR's Microbiology, Surface Water, and Ecotoxicology Programs), and peer review to ensure consistency. A budget change proposal for DPR was released as a part of the May 2023 budget revise that includes six positions to address critical needs related to registration. This proposal will support improved registration timelines while maintaining rigorous scientific quality. This proposal also supports more rapid evaluation and mitigation of risks associated with currently registered products to ensure the continued reduction of harmful pesticide exposure and ensures DPR has legal support to comply with CEQA. DPR will track registration activities to demonstrate processing times have decreased while maintaining the scientific integrity and regulatory requirements of the registration program.

Collectively, these efforts align with the department's broader focus on Sustainable Pest Management. In January 2023, DPR, the California Environmental Protection Agency (CalEPA) and the California Department of Food and Agriculture (CDFA) released the Sustainable Pest Management Roadmap (Roadmap). The Roadmap identifies as a keystone action improving DPR's pesticide registration processes, including prioritizing and expediting the review of safer, more sustainable alternatives and improving registration processes generally.

1. ANNUAL SUBMISSIONS RECEIVED SUMMARY:

Tables 1-4 summarize the total number of submissions received during the past five years, with Table 1 providing a general overview and Tables 2-4 providing data on more detailed subcategories. New product registration submissions include new products containing new active ingredients, products containing currently registered active ingredients, subregistrations, and California-only products. Product amendments include amendments to Section 3 products (i.e., products that require federal and CA registration under FIFRA section 3) and California-only products (i.e., products that do not require

federal registration but do require registration in CA, such as adjuvants). Other submissions include minimum risk pesticides, Emergency Exemptions (Section 18), Special Local Needs (Section 24(c)) registrations, and Experimental Use Permits (EUP). Additional data includes but is not limited to submissions to address conditional registrations, adverse effects, risk assessment, reevaluation, etc.

Table 2 summarizes the total number of new product registration submissions received during the past five years by type. Currently registered active ingredient submissions include all Section 3 and subregistration submissions. Table 3 summarizes the total number of submissions received to amend currently registered products, while Table 4 summarizes the total number of original and amended other submissions received including minimum risk pesticides, Emergency Exemptions (Section 18), Special Local Needs (Section 24(c)) registrations, and Experimental Use Permits (EUP).

Table 1. Total Number of Submissions Received

Submission Type	2018	2019	2020*	2021	2022
New Products	1296	1312	1582	1399	1158
Amendments	2552	2114	2366	2254	1715
Other	36	70	57	40	32
Additional Data	831	836	723	777	745
Total Received per Year	4715	4332	4728	4470	3650

^{*}Increased number of submissions in 2020 related to anti-microbial products in response to the COVID-19 pandemic.

Table 2. New Product Submissions Received

Submission Type	2018	2019	2020	2021	2022
Currently Registered Active Ingredient	1167	1173	1484	1261	1066
CA-Only Products	85	106	73	103	67
New Active Ingredient	44	33	25	35	25
Total Received per Year	1296	1312	1582	1399	1158

Table 3. Product Amendment Submissions Received

Amendment Type	2018	2019	2020	2021	2022
Section 3 Products	2338	2030	2256	2184	1675
CA-Only Products	214	84	110	70	40
Total Received per Year	2552	2114	2366	2254	1715

Table 4. Other Submissions Received

Submission Type	2018	2019	2020	2021	2022
Minimum Risk Pesticides	10	6	1	2	6
Emergency Exemptions (Section 18)	12	13	11	5	2
Special Local Needs (Section 24(c))	14	50	44	33	24
Experimental Use Permits (EUP)	0	1	1	0	0
Total Received per Year	36	70	57	40	32

2. SUMMARY OF REGISTRATION SUBMISSIONS PROCESSED BY YEAR

Table 5 summarizes the number of registration actions completed by year during the past five years. This summary does not include additional data submissions unrelated to a registration action processed in any given year, including but not limited to submissions associated with post-registration activities, such as conditionals, adverse effects, risk assessments, reevaluations, etc.

Table 5. Product Submissions Processed Summary

Submission Type	2018	2019	2020	2021	2022
Currently Registered Active Ingredient	1198	1087	1276	1370	1051
CA-Only Product	102	78	96	78	84
New Active Ingredient	25	28	40	38	30
New Products Subtotal	1325	1193	1412	1486	1165
Sec. 3 Amendment	2270	2096	2044	2057	1704
Sec. 57 unenament	2270	2090	ZU44	2057	1794
CA-Only Amendment	178	117	88	88	44
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3. ANNUAL TIMELINES TO COMPLETE DIFFERENT TYPES OF REGISTRATION SUBMISSIONS

Table 6 summarizes the annual average number of days to complete different types of registration submissions in the past five years. This table also includes timeline ranges for the middle 50% of submissions to complete final registration actions for the 2022 calendar year. The types of registration submissions are consistent with the registration types reported in the previous section (Table 5). Currently registered active ingredient submission types include Section 3 and Section 3 subregistration submissions. This summary does not include additional data submissions processed in any given year, including but not limited to actions associated with post-registration activities, such as conditionals, adverse effects, reevaluations, etc.

Table 6. Summary of Annual Average Timeline (Days) to Complete Registration by

Submission Type

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
New Product with Currently Registered Active Ingredient	122	138	156	195	191	113 – 208
CA-Only Products	111	173	140	179	194	145 - 225
New Active Ingredient	734	701	1242	1125	1191	393 – 1832
Sec. 3 Amendment	82	100	111	144	139	78 - 171
CA-Only Amendment	85	116	129	159	130	64 - 163

^{*}Range represents the number of days for an action for middle 50% submissions completed in 2022

4. ANNUAL TIMELINES FOR PESTICIDE PROGRAMS DIVISION EVALUATION PROGRAM

This section summarizes the annual average number of days for a submission to complete the scientific evaluation process within each PPD evaluation program for the past five years. Note that new active ingredient submissions are not included in the evaluation program-specific data reported in Tables 7–13 below. The current tracking system does not capture individual station timelines when routed concurrently. The data for each evaluation program represents average days by year of completion. Currently registered active ingredient submission types include Section 3 and Section 3 subregistrations. Other submissions include minimum risk pesticides, Emergency Exemptions (Section 18), Special Local Needs (Section 24(c)) registrations, and Experimental Use Permits (EUP). These summaries do not include additional data submissions processed in any given year, including but not limited to actions associated with post-registration activities such as conditionals, adverse effects, risk assessments, reevaluations, etc.

4.1. CHEMISTRY

The Chemistry Program evaluates product chemistry and environmental fate data to support pesticide product registration in California. Chemistry staff draft evaluation reports summarizing submitted data and recommending whether the submitted data meet the requirements for registration in California for the proposed product. In addition to the evaluation of products containing already registered active ingredients shown in Table 7, the Chemistry program evaluates an average of 28 new active ingredient products annually based on a 5-year average.

Table 7. Average Days to Complete Chemistry and Environmental Fate Data Evaluations and Total Completed Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	94	22	24	29	96	49 – 133
# Completed Submissions	188	189	108	112	130	-
CA-Only Products (days)	144	33	42	52	191	154 - 218
# Completed Submissions	14	19	8	10	7	-
Sec. 3 Amendment	93	14	18	26	76	N/A
# Completed Submissions	29	15	7	19	4	-
CA-Only Amendment (days)	170	13	-	-	17	N/A
# Completed Submissions	1	2	0	0	1	_

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

4.2. PEST AND DISEASE PROTECTION

Pest and Disease Protection is a part of the Plants, Pests, and Disease Program. Pest and Disease Protection evaluations analyze product efficacy data for all fungicides and insecticides. They also review phytotoxicity data for new claims requested for currently registered fungicides and insecticides. In addition to the evaluation of products containing already registered active ingredients shown in Table 8, an average of 20 new active ingredient products are reviewed under Pest and Disease Protection annually based on a 5-year average.

Table 8. Average Days to Complete Pest and Disease Protection Data Evaluations and Total Completed Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	66	62	63	102	161	127 – 174
# Completed Submissions	53	56	27	28	38	-
CA-Only Products (days)	87	76	37	118	168	N/A
# Completed Submissions	12	6	2	6	2	-
Sec. 3 Amendment	68	64	50	100	139	126 – 150
# Completed Submissions	45	33	36	62	40	-
CA-Only Amendment (days)	16	67	-	74	118	N/A
# Completed Submissions	1	1	0	1	1	_

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

4.3. PLANT PHYSIOLOGY

Plant Physiology is a part of the Plants, Pests, and Disease Program. Plant Physiology evaluations analyze product efficacy data for herbicides and plant growth regulators, and phytotoxicity data for fungicides and insecticides products with new active ingredients. In addition to the evaluation of products containing already registered active ingredients shown in Table 9, an average of 19 new active ingredient products are reviewed under plant physiology annually based on a 5-year average.

Table 9. Average Days to Complete Plant Physiology Evaluations and Total Completed Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	82	130	102	111	197	73 - 289
# Completed Submissions	15	24	20	15	11	-
CA-Only Products (days)	61	114	149	145	110	N/A
# Completed Submissions	8	12	2	3	2	-
Sec. 3 Amendment	82	131	117	116	240	92 - 383
# Completed Submissions	24	14	6	10	15	-
CA-Only Amendment (days)	51	201	129	-	254	N/A
# Completed Submissions	2	1	1	0	1	-

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

4.4. MICROBIOLOGY

The Microbiology Program evaluates product efficacy for antimicrobial products and product chemistry data for microbial-based products as required by state and federal laws and regulations. Microbiology staff draft evaluation reports that summarize and evaluate submitted data. In addition to the evaluation of products containing already registered active ingredients shown in Table 10, the Microbiology Program also evaluates, on average, 15 new active ingredient products annually based on a 5-year average.

Table 10. Average Days to Complete Microbiology Data Evaluations and Total Completed

Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	39	61	25	34	223	170 - 298
# Completed Submissions	97	118	96	59	18	-
CA-Only Products (days)	-	82	-	4	281	N/A
# Completed Submissions	-	4	0	1	1	-
Sec. 3 Amendment	47	69	18	24	197	120 - 291
# Completed Submissions	89	74	135	108	74	-
CA-Only Amendment (days)	_	-	-	-	-	-
# Completed Submissions	0	0	0	0	0	-

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

4.5. ECOTOXICOLOGY

The Ecotoxicology Program evaluates non-target organism toxicity data to support pesticide product registration in California. Ecotoxicology staff draft evaluation reports summarizing submitted data and recommending whether the proposed pesticide product is expected to pose risks to the environment. In addition to the evaluation of products containing already registered active ingredients shown in Table 11, the Ecotoxicology Program evaluates an average of 30 new active ingredient products annually based on a 5-year average.

Table 11. Average Days to Complete Ecotoxicology Data Evaluations and Total Completed

Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	466	468	515	441	589	436 - 702
# Completed Submissions	5	15	18	10	13	-
CA-Only Products (days)	-	-	-	-	-	-
# Completed Submissions	0	0	0	0	0	-
Sec. 3 Amendment	350	399	481	236	533	N/A
# Completed Submissions	12	5	7	3	2	-
CA-Only Amendment (days)	-	561	_	_	_	-
# Completed Submissions	0	1	0	0	0	-

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

4.5. HUMAN HEALTH ASSESSMENT

The Human Health Assessment Branch (HHA) is responsible for the evaluation of toxicology data in support of registration actions. HHA follows both federal and state toxicology data requirements for new active ingredients and formulated products. The number of annual toxicology data evaluations and completed submissions for formulated products are noted in Table 12 below. In addition to the evaluation of products containing already registered active ingredients shown in Table 12, HHA evaluates an average of 25 new active ingredient products annually based on a 5-year average.

Table 12. Average Days to Complete Human Health Data Evaluations and Total Completed Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	40	59	63	76	106	84 – 133
# Completed Submissions	105	119	94	92	83	-
CA-Only Products (days)	45	60	65	64	119	102 - 158
# Completed Submissions	10	9	5	16	9	-
Sec. 3 Amendment	41	88	67	80	94	71 – 116
# Completed Submissions	15	11	8	12	18	-
CA-Only Amendment (days)	_	53	_	104	144	N/A
# Completed Submissions	0	1	0	1	2	-

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

4.6. ENVIRONMENTAL MONITORING

Environmental Monitoring Branch (EM) includes the Air, Groundwater, and Surface Water Protection Programs. Pesticide product submissions may be routed for evaluation to one or all three EM Programs depending on several criteria including potential environmental concerns, application type, proposed use sites, physicochemical properties, and submitted environmental fate data.

The Surface Water Protection Program (SWPP) is concerned with pesticide impacts to surface water and aquatic organisms. Most of the SWPP evaluations of pesticide products are focused on new active ingredients (AIs). For new AIs, SWPP evaluates risk via the Pesticide Registration Evaluation Model (PREM) using the proposed product label and specific physicochemical, environmental fate, and acute toxicity data extracted from DPR's Chemistry and Ecotoxicology Program reports. In addition to the evaluation of products containing already registered active ingredients shown in Table 13, SWPP evaluates an average of 17 new active ingredient products annually based on a 5-year average.

The Groundwater Protection Program (GWPP) conducts detailed analysis of pesticide and degradate movement in the terrestrial field dissipation studies and utilizes contaminant transport

modeling tools and the product application rate to evaluate the contamination potential of agricultural use pesticides prior to their registration in California. In addition to the evaluation of products containing already registered active ingredients shown in Table 13, GWPP evaluates an average of 2 new active ingredient product annually based on a 5-year average. GWPP relies on the Chemistry program to screen the physicochemical properties of new active ingredients and degradates to determine if they are mobile and persistent in the environment and require additional evaluation.

The Air Program registration evaluations assess potential exposure to humans, adverse effects on non-target plants, and contribution to ground-level ozone through the emission of volatile organic compounds. The Registration and Evaluation Branches initially screen active ingredients and degradates based on their application methods, physicochemical properties, and thermogravimetric properties to determine if further in-depth evaluation is necessary. To evaluate the potential adverse effects of pesticides on human health and the environment, the Air Program uses contaminant transport and dispersion modeling tools, product application rates, and application methods prior to their registration in California. Most of these types of submissions fall under the Additional Data category and are not captured in Table 13.

Table 13. Average Days to Complete Environmental Monitoring Evaluations and Total Completed Submissions by Type and Year

Submission Type	2018	2019	2020	2021	2022	2022 Range* (days)
Sec. 3 Products (days)	113	43	169	208	190	85 - 218
# Completed Submissions	10	16	14	18	8	-
CA-Only Products (days)	-	-	-	-	-	-
# Completed Submissions	0	0	0	0	0	-
Sec. 3 Amendment	369	81	87	273	114	N/A
# Completed Submissions	1	3	10	3	4	-
CA-Only Amendment (days)	-	-	-	-	-	-
# Completed Submissions	0	0	0	0	0	-

^{*}Range represents the number of days to review for middle 50% submissions completed in 2022 N/A - no range shown for scenarios with less than 5 products reviewed in any given year.

5. CONCLUSION

The reported numbers reflect the average completion time for submissions over the past five years. These numbers may be used to estimate the potential timeframes for future submissions. However, the actual completion time for an individual submission could vary depending upon its complexity, review status by U.S. EPA, staff levels at any given evaluation program, and teleworking. Additionally, incomplete or inaccurate submission materials or data may cause significant delays in the review process. This report is also available on DPR's Web site at <cdpr.ca.gov/docs/registration/canot/camenu.htm>.

If you have questions regarding this notice, please contact the Pesticide Registration Branch Ombudsman, Mr. Aron Lindgren at <<u>Registration.Ombudsman@cdpr.ca.gov</u>> or by telephone at 916-324-3563.

Original signed by	June 6, 2023	
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cc: Mr. Aron Lindgren, Senior Environmental Scientist (Specialist), DPR