CEA ACTION PROPOSAL

Per California Code of Regulations, title 2, section 548.5, the following information will be posted to CalHR's Career Executive Assignment Action Proposals website for 30 calendar days when departments propose new CEA concepts or major revisions to existing CEA concepts. Presence of the department-submitted CEA Action Proposal information on CalHR's website does not indicate CalHR support for the proposal.

A. GENERAL INFORMATION

1. Date: 2019-04-12

2. Department: Department of Pesticide Regulation (DPR)

3. Organizational Placement (Division/Branch/Office Name)

Pesticide Programs Division (PPD), Registration and Evaluation

4. CEA Position Title

Assistant Director, Registration and Evaluation

5. Summary of proposed position description and how it relates to the program's mission or purpose. (*2-3 sentences)*

Formulates and implements departmental programs, procedures, and policies related to the Registration and Evaluation Program, including the Human Health Assessment Branch, Registration Evaluation Branch, and Registration Regulatory Branch. Serves as one of the Director's science policy advisors and formulates, implements, and represents the Department on various pesticide regulatory policy issues to protect human health and the environment by regulating pesticide sales and use, and by fostering reduced-risk pest management.

6. Reports to: (*Class Title/Level*)

Chief Deputy Director

7. Relationship with Department Director (*Select one)*

☑ Member of department's Executive Management Team, and has frequent contact with director on a wide range of department-wide issues.

☐ Not a member of department's Executive Management Team but has frequent contact with the Executive Management Team on policy issues.

(*Explain*):

8. Organizational Level *(Select one)*

☐ 1st ☑ 2nd ☐ 3rd ☐ 4th ☐ 5th (mega departments only - 17,001+ allocated positions)

B. SUMMARY OF REQUEST

9. What are the duties and responsibilities of the CEA position? Be specific and provide examples.

Under the administrative direction of the Director and Chief Deputy Director, the C.E.A. B, Assistant Director in the Pesticide Programs Division (PPD) is responsible for all aspects of the Registration and Evaluation Program, including the Human Health Assessment Branch, Registration Evaluation Branch, and Registration Regulatory Branch. The Human Health Assessment Branch has three main functions: Toxicity Data Review, Exposure Assessment and Modeling, and Risk Assessment. The Registration Regulatory Branch processes and evaluates all registration actions after a thorough scientific evaluation has been done by the Registration Evaluation Branch. The incumbent serves as one of the Director's science policy advisors and formulates, implements, and represents the Department on various pesticide regulatory policy issues.

Formulates and implements departmental programs, procedures, and policies relating to the work of PPD. Develops clear and consistent regulatory policy strategies for the Department of Pesticide Regulation. Reviews scientific evaluations that are the basis of proposed regulatory actions for mitigating pesticide risks; manages various advisory committees such as the Pesticide Registration and Evaluation Committee. Interacts and collaborates with US EPA Office of Pesticide Programs on human health and ecological risk assessments, and registration issues including data evaluation regulatory actions. Interacts and collaborates with the Office of Environmental Health Hazard Assessment (OEHHA) regarding risk assessment peer reviews that impacts regulatory decisions. Develops and oversees processes to foster scientific discussions and presentations, public participation, and regulatory transparency. Works in concert with the other Assistant Directors, the Director, and Executive staff to identify the need for new or revised legislation, rules, and regulations. Oversees the execution of critical, high-level initiatives directed by the California Environmental Protection Agency (CalEPA) and/or the Governor's Office.

Manages a budget of $18.3M for the Human Health Assessment Branch, Registration Evaluation Branch, and Registration Regulatory Branch, including the allocation of personnel and fiscal resources within those branches to ensure that departmental policies are implemented efficiently and resources are used to its maximum potential. Manages the Program's budget to ensure personnel and fiscal accountability in accordance with Department of Finance, Office of Administrative Law, Legislative Analyst's Office, and the Legislature. Delegates responsibility for staff functions, provides management direction of these functions, and assists subordinate Branch Chiefs in solving both scientific and administrative problems.

Coordinates interagency actions on pesticide regulatory policy issues related to human health and environmental health risk, including pesticide risks in air, water, and food residues. Provides advice to the Director and Executive staff on major human health and environmental health policy issues, and takes the lead responsibility for managing those major policy issues. Ensures efficient and uniform development and administration of policies relating to human health and environmental protection, including establishing required methods and procedures. In alliance with the other Assistant Directors of PPD, serves as a policy liaison between the Boards and Departments within the CalEPA, the Department of Public Health, and the California Department of Food and Agriculture pursuant to the provisions of the memorandum of understanding between the various Boards and Departments.

Advances departmental strategic initiatives such as performance indicators, quality improvement, and strategic planning. Represents the Department at meetings and conferences on behalf of the Director, including Agency Secretary meetings, and the resolution of sensitive issues with state, local government, private industry, and interest group representatives. As necessary, represents the Director and Executive staff at meetings with external stakeholders. Represents the Department in the resolution of issues with federal and state agencies (i.e., CalEPA's boards, departments, and offices, Department of Food and Agriculture, etc.), other states, and county and local agencies.

B. SUMMARY OF REQUEST (continued)

10. How critical is the program's mission or purpose to the department's mission as a whole? Include a description of the degree to which the program is critical to the department's mission.

- ☑ Program is directly related to department's primary mission and is critical to achieving the department's goals.
- ☐ Program is indirectly related to department's primary mission.
- ☐ Program plays a supporting role in achieving department's mission (i.e., budget, personnel, other admin functions).

Description:

DPR's mission is to protect human health and environment by regulating pesticide sales and use, and by fostering reduced-risk pest management. DPR regulates all aspects of pesticide sales and use, recognizing the need to control pests while protecting human health and the environment, and fostering reduced-risk pest management strategies.

The CEA formulates and implements departmental programs, procedures, and policies related to the Registration and Evaluation Program, including the Human Health Assessment Branch, Registration Evaluation Branch, and Registration Regulatory Branch. The CEA also serves as one of the Director’s science policy advisors and formulates, implements, and represents the Department on various pesticide regulatory policy issues to protect human health and the environment by regulating pesticide sales and use, and by fostering reduced-risk pest management.

The Human Health Assessment Branch is responsible for Toxicity Data Review, Exposure Assessment and Modeling, and Risk Assessment. They use the results of these reviews, along with exposure information from other branches, to assess the adequacy of product labels and conduct health risk evaluations and risk assessments that estimate the potential for adverse health effects in humans.

The Registration Regulatory Branch processes and evaluates all registration actions after a thorough scientific evaluation has been done by the Registration Evaluation Branch.

B. SUMMARY OF REQUEST (continued)

11. Describe what has changed that makes this request necessary. Explain how the change justifies the current request. Be specific and provide examples.

As federal, state, and local pesticide regulations have grown, the complexity of DPR's programs, policies, and procedures have continually increased. DPR is undergoing a reorganization to strengthen the efficacy of the executive management team and realign the department's programs into a more focused and efficient structure. This single CEA manages the Registration Branch, the largest branch in the Department with almost 100 employees under one branch chief. This branch will be reorganized and divided into two branches instead of just one because it has become apparent that the effectiveness and workload in the branch has been compromised, which has led to an informational gap between each section within the branch and the different programs that rely on each other's work products. This type of reporting structure makes it very difficult to communicate with direct reports in a clear and concise fashion that allows for follow-up and a complete understanding of the policy direction from executive management.

The Registration Branch will now be reorganized and divided into Registration-Regulatory and Registration-Evaluation. There will be two branch chiefs as a result of the reorganization, which will both report to the single CEA. The division of the Branch into two branches is necessary because it has become apparent that the branch truly has two distinct programs. One program is the evaluation section, comprised of scientific staff who evaluate data and make decisions regarding if the data supports regulatory registration actions. The other program is the regulatory section, comprised of regulatory scientists who gather all the reports from the evaluation section and then processes the regulatory registration actions for each product or active ingredient. The activities of the two branches will need to be integrated; therefore, the two branches have to regularly communicate to ensure the regulatory policies are consistent. This new structure with two branches will allow the CEA to devote more time and focus to the oversight and improvement of the programs in each branch and ensure consistency in implementation of policies.

One of the critical issues that has impacted the work of the Registration Branch is the increasing concerns on ecotoxicology. More recently, there has been an increased focus on this issue by the public and the scientific community. In 2014, AB1789 was passed which required DPR to develop and finish a risk determination document that evaluates the risk of neonicotinoids to bees. That report required additional scientific expertise and collaboration with USEPA and Canada, especially because the science that determines risks to bees is relatively new. Another critical issue that has recently impacted the work in the regulatory section of the Registration Branch is the need for increased transparency of DPR's decision-making regarding pesticide registrations. DPR was required to implement a more extensive review process due to a lawsuit and must be implemented within a short time frame. Because of the impact of that work on DPR, a budget change proposal for seven permanent positions was granted in 2018 to implement those changes.

The other branch that this CEA will continue to manage is the Human Health Assessment Branch (HHA). There are three programs in HHA: data evaluation, risk assessment, and exposure assessment. There have been various new scientific technologies that will impact the work in this branch, including twenty-first century toxicology and the use of mathematical modeling to evaluate data and use those technologies to evaluate pesticide risks on human health. Staff will need to be trained in these new scientific technologies. The CEA will be required to develop new policies and procedures to make sure the training is consistent and implemented within the branch. Both the current and the new policies and procedures for the branch will need continual revisions over time to ensure HHA staff are proactively incorporating the most recent technologies to accurately evaluate pesticide risks on human health.

C. ROLE IN POLICY INFLUENCE

12. Provide 3-5 specific examples of policy areas over which the CEA position will be the principle policy maker. Each example should cite a policy that would have an identifiable impact. Include a description of the statewide impact of the assigned program.

The CEA exercises independence and authority in developing, implementing, directing, and evaluating DPR's statewide registration and evaluation programs, policies, and procedures. In coordination with the Director and Chief Deputy Director, the position identifies inconsistent policies and/or procedures within the branches and develops and implements strategies to enhance program operations. The CEA will have to develop and maintain new policies in three very critical areas of concern for DPR.

One example of critical changes was brought about by the increasing public demand on transparency when it comes to government decision-making. The Registration Branch has initiated extensive changes in how it communicates the decisions on the registration of pesticides in California. The registration process involves an administrative process and a scientific regulatory process. Both of the processes will now have to be documented, and all the scientific data evaluation in connection with a regulatory decision will have to be transparent and available for any stakeholder to review. That process will now entail an extensive review by several staff members and managers to ensure that the information is accurate and understandable for any stakeholder. To implement these changes, DPR was recently successful in acquiring seven new positions to accomplish the work. The CEA who currently oversees the registration process (both regulatory and evaluation) will have to develop policies and procedures to ensure the process is clearly communicated to all stakeholders.

Another example of continuing challenges that have led to a need for changes in policy is DPR's reviews of ecotoxicological data. In the last two decades, industry has continued to develop new pesticide active ingredients that are less toxic to humans in order to protect public health. However, those pesticides have been identified to be more toxic to the environment which includes bees, birds, small mammals, and aquatic organisms. In 2014, AB1789 was passed and required DPR to develop a risk determination document on neonicotinoids, a group of pesticides that were linked to colony collapse disorder. When DPR identified those ecological risks through it's reevaluation process, it became apparent that the Department needed more expertise in that field. In the last five years, DPR recruited more ecological scientists, after being successful in BCP approvals, to perform an extensive review of those pesticides. The increase in scientists also helped to ensure that the reviews of new ecological studies were accurate and complete. The CEA will need to continually evaluate that process to ensure that ecological risks are mitigated at the same time as protecting public health. The key to that process is developing policies and procedures to streamline the ecotoxicological reviews done by DPR scientists.

Twenty-first century toxicology is a new approach to evaluating toxicological data using a more streamlined and mathematical process. This approach was developed about two decades ago, but is now being used by chemical companies as well as pesticide companies. This approach also uses less live animals and has been successful in predicting toxicological effects of pesticide active ingredients in less time than a conventional animal study. This new approach is being evaluated extensively by the regulatory agencies including USEPA and DPR. With this new approach, new policies will have to be developed to ensure that the integrity of the data is intact, credible, and can be applied to all aspects of human toxicology. This will also impact how the work is done at DPR since the perspective in reviewing those studies has shifted from animal models to mathematical models. Therefore, DPR scientists will have to undergo training to be able to evaluate data submitted by the registrants for their products to be registered in California. The CEA will need to develop new policies and procedures to make sure the training is consistent and that the data is appropriately evaluated based on the new approach.

C. ROLE IN POLICY INFLUENCE (continued)

13. What is the CEA position's scope and nature of decision-making authority?

The Assistant Director will be responsible for ensuring that the activities and functions pertaining to the Registration and Evaluation branches result in thoroughly and efficiently meeting the Department's mission. Decisions and recommendations from the Assistant Director will significantly impact statewide agency operations, DPR management, pesticide programs, and inter-agency operations. The Assistant Director assists the Chief Deputy Director in representing DPR with other State and Federal agencies on unique pesticide programs that require joint interpretation and implementation.

The Assistant Director will serve in a key role in making leadership decisions and providing direction to the branches to timely and effectively deal with changing needs. In addition, the Assistant Director will be responsible for the coordination and implementation of complex pesticide issues which impact all DPR programs. The Assistant Director also works collaboratively with the other Assistant Directors to ensure consistency in the implementation of policy decisions that affect the other branches within the division and the Department.

This CEA will be making regulatory decisions on reevaluation of pesticide active ingredients after reviewing pertinent data. The CEA will then explore options regarding the scientific basis for the recommendation and present them to the Director and Chief Deputy Director for a final decision. In the event that the Director or the Chief Deputy Director is unavailable, the CEA will make the final decision, if necessary. The CEA will also have to make decisions on the extent of the human health risk assessments to ensure that all the pertinent exposure scenarios are evaluated. During the risk assessment process, the CEA will have to ensure collaboration with USEPA and the Office of Environmental Health Hazard Assessment and make decisions on what to include in the final document, based on the comments made by USEPA and OEHHA. In addition, after the risk assessments are done, the CEA will have to make decisions on what recommendations should be made to the Director and Chief Deputy Director if risks were identified in the risk assessment that require mitigation. Once the Director makes a decision to develop mitigation measures, it will be necessary for the CEA to collaborate internally with the other Assistant Directors and other staff at DPR.

14. Will the CEA position be developing and implementing new policy, or interpreting and implementing existing policy? How?

The CEA will be responsible for providing feedback on, interpreting, developing, and implementing policies, as well as consulting with and recommending policy to DPR executive management (Director and Chief Deputy Director). In addition to supporting executive management's overall policy decisions, the CEA will also have significant independent responsibility to create and implement new policies and procedures among the three branches under its responsibility.

In addition to interpreting and implementing existing policies in registration and scientific evaluation, the CEA will also evaluate those policies to see if they are still appropriate or need to be revised and updated. Since the registration issues have evolved due to various changes in the development of new pesticide active ingredients, the existing policies will need to be revised and updated. More importantly, new policies will have to be developed because of new developments in conducting risk assessments in the 21st Century. Data evaluation now involves more objective and mathematical calculations to estimate risk, versus the animal models that have existed for the last 50 years. Improving transparency in making registration decisions will also involve developing new policies and procedures to ensure the process satisfies the public’s needs, especially since transparency may be subject to some legal implications of confidentiality.