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The Special Counsel

March 7, 2018

The President
The White House
Washington, D.C. 20510

VIA ELECTRONIC MAIL

Subject: OSC File No. DI-16-2674

Dear Mr. President:

In accordance with law, the U.S. Office of Special Counsel (OSC) is submitting to you a report of an Environmental Protection Agency (EPA) internal investigation, along with the whistleblower's comments.[1] The whistleblower, who wishes to remain anonymous, disclosed to OSC that the EPA posed a substantial and specific danger to public health by: (1) approving biopesticide products for distribution and sale in the United States without sufficient scientific bases to conclude that they would not cause unreasonable adverse effects on the environment; and (2) failing to consistently and timely enforce registration terms or conditions, thereby allowing noncompliant products to remain on the market without adequate safety assurances.[2] The whistleblower identified the EPA's 2014 registration of Venerate, a biopesticide produced by Marrone Bio Innovations, Inc. (MBI), as a prime example of these problems.

The EPA's report concluded that the agency acted in accordance with its normal and routine registration process in approving Venerate and did not substantiate the whistleblower's allegations. Under federal law, the EPA may not register a pesticide that would result in residues on food or feed items unless it can determine that there is a reasonable certainty of no harm from exposure to the residues in food or other occupational sources. After making the safety determination, the EPA can establish a maximum amount of permissible residue on food, called a tolerance, and may grant exemptions to those limits if federal safety standards are met.

The EPA's report found that, with respect to Venerate, the EPA had an adequate basis to conclude that there would be no unreasonable adverse effects on the environment and a reasonable certainty that no harm would result from aggregate exposure to residue. The EPA noted in its report that, as a primary science reviewer, the whistleblower raised

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[1] *See* 5 U.S.C. § 1213(c) and (e).
[2] This includes two different types of registration: (1) unconditional registration with a term of registration and (2) conditional registration.

several concerns throughout the registration process that the EPA considered and addressed. The EPA explained that while there were issues with MBI providing sufficient data, these issues were not unusual. While the EPA agreed that the whistleblower noted valid concerns about MBI's failure to properly identify metabolites, it found that the information was not necessary to reach the regulatory standard for approval. The EPA also concluded it had sufficient data to evaluate the risk to non-target avian and most aquatic organisms. The EPA unconditionally registered Venerate with a term of registration in order to obtain additional data from MBI. The agency continued to engage with MBI when it did not provide all requested information rather than cancel Venerate's registration. The EPA has expedited its review of Venerate's registration and is requesting additional toxicity data.

In comments, the whistleblower disagreed with the EPA report's conclusion that the agency appropriately followed its normal and routine registration process in approving Venerate and asserted that there was insufficient data to determine that the product was safe for use. The whistleblower asserted, consistent with the objections the whistleblower stated throughout the registration process, that the animal studies MBI provided were of limited value because the manufacturing process was in flux. As a result, according to the whistleblower, the EPA did not receive studies on the same substance that was being manufactured and used in the market. The whistleblower suggested that the EPA should test the substance that is now being used on food to determine whether there are risks to food and worker safety. The whistleblower also raised the following issues with the EPA's report: (1) there were incomplete records of the registration process beginning in 2009; (2) there were incomplete citations to peer-reviewed scientific findings and publicly available information; (3) there was an extraordinary accommodation of MBI by allowing Venerate's registration to proceed with significant changes rather than requiring a new application; (4) there was incomplete adherence to applicable statutes; and (5) there was a lack of an unbiased peer-review process.

The EPA's report also addressed concerns with the conditional registration process. The EPA found that the agency has taken action to implement 2013 Government Accountability Office recommendations regarding the EPA's procedures for conditional registrations. These actions include upgrading its Office of Pesticide Program database, updating guidance, and providing training to management on documenting conditional registration information.

I have determined that the EPA's report contains the information required by statute and that its findings are reasonable. The EPA's investigation found that in approving Venerate, the agency acted in accordance with its normal and routine registration procedures, including the appropriate use of its discretion, and found that the product complies with applicable statutory safety requirements. The EPA is continuing to require MBI to provide updated information necessary for the EPA to review the safety of the continued use of the product. Throughout Venerate's registration process, the EPA

considered and addressed input from staff, including the whistleblower. The EPA also reported that it has implemented improvements to its conditional registration process. I would encourage the EPA to continue carefully considering input and concerns from its scientists whose knowledge and experience are essential for the EPA to properly carry out its regulatory responsibilities.

As required by law, I am submitting the EPA's report and the whistleblower's comments to you, the U.S. House Committee on Science, Space, and Technology, and the U.S. Senate Committee on Environment and Public Works. I am also making these documents available to the public.[3] Our file is now closed.

Respectfully,

Henry J. Kerner
Special Counsel

Enclosures

[3] *See* 5 U.S.C. § 1219(a)(1); *https://osc.gov*.