January 4, 2018

Sheri S. Shilling, Attorney
U.S. Office of Special Counsel
1730 M Street, N.W., Suite 300
Washington, D.C. 20036

Re: OSC File No. DI 16-2674

I was provided the opportunity to comment on the report resulting from my allegations and wish to do so, in the process making the report and allegations public.

Key to understanding the regulatory action in my allegation is, initially this Biopesticide application was made with the intent of conducting a joint review under some sort of NAFTA agreement where the U.S. Environmental Protection Agency and the Pest Management Regulatory Agency of Canada would jointly perform human health and nontarget organism (environmental) risk assessments. These would satisfy requirements under FIFRA in the U.S. and similar statutes in Canada. Not part of a joint review is a separate assessment of food safety under FFDCA that could establish a tolerance or tolerance exemption. This process did not require senior scientists at either agency, relying only on individual scientists for peer-review.

After initial work jointly by the U.S. And Canada, Marrone Bio Innovations, Inc. terminated the action in Canada and chose to proceed with just a U.S. EPA review process. At the same time they chose to change the product to be registered. At that time the U.S. Environmental Protection Agency allowed the application to proceed, despite being an entirely different product.

Also, the second portion of this process, a separate FFDCA tolerance exemption risk assessment, was never conducted. This is not directly addressed anywhere in the EPA response. Fitness for registration under FIFRA does not automatically inform FFDCA and food safety endpoints. It is one matter to allow use of a poison, however specific to the target, and another to uniformly declare that <u>any level of that substance is safe in food and feed</u> - the definition of a <u>food tolerance exemption</u>. Mixed messages in the EPA report indicate that there were safety findings in animal studies, though later in the report there are indications that only later were the extent of metabolites and their activity noted.

Part of the joint review "process" when we started was an agreement which country would perform primary assessments and then the other would peer-review or secondary review these assessments. Canada's PMRA had the lead and identified in 2010 that Marrone Bio Innovations, Inc. applied for a patent that detailed metabolites as a mode of action for the Venerate active ingredient – and that they were different from the current application as an insecticide in that the metabolites killed nematodes and plants ["This application claim priority to U.S. application Ser. No. 61/308,287, filed Feb. 25, 2010 and priority to application Ser. No. 61/406,541, filed Oct. 25, 2010 under 35 U.S.C. 119(e). The contents of U.S. application Ser. No. 61/308,287, filed Feb. 25, 2010 and U.S. application Ser. No. 61/406,541, filed Oct. 25, 2010 are herein incorporated by reference"]. In deficiency letters issued by the PMRA jointly with the EPA in 2011 several concerns were noted including the lack of detail on how the product worked. Anyone with a comprehensive knowledge of the registration process that started in 2010 would have known this – and if adequate records were maintained of the registration process throughout then managers who made decisions later could have been informed by reviewing these records. The allegation that scientists were not part of the decision/registration process and that discrepancies arose later establish that these decisions were not informed by all available information.

Specific to the issue of a food safety risk assessment, there is a review section that specifically states not enough information was provided to make a safety finding for a food tolerance exemption, and there was no specific information on the metabolites to establish a tolerance for them, if found necessary after toxicological review. This is signed by both the primary reviewer and senior scientist - and there is no subsequent peer-review for food safety. What the EPA report alleges is there was further internal deliberation to interpret study results and make a finding for a tolerance exemption while citing the scientific review, as reflected in investigator interviews and correspondence at EPA. Reference to this review is made in the EPA report where "This document concludes that the health effects study is "acceptable – EPA Toxicity Category IV". The fact is that several animal tests were reviewed on a substance but simultaneously there was no accepted manufacturing process approved, as noted in this same review, and so these tests did not support whatever product would eventually be made. To this day the manufacturing process is in flux, and when finalized, testing the resulting product will inform a food safety risk assessment and worker safety labeling.

As for the risk management process, the reliance on individual animal tests of a variable product is not a reliable risk assessment method, and neither is knowing every metabolite produced during production. However, testing the substance that is now applied to a wide variety of food products would inform food and worker safety.

The question of what is produced was always key to registration and safe use of this product. According to readily-available and public information, most of which is not well detailed in official pesticide registration application materials, metabolites produced under differing production methods are alternately lethal to insects, plants, and nematodes. From review of submitted materials and public information there is no information to conclude that when the product is produced to be differentially lethal to insects, plants, and/or nematodes it is also not toxic to mammals or other nontarget organisms.

Also I would like to point out that peer-review is a process whereby equally qualified scientists concur or disagree on hazard and risk endpoints. If the policy mentioned in the EPA report for a disagreement is to defer to the senior scientist – then this is not peer-review, which is key to scientific integrity. Rather, deference denotes hierarchy in science at the U.S. Environmental Protection Agency. This was not part of my initial allegation but is troublesome in that decisions made this way are open to bias and would not reflect rigorous scientific review.

Key points from the EPA report include:

1. Incomplete records of the registration process that started in 2009.
2. Incomplete citation of peer-reviewed scientific findings and of publicly available facts.
3. Extraordinary accommodation allowing a registration action to proceed with significant changes, when typically, a new application is warranted.
4. Incomplete adherence to required statutes, i.e. ignoring FFDCA in favor of FIFRA findings, despite wide uses on foods.
5. Lack of an unbiased peer-review process.

Respectfully,

[redacted]