UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 27, 2017

OFFICE OF
THE ADMINISTRATOR

Mr. Henry Kerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, D.C. 20036-4505

Re: OSC File No. **DI 16-2674**

Dear Mr. Kerner:

Please accept this letter and the enclosed Report of Investigation as the U.S. Environmental Protection Agency's ("EPA" or the "Agency") response to your correspondence of September 23, 2016, in which your office referred a whistleblower's complaint concerning EPA's Office of Pesticide Programs to the agency for investigation. More specifically, the Office of Special Counsel requested that the agency:

1. Determine whether the EPA registered Venerate, a pesticide product by Marrone Bio Innovations, Inc., with sufficient scientific bases to conclude (i) that it would not cause unreasonable adverse effects on the environment and (ii) that there is a reasonable certainty that no harm would result from aggregate exposure to its residue. If the EPA registered Venerate without sufficient scientific bases, identify and describe the material weaknesses in internal controls that enabled this. Describe what actions the agency is taking to resolve these and any other material weaknesses that were discovered during the course of the investigation.

2. Determine whether the EPA published incorrect statements in the Venerate registration action documents about its processes or findings. If the EPA registered Venerate without sufficient scientific bases, identify and describe the material weaknesses in internal controls that enabled this. Describe what actions the agency is taking to resolve these and any other material weaknesses that were discovered during the course of the investigation.

3. Determine whether the EPA should have suspended or cancelled Venerate's registration because (i) MBI failed to satisfy Venerate's registration terms; (ii) it had reason to believe that MBI improperly changed Venerate's manufacturing process or chemical composition; or (iii) it had reason to believe that Venerate's formulation is not "identical or substantially similar" to the formulation approved and registered by the agency. If

suspension or cancellation was appropriate, determine whether the EPA timely suspended or cancelled Venerate's registration.

4. Identify and describe the EPA's actions to resolve the problems identified in the 2013 GAO report about conditional registrations. Identify any outstanding systemic problems with the agency's consistent or timely enforcement of (i) registration conditions and (ii) registration terms.

5. Provide any information that may be relevant but was not responsive to the prior questions.

Pursuant to your letter, the EPA conducted an investigation into the aforementioned issues and the findings of that investigation are set forth in the enclosed Report of Investigation.

I am enclosing two versions of the Report of Investigation. The first contains the names of EPA employees interviewed as part of the investigation into this matter. In the second version, the names of EPA employees have been redacted. I am requesting that your office utilize the redacted version for public release.

If you have any further questions, please do not hesitate to contact my office at [redacted].

Respectfully yours,

Michael P. Flynn
Acting Deputy Administrator

On September 23, 2016 the U.S. Office of Special Counsel transmitted to the Administrator of the United State Environmental Protection Agency (EPA) a request for investigation and report regarding registration of the biopesticide Venerate which is manufactured by Marrone Bio Innovations. In addition, the OSC requested an update on the Agency's status in responding to a 2013 General Accounting Office report on conditional registrations of pesticides. This request was made in response to whistleblower allegations.

This matter was assigned to name redacted, Director of the Science and Ecosystem Support Division in Region 4 for investigation with the assistance of name redacted, Acting Deputy Director, Field and External Affairs Division, Office of Pesticide Programs.

The OSC directed the investigation to address the following:

1. Determine whether the EPA registered Venerate, a pesticide product by MBI, with sufficient scientific bases to conclude (i) that it would not cause unreasonable adverse effects on the environment and (ii) that there is a reasonable certainty that no harm would result from aggregate exposure to its residue. If the EPA registered Venerate without sufficient scientific bases, identify and describe the material weaknesses in internal controls that enabled this. Describe what actions the agency is taking to resolve these and any other material weaknesses that were discovered during the course of the investigation.
2. Determine whether the EPA published incorrect statements in the Venerate registration action documents about its processes or findings. If the EPA registered Venerate without sufficient scientific bases, identify and describe the material weaknesses in internal controls that enabled this. Describe what actions the agency is taking to resolve these and any other material weaknesses that were discovered during the course of the investigation.
3. Determine whether the EPA should have suspended or cancelled Venerate's registration because (i) MBI failed to satisfy Venerate's registration terms; (ii) it had reason to believe that MBI improperly changed Venerate's manufacturing process or chemical composition; or (iii) it had reason to believe that Venerate's formulation is not "identical or substantially similar" to the formulation approved and registered by the agency. If suspension or cancellation was appropriate, determine whether the EPA timely suspended or cancelled Venerate's registration.
4. Identify and describe the EPA's actions to resolve the problems identified in the 2013 GAO report about conditional registrations. Identify any outstanding systemic problems with the agency's consistent or timely enforcement of (i) registration conditions and (ii) registration terms.
5. Provide any information that may be relevant but was not responsive to the prior questions.

Statutory and Regulatory Background:

The EPA has responsibility for regulating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. §136 et seq.). FIFRA has been amended a number of

times most notably by the Food Quality Protection Act and the Pesticide Registration Improvement Extension Act. FIFRA (Section 2(u)) defines a pesticide as:

1. any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest;
2. any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and
3. any nitrogen stabilizer

In addition, EPA has authority under the Federal Food, Drug, and Cosmetic Act to regulate pesticide residues found on food products. Pursuant to FIFRA and FFDCA, EPA must evaluate pesticides intended for use on food or animal feed crops before making registration decisions. If EPA determines that use of the product would result in residues of the chemical(s) in or on food/feed items, the Agency may not register the product under FIFRA unless EPA can determine that the residues are "safe" under the FFDCA. The FFDCA defines "safe" to mean that there is "a reasonable certainty of no harm" from the exposure to the residue in food and from other non-occupational sources. After making a determination as to safety, the Agency may establish a maximum permissible pesticide residue on a particular food or feed commodity or establish an exemption from the maximum residue if granting an exemption meets the FFDCA safety standard. The maximum residue is generally referred to as a “tolerance.”

To address the requirements of FIFRA and FFDCA, EPA has established a registration process with scientific, legal and administrative requirements. This process is set forth in Title 40 of the Code of Federal Regulations (40 CFR) Parts 150-189. In addition to the regulatory requirements, EPA has a number of guidance documents that inform the Agency, the states, potential registrants and the public on the registration process. This includes the Registration Manual, which is maintained online.

For registration purposes, EPA has identified three categories of pesticides:

- Conventional pesticides are generally synthetic chemicals used predominantly to kill insects, weeds, and fungi.
- Biopesticides include naturally occurring substances that control pests (biochemical pesticides), microorganisms that control pests (microbial pesticides), and pesticide substances produced by plants containing added genetic material (plant-incorporated protectants or PIPs).
- Antimicrobial pesticides are substances or mixtures of substances intended to destroy or suppress the growth of harmful microbiological organisms, and pesticides that protect inanimate objects and surfaces from organisms such as bacteria, viruses, or fungi. See FIFRA section 2(mm).

In general, EPA uses the same registration process for the three categories of pesticides, but does have additional and different data requirements for biopesticides and antimicrobials. EPA may

also require additional information for new pesticides as new chemicals or new active ingredients.[1]

Applicants for pesticide registration must provide administrative information and data supporting the registration. Administrative information includes payment of any required fees, appropriate identification of the registrant and its representatives and submission of draft pesticide label language. Applicants are responsible for citing or generating all data to meet data requirements. The purpose of these data requirements is to demonstrate that the product will not cause unreasonable adverse effects and for pesticides that will need a tolerance or tolerance exemption to demonstrate a reasonable certainty of no harm. Data requirements are specified in 40 CFR Part 158. Among other things, these regulations allow EPA to require additional data, accept alternative approaches and/or waive studies. In addition to the data requirements the applicant must submit a Confidential Statement of Formula. (See FIFRA section 3(c)(1)(D), 40 CFR 152.50(f) and 40 CFR 158.320).

If a product is not substantially similar to another registered product, the applicant is required to submit, at a minimum, product chemistry and acute toxicity data for the product. (See Registration Manual and 40 CFR Part 158, Subparts D, U, V & W). Microbial pesticides are subject to a different set of data requirements for registration than conventional chemicals, and are listed in Data Requirements for Registration 40 CFR Part 158, Subpart V. Note, if the microbe is subsequently killed, then the product is neither a microbial pesticide nor a conventional pesticide. For heat-killed pesticides, EPA has historically required pesticide registrants to meet modified Subpart V requirements.

In addition, if the pesticide is for use on food or feed crops, the applicant must submit information indicating if a tolerance or exemption from tolerance exits and if one does not exist submit a petition for establishment of a tolerance or an exemption from the requirement for a tolerance (See 40 CFR Part 180).

Upon receipt of an application, EPA conducts an initial content screen to determine whether the appropriate fee has been paid and that the application contains the necessary forms, draft labeling, and data formatted in accordance with guidance. After Content Screen, a Preliminary Technical Screen is conducted to determine if the pesticide registration application and accompanying information and data are accurate and complete, consistent with proposed labeling and tolerance information such that a full review could result in granting of the application. (See Registration Manual).

Once the application is placed into the EPA's review process, it is reviewed in depth. If during this in-depth review, the EPA determines that there are data deficiencies or that further information is needed in order to complete the review, EPA will notify the applicant of the deficiencies and allow the applicant to make corrections or additions to complete the application.

[1] "New Chemical" or "New Active Ingredient" is an Agency term that refers to a pesticide registration application for a product that contains a pesticide active ingredient that is not contained in any other pesticide product currently registered with the Agency. (See Registration Manual)

EPA assigns application review to the Division responsible for the specific category of pesticide (e.g., conventional, biopesticides or antimicrobials). Once the application is deemed acceptable, EPA provides public notice of the registration decision and for tolerances, provides notice to the public that they may petition for a hearing. If comments are received, EPA responds to comments before finalizing the action. If no comments are received, the action is considered final at the close of the comment period.

In addition to the federal requirements, states also regulate pesticides and as part of the regulatory process, many states also register pesticides for use in that particular state. State regulation of pesticides must be as stringent as the federal requirements.

The Investigation:

In the course of investigating this matter, the following individuals were interviewed:

1. name redacted, Whistleblower and science reviewer
2. name redacted, Director, Office of Pesticide Programs
3. name redacted, former Director, Office of Pesticide Programs
4. name redacted, Senior Policy Advisor, Office of Pesticide Programs
5. name redacted, Director, Biopesticides and Pollution Prevention Division
6. name redacted, Deputy Director, Biopesticides and Pollution Prevention Division
7. name redacted, Regulatory Action Leader, Biopesticides and Pollution Prevention Division
8. name redacted, Acting Chief of the Microbial Pesticides Branch
9. name redacted, former Chief of the Microbial Pesticides Branch
10. name redacted, Team Leader, Microbial Pesticides Branch
11. name redacted, Biopesticides and Pollution Prevention Division
12. name redacted, Senior Scientist, Microbial Pesticides Branch
13. name redacted, Lead Biologist, Microbial Pesticides Branch
14. name redacted, Office of General Council
15. name redacted, Office of General Council

In addition to interviews, the file for the registration decision was reviewed as well as information related to the registration process, EPA's Pesticide Label Review Manual and the federal register notices and docket related to heat-killed *Burkholderia spp.* strain A396 cells and spent fermentation media.

Venerate Registration:

In August 2010, Marrone submitted applications to EPA seeking to register a new end-use pesticide product, Venerate. This product contained a new technical grade active ingredient, *Burkholderia spp.* strain A396 and a new manufacturing product. The applications were submitted pursuant to Section 3 of FIFRA. Concurrently, Marrone also filed a petition for an exemption from the requirement of a tolerance for residues of *Burkholderia spp.* strain A396 in or on all agricultural commodities (food crops). At the time of the original submission, the

material was a live microbe and therefore considered a microbial pesticide by EPA. EPA assigned the review of this application to the Office of Pesticide Program's Biopesticides and Pollution Prevention Division (BPPD), Microbial Pesticides Branch.

Upon submission of the original application, EPA conducted a Content Screen, a Preliminary Screen and then placed the application into EPA's review process. At that time, a team of individuals was assembled to conduct the in depth review of the registration application. This team consisted of a Regulatory Action Leader, who coordinates the regulatory review, scientists to provide primary review of human health and ecological impacts, as well as, senior scientists to provide a secondary review. The initial Regulatory Action Leader was name redacted but the matter was subsequently transferred to name redacted. Name redacted, the Whistleblower in this matter, was assigned as the primary reviewer for human health effects and name redacted was the secondary reviewer. Name redacted was the primary reviewer for ecological issues and name redacted was the secondary reviewer.

After the initial submission, but before the in-depth review was complete, concerns were identified with the live microbe and its potential toxicity. EPA raised these concerns to the registrant and they (Marrone) decided to deactivate (kill) the microbe, changing the formulation to one that was subsequently referred to as heat-killed cells and spent fermentation media with an end-use biological pesticide primarily applied as a foliar spray (Venerate). Subsequent to that decision, EPA considered only the modified formulation in the registration process.[2] Specifically EPA applied the microbial pesticide data requirements except for the requirement the pathogenicity studies.

Interview statements and a review of registration documents indicate that, consistent with regulation and guidance, EPA engaged with Marrone throughout the registration process. This included meeting with Marrone and their representatives in person as well as reviewing the application and subsequent submissions. EPA sent Marrone deficiency letters which prompted Marrone to provide additional information. By all accounts this was an iterative process that involved multiple submissions by the applicant. In the end, EPA considered a variety of scientific and legal issues and concluded that unconditional registration under Section 3(c)(5) of FIFRA should be granted for the new active ingredient heat-killed *Burkholderia spp*. strain A396.

On February 28, 2014, name redacted, Director of the Office of Pesticide Programs at that time, concurred with the recommendation of name redacted, Director BPPD, to unconditionally register the heat-killed *Burkholderia spp.* strain A396 cells and spent fermentation media as a new pesticide active ingredient. The memorandum conveying this recommendation states that adequate data was submitted by the applicant Marrone to satisfy data requirements for an unconditional registration. It further indicates that acute toxicity data supports the registrant's claim that heat-killed *Burkholderia spp.* strain A 396 and spent fermentation media act

[2] It should be noted that name redacted, the Whistleblower, was instrumental in identifying the initial concerns related to the toxicity of the live microbe.

specifically on insects not mammals. The memorandum includes the Biopesticides Registration Action Document (BRAD)[3] signed by name redacted on February 27, 2014 which further indicates that science reviews were provided by name redacted, name redacted, name redacted and name redacted. The BRAD states that EPA scientists reviewed product analysis, toxicology and non-target organism data and information. It states that overall the EPA found such data was adequate for assessing risk, fulfilled data requirements[4] and supported registration of the product under FIFRA section 3(c)(5). Specifically, EPA found that no additional toxicity data were needed nor a qualitative risk assessment because the acute toxicity studies indicate no toxicity to mammals up to the limit doses. The science reviews signed by the named scientists were listed and fully referenced in the BRAD.

Public participation was provided for this registration process. On February 2, 2011, EPA provided notice that it had received an application for registration from Marrone. From February 7 – 21, 2014, EPA made available for public inspection the BRAD and draft labels for Venerate and the technical product. On March 21, 2014, EPA published the Exemption from Tolerance for Venerate in the Federal Register (FR Vol 79, No 59, 15702-15704). The regulation was effective March 21, 2014 and notice was provided that objections and requests for hearings must be received on or before May 20, 2014. No objections or requests for hearing were received.

Finally, it should be noted that in addition to action by EPA at least two states have independently registered Venerate (Florida and New York).

Questions and Findings:

Determine whether the EPA registered Venerate, a pesticide product by MBI, with sufficient scientific bases to conclude (i) that it would not cause unreasonable adverse effects on the environment and (ii) that there is a reasonable certainty that no harm would result from aggregate exposure to its residue. If the EPA registered Venerate without sufficient scientific bases, identify and describe the material weaknesses in internal controls that enabled this. Describe what actions the agency is taking to resolve these and any other material weaknesses that were discovered during the course of the investigation.

Based on the information reviewed and information provided through interviews (name redacted, name redacted, name redacted, name redacted, name redacted, name redacted, name redacted) EPA utilized its normal and routine registration process for the registration of Venerate and its technical grade pesticide. A key component of any pesticide registration is the submission of supporting data from the registrant. Data requirements are set out in the 40 CFR Part 158; however, EPA may at its discretion modify these requirements. In this instance, EPA required the registrant to meet microbial pesticide data requirements but modified those requirements to

[3] The Biopesticides Registration Action Document (BRAD) sets forth the risk management decision and the basis for that decision. The science reviewers are listed in this document and it includes as part of the bibliography a listing of EPA Risk Assessment Memoranda written by the science reviewers to the regulatory action leader.
[4] The memorandum recommending unconditional registration of Venerate indicates that sufficient data was submitted to satisfy the data requirements. The attached BRAD uses more specific language in that it references the microbial data requirements.

exclude information on pathogenicity. For the most part, the registrant met the data requirements by study information to the Agency which was reviewed by the science reviewers. Everyone interviewed indicated the process involved much back and forth with the company. As a primary science reviewer, name redacted was an integral part of this iterative process with Marrone and raised numerous science concerns that were considered and addressed.

In registering the product, EPA states that it found acceptable the scientific studies provided by the registrant. Name redacted disputes this finding and relies on indications in the science reviews that not all aspects of the studies were acceptable. While name redacted is correct in his assertion that not all aspects were found acceptable, during the interview process, other scientists and staff who worked on the registration and reviewed the registration material all stated unequivocally that the Agency had an adequate basis to conclude there would be no unreasonable adverse effects on the environment and a reasonable certainty that no harm would result from aggregate exposure to residue (name redacted, name redacted, name redacted and name redacted). It was acknowledged (name redacted, name redacted, name redacted, name redacted, name redacted, name redacted) that there were a number of instances where EPA determined that data provided by Marrone was insufficient. However, all interviewees indicated that this is not an unusual occurrence in the registration process. In fact, the Registration Manual contemplates that data requirements may not be initially met and provides guidance for commenting and receiving additional information. In addition, all interviewees indicated that a heat-killed microbial pesticide was unusual and required additional communication and evaluation throughout the entire process. Further, name redacted clarified in an email to the investigator that "even without knowing every metabolite, if the safety data shows no effects for the product itself, we can conclude there is a reasonable certainty of no harm.[5]" This approach appears to be consistent across the registration process and so overall, there appears to be no inconsistency in this approach with regard to the Venerate registration.

Risk was evaluated using the data requirements published in the Federal Register on October 26, 2007 and finalized on December 26, 2007. Data required for registration is classified as either acceptable, supplemental, supplemental upgradeable or unacceptable. Acceptable and supplemental data may be used in evaluating risk. EPA uses data provided by the applicant to determine the toxicity category for any given pesticide. The data is provided by the applicant and must include acute oral, acute dermal and acute inhalation studies to evaluate systemic toxicity via the designated routes of exposure. The primary eye irritation and primary skin irritation studies measure irritation or corrosion, while the dermal sensitization study evaluates the potential for allergic contact dermatitis. With the exception of dermal sensitization, each acute study is assigned to a toxicity category based on the study results. (See Label Review Manual, Chapter 7)

In this instance, on September 5, 2013 name redacted and name redacted signed a document discussing the review of submitted studies for FIFRA Section 3 registration of MUP and EP,

[5] Email from name redacted to name redacted on November 3, 2017.

with a food tolerance exemption petition, specifically *Burkholderia spp.* strain A396.[6] This document concludes that the health effects study is "acceptable – EPA Toxicity Category IV". The memorandum states that the product identity and characterization and the AMES assay data were supplemental but upgradeable and supplemental, respectively and that the Exemption from Tolerance was not acted upon. The toxicity category IV is the lowest toxicity category that EPA uses and requires no or minimal risk statements.

These findings are set out in the BRAD and the final action regarding the registration. With respect to the aggregate exposure, EPA concluded there would not be significant exposure to the product through food or drinking water and that even if there was exposure based on the acute oral toxicity, no unreasonable adverse effects would occur. The use of data determined to be acceptable or supplemental in making the risk evaluation for Venerate is consistent with EPA practice and the data requirements set forth in regulation. The Senior Scientist, name redacted, and others interviewed stated that when the microbe was killed, they felt the toxicity concern associated with the live microbe no longer was an issue. This perspective is consistent with the low toxicity finding documented in the BRAD. Name redacted, name redacted and name redacted indicated that in the event there is a difference of opinion among the scientists, the issue is elevated. They further indicated that there were numerous instances of elevation with regard to the Venerate registration and that many of issues were resolved during the registration process. In the event of a difference of opinion among scientists which could not be resolved, name redacted and name redacted indicated it was the practice within the Biopesticide and Pollution Prevention Division to defer to the Senior Scientist. When interviewed, name redacted, the Senior Scientist, indicated there was adequate basis to conclude no unreasonable adverse effects would result from the registration of this product.

Another area of concern raised by name redacted centered around adequately identifying the Venerate metabolites and the metabolite level prior to registration as well as adequate demonstration that the material was substantially the same when it was produced in different batches. As indicated above, EPA found at the time of registration that the data provided by Marrone met the statutory and regulatory standard for registration, and although name redacted raised valid concerns about the identification of metabolites, EPA believed the information was not necessary to find no unreasonable adverse effects.

The pesticide activity in a killed microbe comes from the metabolites for the microbes and in most instances pesticide registrants can determine if different lots of killed microbial pesticides are produced in a consistent manner, but it is generally more difficult for them to identify all the

[6] The BRAD lists additional Risk Assessment Memoranda including a Memorandum from name redacted, Ph.D. and name redacted, Ph.D. to name redacted, dated July 18, 2012; a Memorandum from name redacted, Ph.D. and name redacted, Ph.D. to name redacted, dated July 26, 2012; a Memorandum from name redacted, Ph.D. and name redacted, Ph.D. to name redacted, dated March 14, 2013; a Memorandum from , name redacted, Ph.D. and name redacted, Ph.D. to name redacted, dated September 5, 2013 and the U.S. EPA, 2013c, Environmental Risk Assessment for a FIFRA Section 3 Registration of Heat-killed *Burkholderia spp.* strain A396 cells and spent fermentation media. Memorandum from name redacted, Ph.D. and name redacted to name redacted, dated December 13, 2013.

metabolites present and which ones contribute to the efficacy of the product as a pesticide. Given the documented low toxicity, it was EPA's general practice (as per name redacted) to register the product even without knowing each metabolite. Other scientists interviewed agreed with this approach, indicating if there is adequate information to make the endangerment finding the product should be registered. EPA wanted additional information on the metabolites and thought the company would be able to produce that data, so they required as a term of registration, that the company provide additional information on storage stability, corrosion characteristics and the metabolites integral to Venerate's mode of action as an insecticide. EPA required submission of this information within one year of registration as a term of registration. [7] A term of registration can be used when EPA is seeking confirmatory data regarding information previously submitted.

The term of registration is consistent with the findings of the September 5, 2013 review of studies signed by name redacted and name redacted wherein they indicated that the product identity and characterization was supplemental but upgradeable. Interviewees indicated that it was typical when reviewing microbial pesticides to not know all of the means of action for the active ingredient. In his interview name redacted indicated that even without knowing all of the active metabolites it was his opinion that the Agency was correct in making its finding of no unreasonable adverse effect. In an email from name redacted to the investigator (November 3, 2017), name redacted indicates that since the available data showed no areas of concern, it was EPA's approach when dealing with a killed microbe to proceed with registration. This is consistent with information provided during interviews with name redacted, name redacted and name redacted.

EPA also evaluated the ecological risk associated with the registration, completing an ecological risk assessment dated December 13, 2013. The risk assessment found that there was sufficient data to characterize the risk to non-target avian and most aquatic organisms and noted that data for evaluating the heat-killed *Burkholderia spp*. A396 was incomplete with respect to non-target insects and plants. To address the non-target-exposure the Agency imposed restrictions in the labeling, which is consistent with normal procedures.

EPA utilized acceptable methods to evaluate risk associated with this registration and made reasonable conclusions about unreasonable adverse effects. This is supported by the documents included in the registration decision, the staff interviewed and the fact that where EPA could not address an identified risk concern, it took steps to limit the risk using label restrictions. Where additional information would be useful to further understand the mode of action for the pesticide, EPA made this a term of registration.

Determine whether the EPA published incorrect statements in the Venerate registration action documents about its processes or findings. If the EPA registered Venerate without sufficient scientific bases, identify and describe the material weaknesses in internal controls

[7] If EPA determines the pesticide meets the standard for registration in FIFRA section 3(c)(7), the Agency may grant the application for registration with conditions that require the registrant to provide additional information within a specified time. If the registrant does not comply with the conditions, EPA may cancel the registration pursuant to FIFRA section 6(e).

that enabled this. Describe what actions the agency is taking to resolve these and any other material weaknesses that were discovered during the course of the investigation.

The Office of Special Counsel listed several instances where name redacted asserted that EPA made incorrect statements in the registration including that name redacted is listed as a science reviewer but did not review or sign off on the document prior to its release (in reference to the registration approval and BRAD). During his interview, name redacted asserted that he had not reviewed the final registration documents. The investigator did not find any instance where the documents (Federal Register, Docket or BRAD) indicate that name redacted reviewed or signed off on the final registration documents. EPA acknowledges the importance of accurately reflecting the contributions of scientists in regulatory actions and uses its internal review process to ensure that all contributors are given appropriate recognition.[8] Overall, name redacted was an author of certain documents used in the registration decision and his authorship was correctly noted in the BRAD.

With regard to the Agency's assessment of the food tolerance exemption, this again appears to be a difference of opinion regarding the scientific sufficiency of the information provided by the registrant during the registration decision making process. As stated above, other scientists and managers within the Biopesticide and Pollution Prevention Division reached different conclusions. When interviewed, the senior scientist and management representatives indicated no knowledge of incorrect statements in the Venerate registration documents and upon review of the documents, no discrepancies were identified.

Determine whether the EPA should have suspended or cancelled Venerate's registration because (i) MBI failed to satisfy Venerate's registration terms; (ii) it had reason to believe that MBI improperly changed Venerate's manufacturing process or chemical composition; or (iii) it had reason to believe that Venerate's formulation is not "identical or substantially similar" to the formulation approved and registered by the agency. If suspension or cancellation was appropriate, determine whether the EPA timely suspended or cancelled Venerate's registration.

Subsequent to the registration, EPA continued to address the registration terms with Marrone, specifically the term which required "Within one year of registration, submit studies on the identity (e.g., IUPAC and CAS numbers) and the amounts of bioactive metabolites produced during the manufacture of heat-killed *Burkholderia spp.* strain A396 cells and spent fermentation media. Please provide this information for each batch of material produced during the next 12 months."

Initially Marrone did not submit the data within the requested timeframe. Name redacted indicated in his interview that the Agency did not suspend or cancel the registration regarding the missed deadline because Marrone was manufacturing in batches and therefore tested in batches. EPA anticipated receiving responsive information as batches were created. The investigator

[8] See the U.S. Environmental Protection Agency, Scientific Integrity Policy.

noted that there is not a consistent method of tracking terms of registration in BPPD and that there was uncertainty among the interviewees about whether and how the terms are tracked.

Subsequently EPA and Marrone did engage in discussions regarding the terms of registration. Specifically, on July 7, 2015, EPA sent a 75-day deficiency letter to Marrone regarding their pending manufacturing process amendments and required Marrone to clarify whether the submitted data were developed using batches of the active ingredient produced according to the manufacturing process reviewed at registration or the pending manufacturing process. On March 31, 2016, EPA completed its review of data sent in response to the bioactive metabolite term in the February 28, 2014 notices of registration.

On April 29, 2016, EPA sent Marrone another 75-day deficiency letter which indicated that additional data was needed related to the bioactive metabolite term. On February 10, 2017, Marrone provided a draft response regarding the submission of this data. On August 31, 2017, EPA issued a letter to Marrone indicating that it would not grant amendment to its manufacturing process because the amendments were not supported by existing toxicity and non-target data. The letter also stated:

> Finally, in light of the lack of consistency batch-to-batch of the current manufacturing process that has been confirmed by data submitted since your original registration was granted on February 14, 2014, we also now have concerns that the current human health and non-target organism databases for *Burkholderia spp.* strain A396 may not support your current manufacturing process. As a result, EPA will be requiring product characterization, toxicology, including a 90-day oral toxicity study, and non-target organism data via the registration review process, which we intend to initiate shortly, to support the currently approved formulations.

At the time of registration, EPA felt that the company would be able to identify all of the metabolites in the heat-killed *Burkholderia spp.* strain A396 cells and spent fermentation media and required this as a term of registration. EPA engaged extensively with Marrone regarding the term of registration. Throughout this process, EPA made decisions to continue to engage with Marrone rather than change course and pursue cancellation of the pesticide registration. Section 6 of FIFRA provides for pesticide cancellation only after notice and a hearing. It was through this iterative process with the company that EPA was able to fully understand the wide range of metabolites that the manufacturing process creates and that according to the company have a wide range of pesticidal activity (See name redacted email to name redacted, Friday November 3, 2017). As a result, EPA has expedited the registration review of Venerate and will modify the procedural requirements for initial data on the heat-killed microbe, specifically asking for a 90-day oral toxicity study.

The additional information described above was critical to EPA formulating next steps with regard to the registration and would not have been available if action had been taken to suspend or cancel the registration. In addition, it is not certain what the outcome of the administrative action to suspend or cancel the registration would have been or the time it would have taken;

therefore, EPA's decision to continue to work with the company to obtain more information on the pesticide was not unreasonable.

Identify and describe the EPA's actions to resolve the problems identified in the 2013 GAO report about conditional registrations. Identify any outstanding systemic problems with the agency's consistent or timely enforcement of (i) registration conditions and (ii) registration terms.

On September 9, 2013 the U.S. General Accounting Office (GAO) released a report following an examination of EPA's procedures for granting conditional registrations. In examining this issue, GAO explored the number of conditional registrations granted by EPA and the basis for granting those registrations, the extent to which EPA assured that registrants submitted addition data required by the conditional registration and the views of relevant stakeholders on the conditional registration process.

GAO found that EPA could not accurately provide a total number of conditional registrations for a number of reasons including weakness in guidance, training, management oversight and data management. GAO further found that EPA did not know the extent to which it ensured that companies met the conditional requirements of registration because EPA did not have a reliable system for managing the conditional registrations and that overall constituents of EPA wanted improvement in the conditional registration system.

As a result of this examination, GAO made three recommendations for Executive Action:

1. EPA should complete plans to automate data related to conditional registrations to better track the status of these registrations and related registrant and agency actions and identify potential problems requiring management attention.
2. Pending automation of the data, OPP should develop guidance and take action to ensure that product managers use a uniform methodology to track and document this information, including when data are submitted by registrants and reviewed by EPA.
3. OPP should review and correct, as appropriate, its website on conditional registrations to ensure that the information is clear, concise and accurate.

Following the report, EPA undertook the following corrective actions:

1. Automating the conditional registration tracking: To fully address this issue, EPA must complete upgrades to OPP's database architecture. EPA anticipates completing these upgrades in 2018 and is in the process of collecting information necessary for the update. The finding remains open with the GAO until the upgrades are complete.
2. Develop guidance: In December 2013, OPP updated its guidance and provided training to product managers. This finding is closed.
3. Correct the website: EPA updated its conditional registration webpage in 2014, 2016 and 2017 and is committed to continuing these updates. This finding is closed.

Once the conditional registration tracking system is completed, EPA believes the systemic concerns with conditional registrations will have been addressed. With regard to the terms of registration addressed earlier in this document, EPA will be developing a tracking system.

Provide any information that may be relevant but was not responsive to the prior questions.

No other information is deemed relevant.