



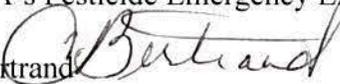
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 13 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Report entitled "Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process."

FROM: Charlotte Bertrand 
Deputy Assistant Administrator

TO: Charles J. Sheehan
Acting Inspector General

This memorandum is in response to the Office of Inspector General's (OIG's) September 25, 2018 Final Report entitled "Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process," Report No. 18-P-0281, Project No. OPE-FY17-0024.

OCSPP's Responses to OIG's Recommendations:

The OIG's June 5, 2018 Draft Report contained eight recommendations, and the Office of Chemical Safety and Pollution Prevention (OCSPP) provided responses with corrective actions and milestone dates in a July 3, 2018 memorandum. OIG's September 25, 2018 Final Report contains the same eight recommendations for the OCSPP's Office of Pesticide Programs' (OPP's) consideration. The Final Report notes that recommendations 2, 3, and 4 are resolved and recommendations 1, 5, 6, 7, and 8 are noted as unresolved.

In accordance with EPA Manual 2750, the resolution process began with the issuance of the Final Report, and a meeting within 30 days was requested between the Acting Principal Deputy Assistant Administrator for Chemical Safety and Pollution Prevention and the OIG's Assistant Inspector General for Audit and Evaluation. **OCSPP hereby provides responses to the unresolved recommendations 1, 5, 6, 7, and 8 for discussion:**

Recommendation 1. Develop and implement applicable outcome-based performance measures to demonstrate the human health and environmental impacts of the EPA's emergency exemption decisions.

OCSPP Response: Requests for emergency exemptions under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are reviewed in accordance with the specific statutory criteria of the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA, to determine whether the use will maintain human health and environmental safeguards consistent with these statutory requirements. The human health and

environmental risk assessments that are conducted for Section 18 emergency exemptions are based on the best available data and assessment procedures and must ensure the same safety findings are made as for uses covered by Section 3 registrations. If OCSPP determines that these public safety requirements are met, and an emergency pest situation has been confirmed, the use may be approved under an emergency exemption. Therefore, OSCPP's position is that the program is currently operating on the basis of this fundamental human health and environmental outcome-based standard.

As discussed during the July 19, 2018 exit conference with the OIG, OCSPP believes that we can explore the feasibility of developing a complementary measure that evaluates other facets of the emergency exemption program in the context of an outcome-based metric.

Proposed Corrective Action and Timeframe for Completion: By June 30, 2020, OCSPP will develop a relevant outcome measure or measures that better demonstrates the way the emergency exemption process, supported by scientific risk assessment, maintains environmental and human health safeguards. Possible indicators include the number of Section 18s that transition to full Section 3 approval (with exceptions) over time.

Recommendation 5. Develop concise emergency exemption application guidance that specifies the minimum requirements of an application submission and is available on the Office of Pesticide Programs Section 18 website.

OCSPP Response: Section 18 application and training materials are currently available through several sources, including the EPA Section 18 website, periodic and regular group training sessions with State Lead Agency personnel, and one-on-one sessions between EPA staff and the State Lead Agencies. OCSPP revised the EPA Section 18 website on March 22, 2018, to be more user-friendly. The updated site provides links to Section 18 training materials, and links to the regulatory language in 40 CFR 166.20, which provide a precise description of the requirements for a specific, quarantine, crisis, or public health exemption. The website also provides an EPA program contact to assist the State Lead Agencies with the application process.

Although OCSPP believes that emergency exemption applicants currently have reliable and useful resources for this information, OPP staff will evaluate how its web resources can be enhanced to respond to this recommendation.

Proposed Corrective Action and Timeframe for Completion: By September 30, 2020, OCSPP will identify and add additional information to its website that assists applicants in accurately and consistently completing applications for Section 18 emergency exemptions on their first submission.

Recommendation 6. Provide clear guidance to State Lead Agencies on how and when they can use efficacy data from other State Lead Agencies to satisfy the emergency exemption application criteria.

OCSPP Response: The example cited by the OIG to support this recommendation does not represent a typical situation. In this particular case, the California Department of Pesticide Regulation (CDPR) requested use of the same antibiotic materials as authorized under exemptions to manage citrus greening disease in Florida citrus (where widespread establishment of the disease has devastated commercial citrus). However, citrus greening had not (at the time) been detected in California's commercial citrus; rather there was only very limited occurrence in residential trees in several areas of the state. To support their request, CDPR cited data from Florida researchers that examined antibiotic use to improve health and production of already-diseased trees. In contrast to the Florida research and uses, California intended to make "prophylactic" treatments to healthy trees to protect them from infection. However, the Florida data did not, in fact, analyze or demonstrate the prophylactic effect on healthy trees that CDPR was seeking. In other words, the data submitted to support the emergency exemption in Florida represented very different conditions from those being experienced in California.

Notwithstanding the challenges in trying to apply the Florida data to the circumstances in California, OCSPP worked collaboratively with California DPR to find a path forward for California growers to be able to use the requested antibiotics to meet their pest control needs. Ultimately, EPA authorized quarantine exemptions to CDPR for the requested antibiotics. The uses allowed in California are for treatment of healthy trees in specified perimeters around positive detects of citrus greening, with the goal of preventing the spread, particularly into commercial citrus.

OCSPP does not believe this is a common misunderstanding since state applicants routinely support efficacy claims for a proposed use with data that are not state-specific. Also, the regulations and guidance on emergency exemptions do not indicate state-specific data is required. However, clarification may be useful to avoid future misunderstandings of this nature.

Proposed Corrective Action and Timeframe for Completion: By September 30, 2020, OCSPP will use the appropriate venue or information process to inform the applicants and other stakeholders that data submitted in the emergency exemption application to address the expected efficacy of a proposed use do not need to be state-specific. If suitable, this may be incorporated into the additional information added to the website under Recommendation 5.

Recommendation 7: Expand the data presented in the Office of Pesticide Programs Section 18 database by considering additional data points, such as application acreage requested, actual acreage applied and registration status of each exempted pesticide.

OCSPP Response: OCSPP agrees with OIG's recommendation and will consider additional data fields or other possible enhancements, such as application acreage requested, decision documents, and registration status of each exempted pesticide, as OCSPP explores ways to improve the website database and expand its overall content.

Proposed Corrective Action and Timeframe for Completion: By June 30, 2020, OCSPP will expand the Emergency Exemption Public Database by including, for

example, requested application acreage, actual application acreage, and current registration status of each approved emergency exemption use.

Recommendation 8. Provide an annual update and information summary to State Lead Agencies to better inform them about any changes to the emergency exemption application and review process.

OCSPP Response: OCSPP will explore how to provide routine and useful program updates to applicants. To accomplish this, OCSPP will work with State Lead Agencies to identify the types of information they may find helpful.

Proposed Corrective Action and Timeframe for Completion: By June 30, 2019, OCSPP will begin contacting applicants at least annually to provide information and technical assistance about the emergency exemption application and review process, programmatic changes, and other information as necessary.