U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals

Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process

Report No. 18-P-0281 **September 25, 2018**

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Abbreviations

CFR	Code of Federal Regulations
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
SLA	State Lead Agency
SOP	Standard Operating Procedure
U.S.C.	United States Code

Cover Photo: Citrus greening (a bacterial disease) occurring on a Florida citrus tree. (U.S. Department of Agriculture)

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U.S. Environmental Protection Agency
Office of Inspector General

18-P-0281
September 25, 2018

At a Glance

Why We Did This Project

We conducted this audit to determine whether the U.S. Environmental Protection Agency (EPA) has a comprehensive pesticide emergency exemption approval process that maintains environmental and human health safeguards.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), all pesticides distributed and sold in the United States must be registered by the EPA for each specific use. Per Section 18 of FIFRA, the EPA can grant federal and state lead agencies the authority to approve—in certain emergency situations—the limited application of a pesticide not registered for that particular use. These short-term pesticide use approvals are called *emergency exemptions*.

This report addresses the following:

- *Ensuring the safety of chemicals.*

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Measures and Management Controls Needed to Improve EPA's Pesticide Emergency Exemption Process

What We Found

The EPA needs outcome measures to demonstrate the benefits or risks of pesticide emergency exemptions on human health and the environment.

The EPA's Office of Pesticide Programs (OPP) does not have outcome measures in place to determine how well the emergency exemption process maintains human health and environmental safeguards. The program office also does not have comprehensive internal controls to manage the emergency exemption data it collects. Finally, the OPP does not consistently communicate emergency exemption information with its stakeholders.

Specifically, we found that the OPP collects human health and environmental data through its emergency exemption application process, including the total acres affected, the proposed and actual quantities of the exempted pesticide applied, and the estimated economic losses. Yet, we found that the OPP does not use these data to support outcome-based performance measures that capture the scope of each exemption or to measure the potential benefits or risks of each exemption.

We also found significant deficiencies in the OPP's online database management, in its draft Section 18 emergency exemption standard operating procedure and application checklist, and in its reports to Congress and the Office of Management and Budget. Some state lead agencies and extension agents that we interviewed also reported that additional guidance is needed to support the preparation of emergency exemption applications, including whether data can be used from applications submitted by other state lead agencies.

Furthermore, we found that the OPP previously sent a "year in review" letter to states that summarized the emergency exemption activity for that year and provided additional information regarding the emergency exemption process. However, the OPP has not sent this letter since 2015.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention develop outcome-based performance measures; develop or update procedures on data collection, database management and the re-use of data submitted by state lead agencies; and communicate changes to the emergency exemption processes in a timely manner. Of our eight recommendations, the EPA agreed with four, neither agreed nor disagreed with two, and disagreed with two. For three recommendations, the agency proposed corrective actions that meet the intent of the recommendations. The remaining five recommendations are unresolved.

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

THE INSPECTOR GENERAL

September 25, 2018

MEMORANDUM

SUBJECT: Measures and Management Controls Needed to Improve EPA's Emergency Pesticide Exemption Process
Report No. 18-P-0281

FROM: Arthur A. Elkins Jr.

TO: Charlotte Bertrand, Acting Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject audit conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this evaluation was OPE-FY17-0024. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The office responsible for issues evaluated in this report is the EPA's Office of Pesticide Programs within the Office of Chemical Safety and Pollution Prevention.

In accordance with EPA Manual 2750, your office provided acceptable corrective actions and milestone dates in response to Recommendations 2, 3 and 4. These recommendations are resolved and no final response is required.

Action Required

Recommendations 1, 5, 6, 7 and 8 are unresolved. In accordance with EPA Manual 2750, the resolution process begins immediately with the issuance of this report. We are requesting a meeting within 30 days between the acting Principal Deputy Assistant Administrator for Chemical Safety and Pollution Prevention and the OIG's Assistant Inspector General for Audit and Evaluation. If resolution is still not reached, the EPA is required to complete and submit a dispute resolution request to the Chief Financial Officer to continue resolution.

We will post this report to our website at www.epa.gov/oig.

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Purpose

The U.S. Environmental Protection Agency's (EPA's) Office of Inspector General (OIG) conducted this audit to determine whether the EPA has a comprehensive emergency exemption process that maintains environmental and human health safeguards.

Background

Pesticides are chemicals used to curb unwanted vegetation, insects, animals or bacteria. Pesticide use has contributed to increased agricultural production and improved public health through control of disease-ridden pests. However, pesticides are poisons. Acute and chronic issues affecting human health and causing environmental harm can be associated with exposure to many pesticides.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was enacted in part to reduce the negative impacts of pesticides on human health and the environment. All pesticides distributed or sold in the United States must be registered (licensed) by the EPA. Before the EPA may register a pesticide under FIFRA, the manufacturer or formulator (also known as the *registrant*) must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment."[1] Under the normal, nonemergency registration requirements of FIFRA, a registrant of a pesticide must register that product for each specific use. Registrants must submit a new application each time they register a new pesticide active ingredient, register a new product for an existing pesticide active ingredient, or add a new use to an existing product registration.

Emergency Exemptions

Unexpected pests, invasive species or resistant strains of insect, weed, microbe or other type of pests that cannot be eliminated or controlled with registered pesticide products are periodically identified. Section 18 of FIFRA allows the EPA to grant federal and state agencies the authority to approve the limited application of a pesticide not currently registered for that use. These short-term pesticide use approvals are called *emergency exemptions*.

Regulations that govern the implementation of Section 18 of FIFRA are found at 40 CFR Part 166. These regulations identify four types of emergency exemptions: specific, quarantine, public health and crisis. As shown in Table 1, each type addresses a different emergency situation, and each has a corresponding allowable time frame for the emergency exemption.

[1] EPA, "Summary of the Federal Insecticide, Fungicide, and Rodenticide Act" webpage, and 7 U.S.C. § 136a(c)(5)(D).

Table 1: Types of emergency exemptions

Type	Maximum duration	Description of emergency exemption
Specific	1 year	The most common emergency exemption. May be authorized in an emergency condition to avert a significant economic loss or a significant risk to endangered species, threatened species, beneficial organisms or the environment.
Quarantine	3 years	May be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species or not known to be widely prevalent or distributed within the United States and its territories.
Public health	1 year	May be authorized in an emergency condition to control a pest that will cause a significant risk to human health.
Crisis	15 days	May be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine or public health exemption.

Source: 40 CFR § 166.2(a–d).

The purpose of an emergency exemption is to allow the application of a pesticide not currently registered for the requested use. Most emergency exemption applications are *specific* types, and nearly all of those applications address impacts to agricultural crops.

Emergency Exemption Process

State and federal agencies can apply for emergency exemptions when a serious pest problem jeopardizes public health or the production of agricultural goods. If the emergency exemption is based on current crop loss, applicants must demonstrate that a significant economic loss will or has occurred and that the pest cannot be countered by a pesticide currently approved for that use. In conjunction with growers and extension agents, a state lead agency (SLA) submits an emergency exemption application to the EPA.[2] The application specifies the estimated significant economic loss without the expanded use, the total requested application acreage, the requested application rate and other parameters of use, and numerous other information points.

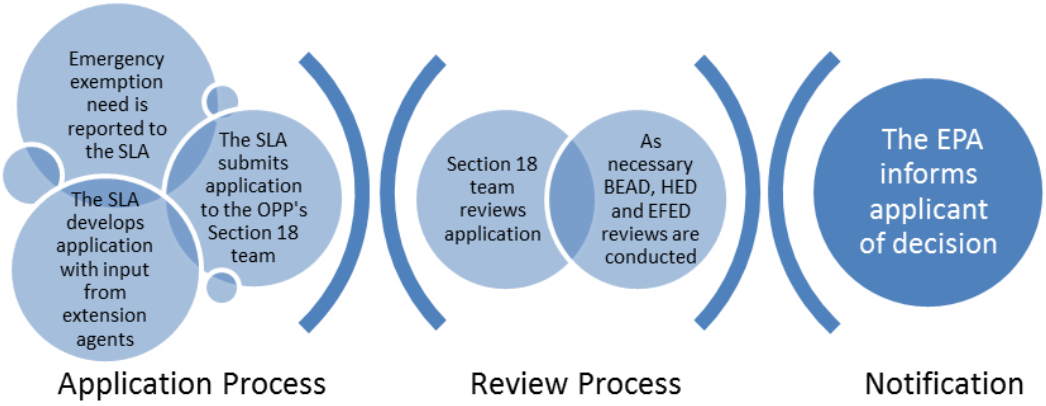
In most instances, an emergency exemption applicant requests approval for the expanded use of a pesticide that has already been registered by the EPA for other uses. Because of the existing registration, the review time for the short-term emergency use is significantly reduced compared to the full registration process under Section 3 of FIFRA. In addition, as shown in Table 1, crisis exemptions can only be approved for 15 days, requiring the EPA's Office of Pesticide Programs

[2] *Extension agents* are employed by land-grant universities and serve the citizens of that state as experts or teachers on topics related to economics, community development, agriculture, family, animal production, diet or nutrition. An example of an *SLA* that would apply for an emergency pesticide exemption is a state department of agriculture.

(OPP) to review those applications as quickly as possible. The other types of emergency exemptions have different review time frames. OPP staff informed us that their goal is to review and approve most emergency exemption applications (other than *crisis* types) within 50 calendar days of receipt. Reviews can take longer if the OPP needs to request more information from the SLA.

Once the OPP receives an emergency exemption application, the office's Section 18 team starts the review process (Figure 1). As a part of the review, the Section 18 team determines whether the emergency exemption request requires public notice in the Federal Register.[3] Then the Section 18 team forwards the applicant's request to the OPP's Biological and Economic Analysis Division, Health Effects Division, and Environmental Fate and Effects Division for economic, health effect and/or ecological risk assessments.[4] The OPP uses these assessments to determine whether the situation is a valid emergency and the efficacy of the requested use. At the end of the review process, the Section 18 team recommends to OPP management whether an emergency exemption should be approved or denied, and the applicant is informed of the final decision. According to the OPP, the agency processes an average of 140 emergency exemption applications annually. The OPP publishes information regarding approved emergency exemptions in a database publicly available on its Section 18 website.

Figure 1: Section 18 emergency exemption process



Acronyms: *BEAD*—Biological and Economic Analysis Division; *EFED*—Environmental Fate and Effects Division; *HED*—Health Effects Division; *SLA*—State Lead Agency

Source: OIG-generated image.

When an emergency exemption is granted, the OPP issues an approval to the SLA that contains general use instructions, use limitations and the emergency

[3] When an exemption request meets the following criteria outlined in 40 CFR § 166.24(1–8), the EPA is required to publish a notice of that request in the Federal Register: the proposed use of a new (unregistered) chemical, the first food use of a chemical, if the chemical's use is currently suspended or cancelled, and other instances where the public can provide comments on the requested exemption.

[4] When an exemption request is for an antimicrobial or biological pesticide, after the Biological and Economic Analysis Division completes its initial evaluation of the emergency economic-loss claim, the request will then be forwarded to the Antimicrobial Division and/or the Biopesticides Pollution Prevention Division.

exemption expiration date. Because FIFRA provides states with primary enforcement authority for pesticide violations, the EPA does not usually conduct oversight of approved emergency exemptions. Instead, approved exemptions require the SLA to conduct implementation and oversight and to submit an end-of-use report to the OPP 6 months after the exemption expires. This end-of-use report details the amount of pesticide used, the total acres treated, any adverse effects reported and other information required by the EPA.

As long as the situation continues to meet the emergency exemption criteria, SLAs have the option of reapplying for a repeat emergency exemption. Based on the regulations governing emergency exemptions, to repeatedly gain approval for a specific or public health emergency exemption use, the registrant must demonstrate progress toward permanent registration of that pesticide use under Section 3 of FIFRA. If after 3 years (or 5 years for some small volume uses) the manufacturer has not made an effort to register the exempted use, the OPP may deny a repeat specific or public health emergency exemption.

Potential Human Health and Environmental Risks

Emergency exemptions to address urgent and nonroutine pest situations can create human health and environmental risks. Issues such as herbicide resistance, the Zika virus and citrus greening (Figure 2) have required emergency exemptions to protect public health and help prevent significant economic loss. However, environmental groups have argued that emergency exemptions have become a mechanism for protecting growers' profit margins while placing human health and the environment at risk.

Figure 2: Examples of emergency exemption situations

Herbicide resistance, Zika virus concerns and citrus greening have required emergency exemptions. Sources *(from left to right)*: the OIG, Centers for Disease Control and Prevention, and U.S. Department of Agriculture.

For example, citrus greening is a bacterial disease spread by the Asian Citrus Psyllid, for which there is no known cure. A 2012 study by the University of Florida estimated that approximately 80 percent of Florida citrus trees are currently infected, and some affected groves no longer produce any fruit. The study further estimated the direct revenue loss to citrus growers to be $1.66 billion over 5 years, or $331 million annually, representing 19 percent of the average grower revenues. Emergency exemption applications related to citrus greening have requested approval to treat the problem by applying antibiotics. However,

misuse and overuse of antibiotics can result in the spread of bacteria that are resistant to them, triggering concern about the continuing long-term ability of these drugs to tackle disease. The Centers for Disease Control and Prevention estimates that more than 2 million people in the United States are infected with antibiotic-resistant organisms each year, leading to 23,000 deaths. Some environmental groups have also expressed concern that exposure to antibiotics can have serious unintended side effects for wildlife, including adverse drug reactions. They further claim that antibiotics used in the environment can cause changes in the chemical composition and pH of waters and soils, with potentially serious consequences.

Responsible Office

The OPP, within the Office of Chemical Safety and Pollution Prevention (OCSPP), is responsible for administering FIFRA and for all regulatory activities associated with the emergency exemption issues evaluated in this report. The OPP's Section 18 team manages the emergency exemption process.

Scope and Methodology

We conducted our work from September 2017 through July 2018. We conducted this audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

The scope of this audit focused on the emergency exemption management process and the internal controls necessary to consistently implement and administer it. We did not evaluate the science used to review emergency exemptions or the subsequent emergency exemption application decisions.

During our interviews, we obtained information about the EPA's emergency exemption process, including the application, review, approval, implementation and oversight of emergency exemptions. We reviewed the universe of emergency exemption applications[5] that were received by the EPA between January 1, 2010, and September 5, 2017. We also determined the five states with the highest percentage of emergency exemption applications between those dates and interviewed SLA representatives regarding their emergency exemption experiences. In addition, we performed the following steps:

[5] According to the Section 18 database, there were 1,033 applications from SLAs during this period. Federal agencies requested 71 emergency exemptions during this period, bringing the total application number to 1,104.

- Reviewed and analyzed relevant EPA regulations, as well as statutory and policy requirements governing the agency's measurement and internal management controls environment.

- Conducted a review of emergency exemption-related reports and articles.

- Interviewed extension agents from three states to discuss their roles, responsibilities and experiences regarding emergency exemptions.

- Interviewed nongovernmental organization stakeholders with interests in pesticides (e.g., Pesticide Action Network, Center for Biological Diversity, Beyond Pesticides and Crop Life America).

Results

The OPP's emergency exemption process provides flexibility to growers and other pesticide applicators during emergency situations. However, the OPP does not have outcome measures in place to determine how well the emergency exemption process maintains human health and environmental safeguards. The program office also does not have comprehensive internal controls to manage the emergency exemptions data it collects. Finally, the OPP does not consistently communicate emergency exemption information to its stakeholders. Without outcome measures, better data management and consistent communication, the EPA cannot demonstrate the benefits or risks of emergency pesticide exemptions on human health and the environment.

Poor Data Use Prevents OPP from Developing Meaningful Performance Measures

The OPP currently has no measures in place to demonstrate how human health or environmental safeguards for the emergency exemption process are being maintained. The OPP informed us that the annual number of emergency exemption applications has fallen over the years. OPP staff said that they believe this reduction shows improved outcomes.

The GPRA Modernization Act of 2010 requires federal programs and activities to develop measures to attain outcome-oriented goals and collect data that support outcome measures.[6] However, as of March 2018, the only official measure for the emergency exemption process was the average number of days to review applications. Information on progress toward the full registration of the pesticide's expanded use is not required to be collected, and the OPP does not

[6] GPRA stands for *Government Performance and Results Act*. The GPRA Modernization Act of 2010 requires every federal agency to have performance measures that "reflect the highest priorities of the agency." Outcome-oriented goals are identified as more impactful than output goals, and output goals are identified as more impactful than customer service goals.

currently report on whether the exempted uses approved under the emergency exemption process later obtain full approval for use under FIFRA.
We found that the OPP collects outcome data through its emergency exemption application process that are not used to describe the human health and environmental impacts of the process, nor are these data reported in the Section 18 public database. Only the following application data are available on the EPA Section 18 database public website:

- Chemical
- Site
- Pest
- Applicant
- Status
- Received Date
- Response Date
- Expiration Date

However, none of these reported data allow the OPP or the public to track any potential risks or benefits to human health or the environment, or even to track and understand the scope of any individual exempted use.

The OPP collects outcome data through its emergency exemption process, but it is not using these data or making these data publicly available on its website. For example, emergency exemption applicants are required to calculate the potential significant economic loss that the exemption will prevent or reduce. The OPP also requires applicants to submit the number of affected acres that the pest is impacting, as well as the number of acres that the exempted pesticide could potentially be applied to. In addition, at the end of the exemption period, applicants must report the number of acres that the exempted pesticide was applied to during the exemption period.

Yet the OPP does not use these data to measure the impacts or potential risks of the pesticides it exempts, nor does it report the total application acres of those pesticides in its emergency exemption database to inform the public of the scope of their risks. As a result, the public is currently unable to determine whether an exempted pesticide was applied to 1,000 acres or 1,000,000 acres because the Section 18 database does not report or measure outputs or outcomes.

Case Study

- In 2014, the EPA denied a pesticide emergency exemption request for the use of a potential endocrine disruptor on a major field crop.
- This decision prevented the environmental and human health exposure to a higher-risk pesticide across as many as 3 million acres of cropland.
- This benefit could be more transparent to the public in the Section 18 database if potential application acreage data were available.

The OPP should use its data to measure outputs and outcomes to determine whether its decisions are protective of human health and the environment. In discussing program outcomes, OPP staff indicated that one factor that suggests that the emergency exemption program has been successful is a decrease in the number of emergency exemption applications over the years. However, the decline in the number of applications does not measure whether there were reductions in risks or increases in benefits to human health or the environment. Without meaningful outcome-based measures in place, the OPP does not know whether a decline in applications also resulted in changes to human health and environmental impacts.

OPP Lacks Internal Controls to Manage Emergency Exemption Data

The OPP does not have comprehensive internal controls to manage the emergency exemption data it collects. We found deficiencies within its online public database, internal guidance documents, and annual progress reports to the Office of Management and Budget (OMB) and Congress.

During our review, we found that the OPP's Section 18 database webpage stated, *"*Our Emergency Exemption Database provides information about actions received since October 1997. This database is updated approximately every two weeks." We found that neither of these statements was accurate. During interviews, OPP staff confirmed that data collected before 2010 were not included in the version of the Section 18 database that we reviewed and that the database was only updated quarterly.[7] During our interviews with the OPP and SLAs, we were also told that there can be significant lags in data entry. Several SLAs said they did not use the database at all or did not find it useful.

Internal guidance documents that address the emergency exemption process lack controls to require accurate and consistent data collection. We found numerous steps in the OPP's internal guidance documents that mention data collection, but these steps lack sufficient specificity to demonstrate consistent control of either data entry or data management. We also found that the OPP does not have a formal method of ensuring consistency in the review process, such as a process flowchart or application checklist. When asked, the OPP did provide an informal Section 18 Application Checklist that was developed by a member of the Section 18 team, but that document is incomplete and not consistently used. For example, there are nine specific line items in the Section 18 Application Checklist that identify data management actions. However, each of those steps has a note stating "TBA, directions," "TBA specific directions" or "TBA Process." Based on our review of the document, we determined that "TBA" indicates a process that is "To Be Announced" and has not yet been developed. These gaps leave staff with incomplete direction and guidance regarding data collection and database management.

We found that these gaps are mirrored in the draft Section 18 standard operating procedure (SOP) document, with numerous steps that expect data to be collected but that do not provide any procedures or specific descriptions regarding what, how and when data points are to be recorded. Based on our discussions with the OPP, we determined that these deficiencies have existed for nearly a decade. Specifically, we identified these gaps in a still-draft SOP document first developed 10 years ago, which was written to update procedures based on regulatory changes made in January 2006, over 12 years ago. Without a finalized

[7] In response to our concerns, the OPP changed the language on its website in March 2018 to reflect that the database only contains information starting from 2010 and that updates are made quarterly rather than biweekly.

SOP document or specific data points defined, the OPP is at risk of not collecting or reporting consistent and accurate data.

Lastly, we found inconsistencies in the way the OPP's emergency exemption implementation is reported to the OMB and Congress. The OPP's 2017 Annual Performance Goal, which was submitted to OMB and Congress as part of the EPA's annual performance plan, states that the OPP's goal is to process emergency exemption applications in an average of 45 days. During our interviews, OPP staff indicated that they strive to achieve a 50-day maximum application processing time frame. This 50-day approval time frame is further reinforced by the EPA's Pesticide Emergency Exemption website. However, this performance target is not mentioned in the emergency exemption draft SOP or Section 18 Application Checklist documents.

In fiscal year 2016, the OPP reported an average application review time of 48 days to the OMB and Congress. This level of performance meets the OPP's internal goal of 50 days but fails to meet the Annual Performance Goal commitment of 45 days. Since emergency exemption requests are based on the urgent need for a solution, this discrepancy could result in SLAs and growers waiting longer to obtain solutions to emergencies than if the OPP worked to meet the Annual Performance Goal reported to the OMB and Congress. It also means that OPP staff are working to meet an internal goal (50 days) that is not consistent with the performance target (45 days) that the OMB and Congress are expecting them to achieve.

EPA Needs to Improve Communication Regarding Its Emergency Exemption Process

The OIG has previously reported on the value of increased communication to stakeholders and the public regarding the EPA's management of chemicals and pesticides.[8] OPP staff stated that the Section 18 team communicates often with emergency exemption applicants. However, SLAs and extension agents with whom we spoke stated that communication could be further improved with better guidance and timely emergency exemption updates.

Pesticide efficacy data and potential economic loss calculations are a required part of emergency exemption applications. Invasive species and diseases can migrate from state to state, and SLAs may try to proactively address an emergency that they expect to impact their state. For example, once trees contract citrus greening,

[8] The OIG previously issued three reports related to this topic:

- EPA OIG, *EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities*, Report No. 10-P-0066, February 17, 2010.
- EPA OIG, *Changes Needed to Improve Public Confidence in EPA's Implementation of the Food Quality Protection Act*, Report No. 2006-P-00003, October 19, 2005.
- EPA OIG, *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner*, Report No. 16-P-0019, October 27, 2015.

there is no cure, so SLAs may look to prevent the disease from even reaching their state. However, because the "emergency" does not yet exist in their state, these SLAs do not have access to state-specific pesticide efficacy data. One stakeholder was concerned that the lack of state-specific data would prevent an SLA from proactively requesting an emergency exemption. In addition, one extension agent we interviewed said that it is unclear whether the OPP allows applicants to use data for the same pest and same pesticide use from another SLA's application. The OPP needs to clarify the guidance regarding whether states must use efficacy data only from their state to justify an emergency exemption request.

Staff within the OPP stated that the office's online training module is its main tool for communicating with applicants about the emergency exemption process. Yet, some of the various stakeholders with whom we spoke were unfamiliar with the training module. One SLA that was aware of the module stated that it would prefer shorter guidance. However, the OPP does not provide concise emergency exemption guidance for applicants. Applicants are directed to either use the online training module, which contains 174 slides, or contact the Section 18 team with any questions. We also found that the emergency exemption training module provides general information about the entire emergency exemption process but does not provide specific data requirements or answers to frequently asked questions. Conversely, on another OPP-managed pesticide website focused on FIFRA Section 24(c) registrations, there are quick links to relevant information and specific examples of how to submit applications. In addition, this OPP website has links to general policies and a question-and-answer webpage.

Lastly, the SLAs we spoke with indicated that communication from the Section 18 team regarding the status of the emergency exemption applications could be improved. The OPP previously sent an annual "year in review" letter that summarized the emergency exemption activity for that year. The letter also provided additional information from the Section 18 team regarding the emergency exemption process. According to the OPP, the most recent letter was sent in 2015. Some SLAs with whom we spoke requested that the OPP reinstate this end-of-the-year letter.

Conclusion

Emergency exemptions represent a necessary element in a grower's toolbox to handle nonroutine and urgent situations caused by unexpected pests, invasive species or pesticide resistance. However, we found that the OPP does not have outcome measures in place to determine whether the emergency exemption process protects human health and the environment. The OPP is missing key data management controls that would support its ability to manage its emergency exemption process. The OPP's emergency exemption process also faces challenges regarding the collection and dissemination of reliable emergency exemption information. To mitigate these challenges, the OPP needs meaningful

measures, better data management and consistent communication to increase the agency's ability to manage its emergency exemption process.

Recommendations

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

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

2. Determine which application review performance target for emergency exemption applications the Office of Pesticide Programs plans to meet, and make that target consistent between its Annual Performance Goal and its internal controls governing the emergency exemption process.

3. Update and finalize the draft standard operating procedure that the Office of Pesticide Programs uses to guide the emergency exemption process.

4. Develop formal emergency exemption application review procedures that detail specific data collection, management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the Office of Pesticide Programs Section 18 database.

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.

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.

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.

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.

Agency Response and OIG Evaluation

In the EPA's official comments regarding the draft report, the agency agreed with Recommendations 3, 4, 7 and 8; neither agreed nor disagreed with Recommendations 2 and 5; and disagreed with Recommendations 1 and 6. The OIG accepts the proposed corrective actions and scheduled completion dates for Recommendations 2, 3 and 4. During our exit conference and other discussions with OCSPP staff, the OIG tried to reach resolution on sufficient corrective actions for Recommendations 1, 5, 6, 7 and 8; however, no resolution was reached, and these recommendations remain unresolved. The following list summarizes the status of our recommendations:

- The OCSPP concurred with Recommendations 3 and 4, and it provided acceptable planned corrective actions and completion dates. Although the agency did not agree or disagree with Recommendation 2, it provided an acceptable corrective action "to avoid future confusion." This corrective action meets the intent of the recommendation. These three recommendations are therefore resolved with corrective actions pending.

- The EPA disagreed with Recommendations 1 and 6. Regarding Recommendation 1, the OCSPP stated that the development of an outcome-based performance measure for the Section 18 emergency exemption process was neither appropriate nor feasible. Although we attempted to reach resolution on Recommendations 1 and 6, the EPA did not formally propose corrective actions. Recommendations 1 and 6 remain unresolved.

- The OCSPP neither agreed nor disagreed with Recommendation 5. Based on our analysis of the emergency exemption application guidance, as well as stakeholder comments regarding that guidance, we believe that a corrective action is warranted. The agency did propose corrective action for this recommendation, but it was insufficient to meet the intent of the recommendation. This recommendation remains unresolved.

- Although the EPA agreed with Recommendations 7 and 8, the proposed corrective actions were insufficient to meet the intent of the recommendations. For Recommendation 7, the OCSPP proposed only that it "will consider additional data points" and did not commit to expanding the data presented in the Section 18 database. For Recommendation 8, the EPA proposed to "develop a strategy which details the activities that might be conducted to provide periodic and useful program updates to applicants." However, the agency needs to clarify the term "periodic" before we can determine whether the proposed corrective action is acceptable. Therefore, both recommendations remain unresolved.

The agency provided technical comments on the draft report, which we incorporated into our final report as appropriate. Appendix A includes the agency's official response to the draft report.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	11	Develop and implement applicable outcome-based performance measures to demonstrate the human health and environmental effects of the EPA's emergency exemption decisions.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
2	11	Determine which application review performance target for emergency exemption applications the Office of Pesticide Programs plans to meet, and make that target consistent between its Annual Performance Goal and its internal controls governing the emergency exemption process.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/19	
3	11	Update and finalize the draft standard operating procedure that the Office of Pesticide Programs uses to guide the emergency exemption process.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/19	
4	11	Develop formal emergency exemption application review procedures that detail specific data collection, management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the Office of Pesticide Programs Section 18 database.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	7/31/19	
5	11	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.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
6	11	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.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
7	11	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.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		
8	11	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.	U	Assistant Administrator for Chemical Safety and Pollution Prevention		

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Agency Response to Draft Report

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL -3 2018

MEMORANDUM

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

FROM: Charlotte Bertrand
Acting Principal Deputy Assistant Administrator

TO: Arthur A. Elkins
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG's) June 5, 2018 Draft Report entitled "Measures and Management Controls Needed to Improve EPA's Emergency Pesticide Exemption Process," Project No. OPE-FY17-0024.

OCSPP's Responses to OIG's Recommendations:

The Draft Report contains eight recommendations for the Office of Chemical Safety and Pollution Prevention's (OCSPP's) Office of Pesticide Programs (OPP):

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

> **OCSPP Response:** OCSPP does not agree that outcome-based performance measures to demonstrate the human health and environmental impacts of EPA's emergency exemption decisions are appropriate or feasible. Requests for FIFRA Section 18 emergency exemptions are reviewed in accordance with the specific statutory criteria of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). OPP assesses all emergency exemptions for human and environmental safeguards consistent with these statutory requirements. In addition, each emergency exemption decision details the conclusions of OPP's

assessment and the public safety requirements necessary to support the approved use. As a result, the decision to authorize an emergency exemption under FIFRA Section 18 ensures that the pesticide can be used safely, in accordance with Federal law. The human health and environmental risk assessments that are done for all Section 18 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. As such, OPP believes that emergency exemption decisions, which are scientifically supported by risk assessments, show that EPA has adequately met its obligations under our regulatory statutes.

Proposed Corrective Action and Timeframe for Completion: OCSPP disagrees with this recommendation and is not providing a timeframe for completion.

Recommendation 2. Determine which application review performance target for emergency exemption applications the Office of Pesticide Programs plans to meet, and make that target consistent between its Annual Performance Goal and its internal controls governing the emergency exemption process.

OCSPP Response: EPA's Annual Performance Plan has a performance metric of 45 days for completing emergency exemption applications. OCSPP has historically advised applicants to allow 50 days for EPA to render a decision on an emergency exemption request, but to avoid future confusion, OCSPP will state 45 days as the timeframe for completion whether referring to estimated processing time, target completion, or performance goals.

Proposed Corrective Action and Timeframe for Completion: By July 2019, OCSPP will consistently reference the 45-day decision period, as is reflected in EPA's Annual Performance Assessment (https://www.epa.gov.sites.production/files/2018-03/documents/fy19-cj-14-program-performance.pdf). In particular, internal control documents and public-facing discussion of the processing timelines will cite 45 days.

Recommendation 3. Update and finalize the draft standard operating procedure that the Office of Pesticide Programs uses to guide the emergency exemption process.

OCSPP Response: OCSPP agrees with OIG's recommendation that the standard operating procedure (SOP) guidance for emergency exemptions needs to be updated and finalized.

Proposed Corrective Action and Timeframe for Completion: OCSPP will update and finalize the standard operating procedures and/or guidance for emergency exemptions by July 2019.

Recommendation 4. Develop formal emergency exemption application review procedures that detail specific data collection, management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the Office of Pesticide Programs Section 18 database.

OCSPP Response: OCSPP agrees with OIG's recommendation to develop formal emergency exemption application review procedures that detail specific data collection,

management and reporting control steps, as well as procedures that require specific management controls for accurately and consistently updating the OPP Section 18 database. As part of the updates to the standard operating procedures guidance cited in recommendation 3, OCSPP will also incorporate recommendation 4.

Proposed Corrective Action and Timeframe for Completion: OCSPP will update and finalize the standard operating procedures and/or guidance for emergency exemptions by July 2019.

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. The most recent update to the EPA Section 18 website was on March 22, 2018. 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 OPP believes that emergency exemption applicants currently have reliable and useful resources for this information, EPA staff will evaluate how its web resources can be enhanced to respond to this recommendation.

Proposed Corrective Action and Timeframe for Completion: If, after evaluating our current web resources, OCSPP determines that enhancements to the Section 18 website are necessary, OCSPP will implement any needed web updates by December 2019.

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: As a routine matter, state applications can readily address the expected efficacy of a proposed use, and data do not need to be state-specific.

The sole example cited by the OIG to support this recommendation represents an extremely rare situation. In this particular situation, the California Department of Pesticide Regulation (DPR) requested use of the same antibiotic materials as authorized under exemptions for use 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, with only very limited occurrence in residential trees in several areas of the state. To support their request, California 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 California 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 California 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.

Proposed Corrective Action and Timeframe for Completion: OCSPP disagrees with this recommendation and is not providing a timeframe for completion.

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 points, such as application acreage requested, decision documents, and registration status of each exempted pesticide, as OCSPP explores ways to improve the website database and its overall content.

Proposed Corrective Action and Timeframe for Completion: By December 2019, the Registration Division will make recommendations to the Director of the Office of Pesticide Programs for enhancing the Section 18 database. The recommendations will consider the additional data points suggested in Recommendation 7. By December 31, 2019, the Director of the Office of Pesticide Programs will provide a memorandum to the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention with a plan for updating the Section 18 database addressing these recommendations.

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 agrees with OIG's recommendation and will explore how to provide periodic 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 for periodic updates.

Proposed Corrective Action and Timeframe for Completion: By December 2019, OCSPP will develop a strategy which details the activities that might be conducted to provide periodic and useful program updates to applicants.

Appendix B

Distribution

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