

U.S. ENVIRONMENTAL PROTECTION AGENC

OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals Compliance with the law

EPA Can Better Reduce Risks From Illegal Pesticides by Effectively Identifying Imports for Inspection and Sampling

Report No. 17-P-0412

September 28, 2017



Report Contributors:

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Abbreviations

ACE	Automated Commercial Environment
ACS	Annual Commitment System
CBP	U.S. Customs and Border Protection
CFR	Code of Federal Regulations
CMS	Compliance Monitoring Strategy
CTAC	Commercial Targeting Analysis Center
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FY	Fiscal Year
NOA	Notice of Arrival
NPMG	National Program Manager Guidance
OECA	Office of Enforcement and Compliance Assurance
OIG	Office of Inspector General

Cover photos: Containers of imported pesticides observed during a tour of the Customs Central Examination site in Bensenville, Illinois. (EPA OIG photos)

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U.S. Environmental Protection Agency Office of Inspector General

At a Glance

Why We Did This Review

We conducted this review of the U.S. Environmental Protection Agency's (EPA's) Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) import inspection program to determine whether the EPA is effectively identifying imported pesticides for inspection and sampling to deter imports of harmful pesticides and protect human health and the environment.

Illegal imports of pesticides can present significant human health and environmental risks, and have been linked to poisonings of children and pets. Illegal imports include high-risk pesticides that can be counterfeit, produced at unregistered establishments, or produced using unauthorized ingredients. According to the EPA, inspections are a key method to deter the import of harmful pesticides.

This report addresses the following:

- Ensuring the safety of chemicals.
- Compliance with the law.

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What We Found

The EPA is at risk of not effectively identifying imported pesticides for inspection and sampling. EPA regions did not meet the voluntary frequency goal of inspecting 2 percent of all shipments of imported pesticides nationwide in fiscal years 2015 and 2016. In fiscal year 2016, the EPA's

Low rates of inspections and sampling can create a risk that the EPA may not be identifying or deterring the import of pesticides harmful to people or the environment.

10 regions conducted only 73 inspections of 46,280 pesticide shipments. This is an inspection rate of 0.002; an inspection rate of 2 percent would have been about 926 inspections. Consequently, there is limited assurance that imports in violation of FIFRA will be identified or prevented entry into the United States.

We found that in two EPA regions, inspections were more likely to be conducted close to the regional office rather than where the greatest number of pesticides entered the region. In the last 5 years, the seven EPA regions we reviewed had sampled and tested the integrity of only seven pesticides out of approximately 145,000 shipments of imported pesticides. Regional resources available to carry out inspections are not considered part of strategic planning, and regional participation in achieving the agency's inspection frequency goal is voluntary.

The EPA's implementation of the required U.S. Customs and Border Protection Automated Commercial Enterprise system for automatic processing of import notices will allow EPA regions more time for targeting and inspections. However, the agency has no guidance or training available on how EPA regions can use information from this system to target future inspections or develop their own targeting strategies. Guidance or protocols for how EPA regions can coordinate with U.S. Customs and Border Protection will also help to ensure that the EPA is notified of any potentially illegal pesticides not found during the agency's review of import notices.

Recommendations and Planned Agency Corrective Actions

We made four recommendations that the Assistant Administrator for Enforcement and Compliance Assurance establish national compliance monitoring goals based on regional resources; implement controls to monitor and communicate progress on regional goals; develop guidance and train EPA regions to use the Automated Commercial Enterprise system for regional targeting of importers, manufacturers and pesticide products; and direct each EPA region to develop guidance or protocols for coordinating with local U.S. Customs and Border Protection offices regarding illegally imported pesticides. The EPA concurred with developing protocols for coordinating with local U.S. Customs and Border Protection offices. The remaining three recommendations are unresolved.



THE INSPECTOR GENERAL

September 28, 2017

MEMORANDUM

SUBJECT:	EPA Can Better Reduce Risks From Illegal Pesticides by		
	Effectively Identifying Imports for Inspection and Sampling		
	Report No. 17-P-0412		
FROM:	Arthur A. Elkins Jr. Juthuy a. Phi-		

TO: Lawrence Starfield, Acting Assistant Administrator Office of Enforcement and Compliance Assurance

This is our report on the subject review conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this review was OPE-FY16-0025. 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.

Action Required

In accordance with EPA Manual 2750, the Office of Enforcement and Compliance Assurance and the OIG will meet within 30 days to discuss unresolved Recommendations, 1, 2 and 3. Final decisions on the unresolved recommendations will be timely posted on the OIG's website following the resolution process in EPA Manual 2750. No further response is required on Recommendation 4.

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

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Chapter 1 Introduction

Purpose

The purpose of this report was to determine whether the U.S. Environmental Protection Agency's (EPA's) Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) import inspection program is effectively identifying imported pesticides for inspection and sampling,¹ for the purposes of deterring imports of harmful pesticides and protecting human health and the environment.

Background

A pesticide is any substance or mixture of substances—and a pesticide device is an instrument—intended for preventing, destroying, repelling,

mitigating or trapping any pest. Illegal imports of pesticide products from other countries can present significant human health and environmental risks, and have been linked to poisonings of adults, children and pets (see box for an example). Interception of such pesticides before they enter the United States is critical. Illegal pesticide imports include a wide range of products, including a variety of high-risk unregistered, misbranded, adulterated, counterfeit or imitation pesticides produced at unregistered establishments or by using unauthorized sources of active ingredients. In addition, the EPA has stated that illegal imports of pesticides can create an unfair playing field, presenting significant financial impacts for those companies importing and selling legal products.



Example of an Illegal Pesticide:

Chinese Chalk, and Miraculous Insecticide Chalk—are dangerous. These may be sold in a neighborhood store or on the street for about \$1 a box. These products are mostly imported illegally from China, and often bear a label in both English and Chinese. Sometimes the manufacturer claims that the chalk is "harmless to human beings and animals" and "safe to use." Children can easily mistake insecticide chalk for blackboard chalk or put it in their mouths. State agencies have reported illnesses of children linked to ingestion or handling of the chalk. Some insecticide chalks can cause serious health problems, including vomiting, stomach pains, convulsions, tremors, loss of consciousness, and serious allergic reactions. *Source: EPA*

¹ The agency identified non-inspection activities that support the FIFRA imports program. These can include desk audits, producer establishment and marketplace inspections with an imports component, compliance assistance for importers, and participation in international working groups.

The EPA regulates pesticide and pesticide device imports in accordance with FIFRA. Section 17(c) of FIFRA and the corresponding U.S. Customs and Border Protection (CBP) regulations (19 CFR §§ 12.110–12.117) require any importer of a pesticide or device into the United States to submit a Notice of Arrival (NOA) to the EPA prior to arrival of the shipment. Prior to December 31, 2016,² all NOA forms were sent to the EPA regional office having jurisdiction over the port of entry. EPA regions would review, evaluate and advise on the disposition of the import shipment to CBP at the port of entry. Once the EPA's evaluation is completed, the NOA is annotated, signed and dated by the EPA case officer and returned to the importer for presentation to CBP at the time of entry. The shipment is then released, detained or denied entry by CBP based on the EPA recommendation.

According to the EPA, inspections are the "core" of the FIFRA compliance monitoring program. Inspections are intended to prevent the unlawful entry of pesticides into the United States, help bring regulated entities into compliance, and collect evidence to take appropriate enforcement actions. The EPA's 10 regional offices are the primary source of inspections and enforcement for imported pesticides. States may become involved through region-to-state referrals to monitor post-entry import compliance. States may also encounter imported products during the course of other compliance monitoring inspections.

Enforcement Priority Placed on Imported Pesticides

Annual Commitment System

The EPA's Office of Enforcement and Compliance Assurance (OECA) monitors regional, state and tribal implementation activities using regional and state results entered in OECA databases, the Annual Commitment System (ACS), and data collected in the implementation of national enforcement initiatives. For the FIFRA program, the ACS commitment for each EPA region is a minimum of 10 FIFRA inspections; this may or may not include import inspections. According to OECA, the types of inspections conducted depend on each region's priorities.

National Program Manager Guidance

Since fiscal year (FY) 2009, OECA has identified enforcement against illegal importation of pesticides as a national priority through its National Program Manager Guidance (NPMG). The goal of priority setting is to focus the agency's compliance monitoring efforts on program areas with the greatest need first. To support this national priority, the NPMG suggested activities for EPA regions that include:

• Monitoring pesticide import compliance through inspections at entry ports and designated destination points (e.g., after imported products have been released by CBP and have entered U.S. commerce).

² As of December 31, 2016, the EPA started its required transition to the CBP's Automated Commercial Environment (ACE) system for electronic receipt and processing of NOAs for pesticide imports.

• Collecting pesticide samples and submitting these samples to laboratories for formulation analysis to ensure product composition complies with terms of product registration.

As part of the NPMG priority-setting effort, the EPA also develops national targeting strategies. The goal of targeting is to focus on the most significant environmental problems within a priority area by identifying specific pesticide products or producers that may pose the greatest risk of harm to human health or the environment due to noncompliance. According to OECA staff, in FY 2015, as a result of regional enforcement efforts, the EPA addressed 6.7 million pounds of noncompliant pesticide imports and assessed just over \$456,000 in penalties.

For FY 2015, the EPA's draft regional implementation strategy for its NPMG priority focused on "high-risk" unregistered pesticides and importers with a history of noncompliance, and significant importation activity from countries frequently associated with noncompliant shipments. The implementation strategy called for EPA regions to:

- Conduct inspections based on identified targets.
- Evaluate compliance and identify potential violations of FIFRA.
- Take samples of imported pesticides when potential discrepancies in information provided by the importers are identified.

FIFRA Compliance Monitoring Strategy

In 2015, OECA issued its *FIFRA Compliance Monitoring Strategy* (CMS) to work in conjunction with the NPMG. The CMS established an "aspirational" compliance monitoring goal ("inspection frequency") for EPA regions to voluntarily achieve in support of the NPMG's and EPA's national enforcement priority focusing on imported pesticides:

- Inspect nationwide 2 percent of all imported pesticide shipments annually (or 480 total inspections per year across all 10 EPA regions).³
- Target pesticide imports using for-cause and neutral scheme inspections as well as pesticide formulation sampling.

While the CMS provides an aspirational goal, according to OECA, the EPA's ACS measure of a minimum of 10 FIFRA inspections is considered to be the agency goal and commitment for each region.⁴ The CMS provides guidance to the regions on how to target inspections to raise compliance rates by focusing on identifying

³ The CMS estimated the total number of NOAs received to be 24,246 based on data collected from EPA regions through July 2009.

⁴ Since FY 2010, the OECA NPMG has included an ACS measure specifying that each EPA region should conduct a minimum of 10 FIFRA inspections. This measure is not specific to import inspections. It can include the following different types of FIFRA inspections: import, export, use, pesticide producer establishment, certified applicator, restricted-use pesticide dealer, marketplace, worker protection standard, or Good Laboratory Practice inspections and data audits.

specific pesticide products that may pose the greatest risk of harm to humans or the environment. The CMS also states that the EPA can provide a deterrent effect by maintaining a visible presence in the FIFRA-regulated community as a whole, and lists FIFRA imports as a "core" area for deterrence purposes.

Import Inspections and Sampling

EPA regions conduct inspections to ensure that imported pesticides comply with the requirements of FIFRA. Under FIFRA, the EPA conducts for-cause inspections in response to a suspected violation based on a NOA review, a tip or complaint, or as a follow-up to an ongoing investigation. The EPA can also



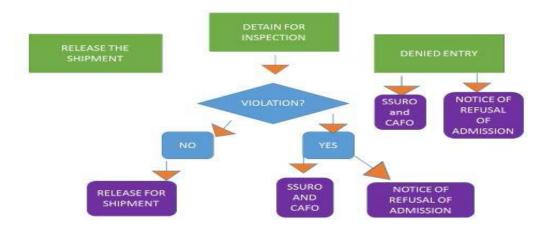
Pesticides set aside to be inspected. (EPA Office of Inspector General [OIG] photo)

conduct neutral scheme inspections, which monitor compliance based on a set of unbiased criteria rather than information that a pesticide may be in violation.

During import inspections, EPA regional staff can examine the pesticide labels for mandatory labeling requirements, check for collateral labeling (such as books and pamphlets), and check the condition of the entire shipment. EPA regions can also collect formulation samples and submit them to a laboratory for analysis to ensure the pesticide's composition is not adulterated and complies with the terms of its EPA registration. If the pesticide is in compliance, the region then notifies CBP that the shipment can be

released to the importer. As illustrated in Figure 1, if a violation is found, the EPA can take enforcement actions such as: denying a shipment entry with a Notice of Refusal of Admission; issuing a Stop Sale, Use or Removal Order; or issuing a fine or penalty. The EPA may also seek injunctive relief in certain circumstances where a violation continues after the agency has taken an enforcement response.

Figure 1: NOA review process for imported pesticides



SSURO: Stop Sale, Use or Removal Order CAFO: Consent Agreement and Final Order

Source: EPA Region 6.

Automated Commercial Environment Database

The CBP's Automated Commercial Environment (ACE) is intended to be the primary system through which the trade community reports imports and exports and the government approves pesticide products for entry into the United States. Executive Order 13659, *Streamlining the Export/Import Process for America's Businesses*, issued February 19, 2014, aimed to significantly reduce processing and approval times for importers and exporters.⁵ In response to Executive Order 13659, the CBP transitioned all partner government agencies—such as the EPA—to begin using ACE on January 1, 2017. ACE electronically processes the majority of NOAs, significantly reducing the need for manual review and approval by the EPA. Importers can continue to file paper NOAs, and the EPA will continue manual reviews and approvals as necessary.

Responsible Offices

OECA's Office of Civil Enforcement and Office of Compliance set national priorities through the EPA's NPMG, and issue national guidance for conducting FIFRA inspections and NOA reviews. OECA's Office of Compliance also develops the EPA's inspection sampling guidance (documentation, how much to collect, chain of custody, etc.) and conducts both basic and FIFRA-specific inspector training.

The Office of Chemical Safety and Pollution Prevention provides as-needed support to EPA regions on product registration, and its Biological and Economic Analysis Division provides laboratory support to the regions for sampling analysis of pesticide imports.

Scope and Methodology

We conducted this performance 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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. We conducted this audit from May 2016 through July 2017.

We reviewed relevant materials, including FIFRA implementing regulations, and EPA procedures and guidance for pesticide imports. Our review included documents such as OECA's 2015 Compliance Monitoring Strategy for FIFRA,

⁵ The International Trade Data System, as described in Section 405 of the Security and Accountability for Every Port Act of 2006 (SAFE Port Act) (Pub. L. 109-347), was established to modernize and simplify the way in which partner government agencies—including the EPA—interact with the trade community by creating a single portal through which filers submit the data elements required for import or export of cargo. CBP designed ACE to provide that "single window" for the electronic filing of import entries.

OECA's NPMG (FYs 2010–2017), the EPA 2013 FIFRA Inspection Manual, the OECA National Guidance for Review and Processing of Notice of Arrivals for Pesticides and Devices, regional guidance and procedures for pesticide imports, and EPA Office of Environmental Information guidance on CBP's ACE portal system.

We gathered data from all 10 EPA regional offices and selected seven (Regions 4, 5, 6, 7, 8, 9 and 10) as the focus of our evaluation.⁶ We reviewed import inspection reports from the selected regions. We reviewed pesticide import sampling reports from EPA Region 10. We interviewed personnel from the Georgia Department of Agriculture, Pesticides Division, about federal inspections conducted on behalf of EPA Region 4.

We interviewed OECA staff, Office of Pesticide Programs staff, Office of Environmental Information technical staff, and EPA regional pesticide and enforcement managers and staff. We also interviewed regional FIFRA import coordinators and inspectors to better understand the FIFRA regional import review and inspection process.

We reviewed CBP regulations regarding pesticide imports. We interviewed CBP personnel who work with EPA Regions 5, 9 and 10 about their roles and responsibilities in monitoring, inspecting and detaining pesticide imports, as well as their roles in coordinating with EPA regional FIFRA import coordinators and inspectors.

We reviewed the NOA databases for Regions 6 and 9, as well as OECA's SharePoint website for FIFRA Import Coordinators.

We also interviewed U.S. Food and Drug Administration staff regarding their Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting program. We reviewed information on this targeting tool provided by the U.S. Food and Drug Administration.

⁶ We collected NOA and inspection totals from all 10 EPA regions for FYs 2015 and 2016 (see Table 1).

Chapter 2 EPA Has Not Met Its Inspection Frequency Goal for Imported Pesticides

In FYs 2015 and 2016, EPA regions did not meet the agency's voluntary frequency goal of inspecting 2 percent of all imported pesticide shipments nationwide. In FY 2016, the 10 EPA regions combined conducted only 73 inspections of 46,280 shipments of imported pesticides. This is an inspection rate of 0.002; 2 percent of the 46,280 would have been 926 inspections. We found that in two EPA regions, inspections were more likely to be conducted close to the EPA regional office rather than where the greatest number of pesticide shipments enter the region. In the last 5 years, the seven EPA regions we reviewed only tested the product composition of seven products out of approximately 145,000 shipments. The EPA's strategic planning for inspecting and sampling imports did not take into account regional resources available. Further, regional participation is also considered voluntary. These challenges create a risk that the EPA cannot effectively detect misrepresentations, errors and discrepancies of pesticide shipments, or deter the importing of harmful pesticides.

EPA Regions Have Not Met the CMS Inspection Frequency

The EPA only inspected 0.002 of all known shipments of pesticides imported into the United States in FYs 2015 and 2016 (Table 1).⁷

EPA Region	NOAs (FY 2016)	Inspections	NOAs (FY 2015)	Inspections
Region 1	2,212	0	2,018	4
Region 2	8,151	13	6,608	11
Region 3	1,130	8	1,239	5
Region 4	6,093	3	3,819	N/A
Region 5	5,411	12	5,950	9
Region 6	14,106	5	8,573	10
Region 7	1,845	14	2,202	3
Region 8	523	3	610	3
Region 9	4,326	9	3,737	6
Region 10	2,483	6	2,020	4
Totals	46,280	73, or .002	32,957*	55, or .002

* Region 4 is excluded from this total because it was unable to provide the number of inspections for FY 2015. Source: EPA OIG.

⁷ In FY 2015, there were an additional 48 state-led FIFRA import inspections (using federal credentials), 78 percent of which were conducted in the U.S. territories of the Commonwealth of the Northern Mariana Islands (23) and Puerto Rico (14). In FY 2016, there were 64 state-led FIFRA import inspections, 50 percent of which were conducted in the Commonwealth of the Northern Mariana Islands (27) and Puerto Rico (5).

This is significantly below the agency's CMS frequency goal of inspecting 2 percent of all shipments of imported pesticides; 2 percent of the 46,280 would have been 926 inspections. Regional staff are focused on completing NOA



Pesticide import screening area. (EPA OIG photo)

reviews as required under FIFRA and CBP regulations. A Region 5 import inspector said noncompliance issues (such as torn, missing or unreadable labels and leaks from containers) can be found during inspections, including routine inspections, but cannot be detected through a review of a NOA for a shipment.

OECA's 2015 FIFRA CMS provided national pesticide compliance monitoring expectations to EPA regions. The CMS established an aspirational and voluntary frequency goal of inspecting 2 percent (approximately 480 total inspections across all 10 EPA regions) of all shipments of imported pesticides each year. However, as of our review, the regional offices had committed to conducting only 10 FIFRA inspections per year, which may or may not include any import inspections. The CMS stated that the aspirational frequency goal "presume[s] adequate funding and resources and, therefore, the actual number of inspections conducted may differ from the frequencies set forth."

The large gap between the current agreed-upon commitment level of inspections and the frequency goal indicates a disconnect that needs to be addressed, given funding and resources. OECA headquarters staff stated that no analysis of available resources or regional input was used to develop this CMS frequency goal. It is unclear how regions without "adequate funding and resources" will achieve the inspection frequency goal, or what the performance expectation is for regions without these resources.

Some EPA Regions Are Not Inspecting at High-Traffic Ports

Our review of two EPA regions (Regions 5 and 6) found that when some EPA inspections occur, they are more likely to be conducted in close proximity to the respective regional office rather than in areas where the greatest number of imported pesticides shipments are entering that region. For example, between FYs 2012 and 2015, Region 6 did not conduct any inspections at the port of Laredo, Texas, even though it was the busiest port in the region, with 21,549 NOAs for shipments of imported pesticides received. Instead, all 29 inspections conducted by Region 6 took place close to the EPA's regional office in Dallas, Texas, where only 639 NOAs were received (Figure 2).



Figure 2: EPA Region 6 high-traffic ports and inspection locations (FYs 2012–2015)

Flag denotes inspection location and inspection numbers. The circles show the number of NOAs for shipments of imported pesticides received by location. (Source: EPA OIG)

Similarly, in Region 5, there were no import inspections conducted at its busiest port—Port Huron, Michigan—during FYs 2012 through 2016, where 9,682 NOAs for imported pesticide shipments were received (Figure 3). Region 5 staff said that budget constraints on travel impact their ability to inspect ports. In Region 5, about 81 import inspections were conducted near the regional office in Chicago, Illinois, where 4,375 NOAs were received.



Figure 3: EPA Region 5 high-traffic ports and inspection locations (FYs 2012–2016)

Flags denote inspection locations and inspection numbers. The circles show the number of NOAs for shipments of imported pesticides received by location. (Source: EPA OIG)

The NPMG suggests that EPA regions should monitor import compliance through inspections at entry ports and designated destination points to assist with deterrence. The CMS further emphasizes the need for "maintaining a visible presence in the FIFRA-regulated community" for pesticide imports to help deter noncompliant imports. OECA headquarters staff said that a key method to maintaining this visible presence is conducting an adequate number of on-the-ground inspections so that industry is aware that the EPA is monitoring compliance. With near zero inspection presence at high-volume ports in some EPA regions, the agency is not maintaining the visible presence called for in its CMS. For example, a regional manager indicated the particular region was once targeted by the pesticide import industry as the port of choice for import entry because of a lack of inspections. This creates the risk of noncompliant pesticides entering the United States.

Some Regions Are Not Conducting Neutral Scheme Inspections

Further, the CMS encourages the EPA regions to conduct both for-cause and neutral scheme inspections. However, we found that some regions were not conducting neutral scheme inspections. Neutral scheme inspections monitor compliance based on a set of criteria rather than information that a violation has occurred or is occurring; these inspections can rely on random selection or selection by relevant statistics. EPA Regions 4, 6, 7 and 9 only conducted for-cause inspections initiated in response to an already-suspected violation identified from a tip, complaint or information on a NOA. Regions 5, 6, 8 and 10 conducted some neutral-scheme FIFRA import inspections. OECA staff said that the agency prefers that regions conduct for-cause inspections because that means there is a suspected violation and the ability for the agency to stop potential harm. However, a review



EPA staff sampling pesticide imports. (EPA Region 10 photo)

of Region 5 inspection reports showed that neutral scheme inspections found instances of FIFRA noncompliance.⁸

EPA Regions Sample Few Imported Pesticides

In the past 5 years, of the seven regions reviewed, Regions 4, 7 and 10 sampled seven imported pesticides for product formulation out of an estimated 145,000 known pesticide shipments to these seven regions. Region 10 is the only current "active" sampling region. Regions 5, 6, 8 and 9 do not conduct any product formulation analysis, even though these regions have done so in the past.⁹ Some regions that do not sample instead emphasize label review, and photograph actual labels or containers from imported pesticides during inspections for comparison to EPA product registrations.

⁸ Noncompliance issues identified included labels on imported pesticides that do not match EPA-approved labels, imported goods missing labels, and pesticide containers leaking pesticide liquid and residue.

⁹ On July 28, 2015, OECA provided training to EPA regions on how to sample pesticides shipped in bulk containers and provided each region with equipment.

For FYs 2013, 2016 and 2017, OECA's NPMG directed EPA regions to review NOAs for potential discrepancies relating to the source of active ingredients and countries of origin. Two regions said that they do not have the capability to analyze samples (e.g., no laboratory nearby, laboratory lacking formulation analysis expertise). Other EPA regions indicated they did not see the benefit of sampling, or rely on the NOA review process to refuse entry of a shipment without having to sample. Representatives at the agency's designated headquarters laboratory for sampling analysis said they do not actively promote their pesticide formulation analysis capabilities because they do not have the resources to properly assist all 10 EPA regions.

OECA headquarters staff said that, over the past several years, the EPA has seen an increase in pesticide imports (as well as those that are domestically produced) having modified or "off-spec" product formulations that are different from their EPA-registered formulas. Since formulation sampling is so limited, the EPA cannot validate whether product composition of imports is a potential threat, or demonstrate the value of sampling for regions that are not actively doing it.

EPA National Targeting Results in Few Inspections

Our review of two EPA regions (Regions 6 and 9) found that the EPA's national targeting effort may result in only a few imported pesticides being identified by the regions for inspection. For FY 2015, the EPA developed a list of targeted manufacturers and pesticide importers for each region to pursue neutral scheme and for-cause inspections. We compared the electronic NOA databases for Regions 6 and 9 to regional inspection reports. We found that for the 11 targeted importers in these two regions, only one inspection was conducted despite receipt of 4,637 NOAs from the 11 importers during this period. The agency provided data that showed that only three EPA regions conducted a few import inspections based on targeting efforts.

The EPA also initiated another national-level targeting effort through its participation in the Commercial Targeting Analysis Center (CTAC).¹⁰ According to a former EPA liaison for CTAC, the focus of the targeting was to review NOAs from certain pesticide importers with "more scrutiny." The CTAC targeting plan instructs EPA regions to inspect and sample "as appropriate."¹¹ However, the former liaison further added that a targeting effort is not intended to result in a rise of inspection events.

¹⁰ The EPA is a member agency of the CTAC, which is a CBP-led inter-agency workgroup designed to streamline and enhance federal efforts to address import safety issues. The CTAC combines the resources and manpower of the CBP and other government agencies to protect the American public from harm caused by unsafe imported products by improving communication and information-sharing, and reducing redundant inspection activities.

¹¹ The targeting plan states: "EPA regional inspectors will conduct import entry document reviews and conduct pesticide import inspections, as appropriate, based on identified targets ... at targeted ports of entry and take samples of imported pesticides when potential discrepancies are noted, including but not limited to the country of origin and sources for active ingredients used to produce registered pesticides as identified on their Confidential Statements of Formula."

The CMS states that the goal of targeting is to focus on the most significant environmental problems within a priority area by identifying specific pesticide products and producers that may pose the greatest risk of harm to human health or the environment due to noncompliance. The agency's FY 2015 NPMG draft FIFRA imports implementation strategy also details the use of inspections for evaluating compliance and identifying potential violations of FIFRA. A targeting strategy focused primarily on reviews of NOAs does not provide more assurance that noncompliance by high-risk importers and pesticides are detected.

Example of a Targeting Strategy



A port located in EPA Region 10. (EPA photo)

EPA Region 10 has developed a targeting strategy that includes risk-based criteria to help inform a decision on whether to inspect an imported pesticide. This strategy uses criteria such as product label signal words (e.g., danger, skull and crossbones), toxicity, completeness and accuracy of the NOA, country of concern, and compliance history to determine an overall score or "targeting value." Based on this score, an import is assigned an inspection priority of high, medium or low. Since 2005, Region 10 stated that this strategy has resulted in over 15 million pounds of pollution reductions and more than \$65,000 in penalties, and that recent inspections have showed an increase in compliance with FIFRA.

OECA Lacks Regional Data and Feedback on Its Imports Focus Area

OECA headquarters staff said that regional analysis of resources is considered during the setting of regional ACS commitments for FIFRA inspections. The inspections negotiated may or may not include pesticide imports. OECA said that regional resources were not considered to develop its aspirational inspection frequency or national targeting strategies. Any inspections or sampling done by the regions in support of these strategies are considered supplemental. OECA headquarters staff rely primarily on the regions to determine what activities to pursue. This can include non-inspection compliance and enforcement activities that support the FIFRA imports program.

OECA formally monitors the progress of EPA regions toward the ACS commitment of conducting 10 FIFRA inspections (which may or may not include imports). However, OECA headquarters does not monitor or evaluate the progress of regional offices related to achieving the CMS voluntary inspection frequency or the activities in its national targeting strategies.¹² At the conclusion of one of the agency's targeting documents, it states that "Regions will report results for FY 15 imports enforcement activities" to OECA. When asked, OECA could not share with us the results because the regions did not provide OECA with any information.

¹² OECA participates in regular conference calls and issues specific consultations for regional import coordinators.

An OECA staff member told us that headquarters generally compiles any available information related to the strategies themselves from EPA databases. As a result, compliance monitoring activities suggested in the CMS and targeting strategies for EPA regions to pursue are not clearly linked to what resources the regions have available to accomplish them. Without monitoring, the EPA lacks information on regional inspection and non-inspection activities in order to evaluate effectiveness, update strategies in response to progress made, and communicate achievements.

Conclusion

EPA regions face challenges meeting the 2 percent aspirational inspection frequency for pesticide imports. With a near zero inspection presence at highvolume ports in some EPA regions, the agency is also at risk of not maintaining the visible presence called for in its CMS. The low rate of inspections and product sampling is a result of the agency's lack of internal controls over strategic planning and accountability. This creates a risk that the EPA's current strategies are not detecting misrepresentations, errors and formulation discrepancies of actual imported pesticides.

Recommendations

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance:

- 1. Establish national compliance monitoring goals based on assessment and consideration of available regional resources.
- 2. Implement internal controls to monitor and communicate progress on regional goals.

Agency Comments and OIG Evaluation

In the EPA's official comments, the agency disagreed with Recommendation 1 and proposed no further corrective action. The agency partially agreed with Recommendation 2, but it did not propose a corrective action that met the full intent of the recommendation. In its August 16, 2017, supplemental response, the EPA proposed a revised corrective action for both Recommendations 1 and 2. However, this action does not satisfy the full intent of the recommendations. Therefore, these recommendations are unresolved. The agency also provided technical comments on the draft report, which we incorporated into our final report as appropriate.

The EPA's detailed official response is in Appendix A and its supplemental response is in Appendix B.

Chapter 3

EPA Can Better Plan How to Use ACE Capabilities to Inspect and Sample Imported Pesticides

The EPA does not have a plan or training on how regions can best use the capabilities and information available from CBP's ACE system to target future inspections and sampling. The EPA works with local CBP staff when EPA regions are alerted to potential illegal pesticide imports not found during the EPA's NOA reviews. Guidance or protocols for how EPA regions will coordinate with CBP on activities outside the automated import review process will help ensure that the EPA is notified by CBP of any potential illegal pesticides not found during the EPA's NOA reviews.

EPA Needs Training and Guidance on How to Use ACE for Targeting

As of December 31, 2016, the EPA started its required transition to the ACE system.¹³ Prior to ACE, regional import coordinators were required to manually review each NOA received.¹⁴ EPA Office of Environmental Information staff said ACE will provide the EPA with access to previously unavailable information on shipments and provide the EPA with the ability to produce reports that will assist the regions with targeting. ACE also allows EPA regions to routinely stop incoming shipments or ask for re-delivery of a shipment from an importer.

The purpose of the ACE system is to automate electronic review of NOAs. ACE will review the electronically submitted NOAs. If all fields are correctly filled in, the system will in most cases automatically release the pesticide shipment. ACE will generally only forward to import coordinators for their review NOAs with either erroneous or missing information. OECA staff said it will take the agency the next year or beyond to determine what activities will be the new or additional focus of regional import coordinators.

Both OECA headquarters and regional import staff said ACE would allow for additional data mining to target inspections. EPA Office of Environmental Information staff said the information in ACE can be used by EPA regions to also develop their own targeting strategies. The CMS states that the goal of targeting is to focus on the most significant environmental problems within a priority area by identifying specific pesticides or producers that pose the greatest risk of noncompliance. Using ACE for risk-based prioritization of inspections and

¹³ According to agency staff, during the time of our review, only about 10 percent of pesticide imports were going through the ACE portal; regional coordinators were still reviewing 90 percent of the NOAs manually for the first year.

¹⁴ On August 29, 2014, OECA issued national *Guidance for Review and Processing of Notice of Arrivals for Pesticides and Devices* to ensure the consistency of NOA reviews across EPA regions.

sampling would help to ensure that the agency is not only deterring bad actors but targeting certain pesticides that pose the greatest risk to people and the environment.

EPA Regions Could Improve Coordination With CBP on Pesticides Without Import Notices

Both OECA headquarters and EPA regional staff said that local CBP staff generally alert the EPA to illegal pesticides not found during the NOA review.

Newspaper Reports on Import Seizures by EPA and CBP

U.S. EPA and Customs joint operations at Southern California ports result in fines and seizure of illegal engines and pesticides

LOS ANGELES — On January 19, 2017, the U.S. Environmental Protection Agency and U.S. Customs and Border Protection announced \$217,998 in fines and more than 5,325 items seized or denied entry to the United States. These are the latest results of continued joint operations at the ports of Los Angeles and Long Beach targeting foreign-made engines, including scooters, ATVs, chainsaws and construction equipment without proper emission controls, as well as pesticides that violate federal law.

> Source: Highland Community News, Highland, California

These illegal products include pesticides entering without an EPA-approved NOA and unregistered products.¹⁵ However, most of the EPA regions we spoke with work with CBP on an as-needed basis following their NOA reviews. None have written guidance or protocols for working with CBP on activities related to illegal pesticides without NOAs.

The EPA FIFRA Inspection Manual states that it is up to the regional offices to maintain a close cooperative working relationship with CBP, as each port of entry may follow a somewhat different protocol. During our interviews with EPA regional staff, we found that most EPA regions maintained varying relationships with CBP staff based on local protocols.

Guidance or protocols specific to each EPA region's relationship with CBP for illegally imported pesticides would help assist with ongoing identification of illegal pesticide imports not found during the EPA's review of NOAs.

Conclusion

With the automated processing of NOAs through ACE, regional import coordinators will now have more opportunities to focus on targeting imported pesticides for inspection. Guidance or protocols specific to each EPA region's relationship with CBP for illegally imported pesticides outside of the agency's NOA review process would help to ensure that EPA regions are notified when

¹⁵ For example, in June 2016, the CBP office from the port of Los Angeles notified EPA Region 9 about a suspicious shipment of devices imported from China. Region 9 determined that the devices did not contain a valid EPA Establishment Number, and were therefore determined to be misbranded in accordance with FIFRA Section 12. EPA Region 9 subsequently notified the Los Angeles CBP office that the shipment should be "Denied Entry-Refused Delivery into the United States pursuant to the authority of Section 17(c) of FIFRA."

these types of shipments are discovered, and that inspection and sampling-related activities for these illegal pesticides are carried out. Guidance in this area increases assurance that the agency is managing or reducing its risk concerning deterring bad actors and targeting pesticides that pose the greatest risk to people and the environment.

Recommendations

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance:

- 3. Develop agency guidance and training for EPA regions on how to use the Automated Commercial Environment system for regional targeting of importers, manufacturers and pesticide products.
- 4. Direct each EPA region to develop guidance or protocols that define how the region will coordinate with local U.S. Customs and Border Protection offices on illegal pesticides that are imported without Notices of Arrival.

Agency Comments and OIG Evaluation

In the EPA's official comments, the agency agreed with Recommendation 3, but it did not provide corrective actions that meet the intent of the recommendation. In its August 16, 2017, supplemental response, the EPA proposed revised corrective actions. This revised action still does not meet the full intent of the recommendation. Therefore, Recommendation 3 is unresolved.

The agency agreed with Recommendation 4 and provided appropriate corrective actions. The agency also provided technical comments on the draft report, which we incorporated into our final report as appropriate.

The EPA's detailed official response is in Appendix A and its supplemental response is in Appendix B.

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	13	Establish national compliance monitoring goals based on assessment and consideration of available regional resources.	U	Assistant Administrator for Enforcement and Compliance Assurance		
2	13	Implement internal controls to monitor and communicate progress on regional goals.	U	Assistant Administrator for Enforcement and Compliance Assurance		
3	16	Develop agency guidance and training for EPA regions on how to use the Automated Commercial Environment system for regional targeting of importers, manufacturers and pesticide products.	U	Assistant Administrator for Enforcement and Compliance Assurance		
4	16	Direct each EPA region to develop guidance or protocols that define how the region will coordinate with local U.S. Customs and Border Protection offices on illegal pesticides that are imported without Notices of Arrival.	R	Assistant Administrator for Enforcement and Compliance Assurance	9/30/18	

- $\label{eq:constraint} \begin{array}{l} C = Corrective \mbox{ action completed}.\\ R = Recommendation resolved \mbox{ with corrective action pending}.\\ U = Recommendation \mbox{ unresolved with resolution efforts in progress}. \end{array}$

Appendix A

Agency Response to Draft Report and OIG Evaluation

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

JUL 2 7 2017

MEMORANDUM

- SUBJECT: Response to the Office of Inspector General Draft Report: "EPA Can Better Reduce Risks From Illegal Pesticide Imports," dated June 27, 2017, Report No. OPE-FY16-0025
- FROM: Lawrence Starfield 12 27 Acting Assistant Administrator
- TO: Carolyn Cooper Assistant Inspector General Office of Program Evaluation

Thank you for the opportunity to respond to the draft findings and recommendations presented in the Office of Inspector General (OIG) Draft Report, "EPA Can Better Reduce Risks from Illegal Pesticide Imports" (Report). Following is a summary of comments from the Office of Enforcement and Compliance Assurance (OECA), followed by OECA's position on each of the Report's recommendations. For those Report recommendations with which OECA agrees, we propose corrective actions and estimated completion dates. For those Report recommendations with which OECA does not agree, we explain how EPA is already performing the recommended action. OECA's comments are provided below for your consideration in revising the draft Report.

Background and Summary Comments

This Report focuses on whether the Environmental Protection Agency's (EPA) Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) import inspection program is effectively identifying imported pesticides for inspection and sampling for the purpose of deterring imports of harmful pesticides and protecting human health and the environment. OECA agrees that illegal pesticide



OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

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imports can present significant human health and environmental risks. Because of these risks, OECA and the regional offices have focused resources in this area and made significant progress in intercepting noncompliant products and returning them to compliance before entry, or preventing those products from entering into U.S. commerce. The quantities of noncompliant pesticide imports that are addressed through OECA's national imports compliance monitoring and enforcement efforts greatly exceed the amount the Agency addressed ten years ago. The Report draws a direct correlation between the numbers of inspections EPA conducts and the amount of illegal imports EPA is able to identify; OECA feels strongly that this is an incorrect description of our program. In particular, the Report fails to capture the variety of ways that EPA identifies unlawful imports and deters noncompliance, which are described in more detail below.

OIG Response: The scope of this evaluation and report focuses on how the EPA is identifying imports specifically for inspection and sampling. Our focus on inspection and sampling activities within the FIFRA program reflects the emphasis placed on these activities in OECA monitoring and enforcement guidance to EPA regions. Since FY 2009, the OECA NPMG has identified FIFRA imports as a national enforcement priority. To support this priority, the NPMG lists inspections and sampling as compliance monitoring activities that the regions should conduct. The ACS measure for the FIFRA NPMG is a minimum of 10 FIFRA inspections conducted by EPA regions. OECA's FY 2015 Draft FIFRA NPMG Regional Implementation Strategy also emphasizes two compliance activities, inspections and sampling. The OECA CMS for FIFRA imports (2015) establishes an "aspirational" inspection frequency of 2 percent of all FIFRA imports nationwide and states that the EPA should conduct both for-cause and neutral scheme inspections.

EPA has significantly strengthened the pesticide imports compliance assurance and enforcement program over the past ten years. Program improvements include: (1) ensuring consistency across regions when reviewing Notices of Arrival for Pesticides and Devices (NOA) through protocols and guidance; (2) improving communications among regional import specialists through monthly coordination calls and an intranet-based Import Forum for sharing information; (3) emphasizing aggressive enforcement against noncompliant import products; (4) establishing import compliance as a focus area in OECA's National Program Manager's Guidance (NPMG); (5) increasing regional inspection capabilities so that each region has at least minimal capacity to conduct FIFRA inspections, including import inspections; (6) providing pesticide bulk sampling training for the regions and providing sampling equipment for those inspection activities; and (7) arranging for analytical support from the National Enforcement Investigations Center (NEIC) and the Fort Meade pesticides laboratory operated by the Office of Pesticides Program's (OPP) Biological Evaluation and Assessment Division (BEAD) for regional pesticide enforcement cases, including imports cases.

OIG Response: The scope of our review did not include an assessment of all the EPA's non-inspection compliance activities, enforcement or improvements to the FIFRA imports program. Therefore, we cannot offer an independent opinion on the claimed strengths or improvements. However, our report acknowledges several of the FIFRA program improvements listed above that were related to the scope of our review, such as identifying imports for inspection and sampling.

In addition, EPA has conducted activities to improve FIFRA imports compliance assurance and enforcement generally, including: providing direct compliance assistance to importers,

manufacturers, and brokers; engaging other countries through OECD working groups; and providing FIFRA training to U.S. Customs and Border Protection (CBP) import specialists and inspectors to help them identify regulated pesticide products. OECA has updated its enforcement database, ICIS, to improve EPA's ability to track entry denial enforcement actions and their resulting environmental benefits. Collectively, these efforts have created a much stronger pesticide imports enforcement program that EPA continues to make significant strides towards improving.

OIG Response: This evaluation focused on the inspection and sampling activities of the FIFRA imports program. We did not assess the extent or effectiveness of other import compliance assistance and enforcement, or all external engagements undertaken by the agency. Our review included discussions with CBP and EPA staff in Regions 5, 9 and 10 about coordinating on inspections and identifying pesticides attempting to be illegally imported outside the NOA process. Based on these discussions, we concluded that guidance or protocols specific to each EPA region's relationship with CBP would help to ensure that the EPA is consistently notified about shipments of imported pesticides without a NOA.

We disagree with the Report's premise that the numbers of inspections EPA conducts determines the amount of illegal imports EPA is able to identify and deter. We deter the entry of noncompliant pesticide products through a broad array of mechanisms, only one of which is on-site inspections. In fact, import inspections are not one of the main approaches EPA uses to detect and prevent entry of noncompliant pesticide products into United States commerce. Electronic investigations, tips and referrals from CBP, and other (non-inspection based) investigatory tools are efficient and effective ways to identify noncompliance. Import inspections are used primarily to confirm suspected noncompliance (in the minority of instances where EPA is not able to confirm compliance using the investigatory tools listed above), or to confirm a return to compliance for shipments that have been denied entry due to a violation that can be corrected.

OIG Response: We concluded that low rates of inspections and formulation sampling can create a risk that the EPA may not be identifying, or deterring, the import of pesticides harmful to people or the environment. The OECA NPMG consistently suggests that EPA regions monitor compliance through inspections at ports of entry, and the CMS suggests further engaging in both for-cause and neutral scheme inspections and using targeting strategies to identify imports for possible inspection.

One of EPA's best sources of information regarding suspect shipments attempting to enter the country is CBP. CBP and EPA share regulatory authority at the border, and consistent with the regulations, we rely on each other's expertise and procedures to identify and handle illegal shipments. CBP frequently identifies pesticide imports for which no NOA was submitted and which might require a NOA based on criteria EPA has provided to CBP to help identify such products. In these cases, CBP notifies and then coordinates with EPA on an appropriate course of action, *i.e.*, whether an inspection should occur, whether the shipment should be held and for how long, or whether it should be released under bond, and CBP then responds to the broker or importer to implement the response. This shared responsibility allows EPA to efficiently and effectively identify noncompliant shipments. By utilizing CBP's authority to hold and direct the movement of noncompliant shipments, EPA can determine whether an inspection and/or sampling is needed or whether noncompliance is clear, in which case EPA would work with the importer to assure compliance before releasing the shipment. EPA and CBP's coordination is now entering into a new

electronic era with implementation of the Automated Commercial Environment / International Trade Data System (ACE/ITDS). As that new process gets better established with the regulated trade community, and as our regional pesticide import staff become more comfortable with how the system operates and its capabilities, the ACE/ITDS system is expected to be a significant enhancement for our compliance monitoring efforts.

OECA's current data system does not track many of our efforts to return goods to compliance before they enter U.S. commerce. The system only tracks the enforcement actions that result in entry denial, entry under a Stop Sale, Use or Removal Order (SSURO), or unlawful entries for which a penalty was assessed. The data system does not account for the millions of pounds of noncompliant products that are "delayed" entry while they are returned to compliance. Indeed, providing importers the opportunity to return noncompliant products to compliance before they enter the domestic consumer market, often with the understanding that a penalty action will follow for the illegal import, represents a large part of this program's success in achieving compliance and deterrence. Although EPA data does not capture these activities, the Report should acknowledge this substantial work, and recommend working with EPA to improve tracking in this area.

OECA requests that the OIG reassess its basic assumption that inspections are the primary metric by which to judge the success of the pesticide imports enforcement program, reconsider its findings based on a review of the whole program, and revise the narrative of its Report accordingly. In the attached "Technical Comments to the Draft OIG Report on FIFRA Imports Enforcement Program" document, we have provided specific suggestions for revisions of the Report's text that more accurately reflect the status of the FIFRA imports enforcement program and incorporate appropriate recommendations.

OIG Response: The scope and focus of this evaluation was EPA regional inspections and sampling in the context of the ACS measure, voluntary inspection frequency in the FIFRA CMS, and suggested regional activities in NPMG. Our findings and recommendations are limited to how imports are identified by EPA regions to inspect or sample. Based on the agency's response and technical comments, we have made changes to the report where appropriate.

<u>**Recommendation 1:**</u> Strengthen internal controls by establishing national compliance monitoring goals based on assessment and consideration of available regional resources.

OECA does not agree with this recommendation. While the OIG correctly notes the importance of considering regional resources in developing commitments for inspections and other compliance monitoring activities, OECA already assesses and considers available regional resources as part of the Annual Commitment System (ACS), and its interplay with the FIFRA Compliance Monitoring Strategy (CMS), the OECA NPMG, and the FIFRA Cooperative Agreement Guidance (CAG).

OIG Response: The OIG is recommending that OECA revise its current aspirational frequency goal for import inspections to align more closely with what EPA regions can realistically achieve.

The Report seems to interpret the CMS inspection frequency for imports as a commitment that did not take into consideration regional resources. As explained during the OECA/OIG meeting held on May 11, 2017, the inspection frequency chart should not be taken out of context. The introduction to that chart is very clear and explains the purpose of inspection frequencies and sets forth that:

"Inspection frequencies are intended to help EPA, the states and tribes to understand and meet today's challenges by providing benchmarks that set aspirational compliance monitoring goals. The frequencies presume adequate funding and resources and, therefore, the actual number of inspections conducted may differ from the frequencies set forth below." Further, the CMS reads, "[a]ctual annual program commitments for ALL inspection types are negotiated as part of the cooperative agreement process or are subject to the annual commitment system process. Individual regional, state and tribal circumstances, including resource and workload issues, are addressed during those processes." A proposed aspirational goal is not and was never intended to be a regional commitment. It is possible that the Report has mistakenly interpreted the proposed inspection frequency for imports in the CMS as a commitment by the regions to conduct inspections of 2% of all NOAs. It is not. Regional resources are considered and incorporated, not in setting inspection frequencies in the multi-year framework of the CMS, but, rather in the Annual Commitment System (ACS) process. Since the inspection frequency "presumes adequate funding," inadequate funding can cause EPA to not meet the aspirational goals in the CMS.

OIG Response: The report identifies this inspection frequency goal as voluntary, not as a regional commitment. At the time of our review, we found that EPA had an inspection rate of 0.002 versus the voluntary inspection frequency goal of 2 percent. The report states that the CMS voluntary inspection frequency "presumes adequate funding." However, it is unclear from our review of the CMS what "adequate funding" would be for each region or OECA's strategy to achieve this aspirational goal.

The ACS process is conducted annually and specifically takes into consideration the regional resources in developing the number of inspections to be conducted by program. Commitments made during the ACS process are the annual compliance monitoring goals (not the inspection frequencies in the CMS). The region commits to the negotiated number of inspections for the year. The FIFRA ACS requirement specified, "A minimum of ten (10) FIFRA inspections will enable regional FIFRA inspectors to manage the federal FIFRA program and retain the skills to adequately oversee inspections conducted by FIFRA grantees." Depending upon the resources available, regions have committed to a varying number of inspections as part of the ACS process. The number of those resources committed to import inspections would depend on the balanced pesticide program developed in that region.

The Report fails to place appropriate emphasis on the value of regional NOA reviews and other import-related activities. Inspections are not the whole picture of import compliance monitoring. Specifically, the CMS reads, "It is increasingly challenging to monitor compliance and maintain adequate enforcement response capabilities in the face of a regulated community that continues to grow in size and complexity. While still important, our traditional approach of conducting on-site inspections and pursuing enforcement cannot keep up with expanding responsibilities. It is imperative that compliance monitoring and enforcement agencies be flexible and creative in designing approaches to identify and address violations that pose risk to human health and the environment while maximizing available resources. Therefore, EPA is expanding the range of compliance monitoring activities...." The CMS acknowledges that reducing risk and creating a deterrent effect may be achieved by other means besides traditional inspections and these creative solutions may be a viable way to maximize resources. In fact, where funding and resources have been and will continue to be reduced, EPA will use many of these alternatives to on-site inspections.

Reviewing NOAs and issuing denials and/or conditions is exactly the effective, flexible, creative approach envisioned by this passage in the FIFRA CMS. EPA has the ability to prevent illegal imports from entering the country without expending the resources necessary to conduct inspections at a port of entry. The Report focuses almost exclusively on inspections and does not adequately identify how NOAs provide an enforcement presence and serve a valuable function as a compliance monitoring tool. As presented, the Report may lead readers to believe that people are at risk when the number of inspections decline, when in fact, other compliance monitoring tools, like NOA reviews, provide a strong enforcement presence and deterrent effect. The Report identifies the number of NOA reviews in FY16 (almost 50,000) and FY15 (almost 33,000) conducted by the regions, but overlooks the significance of these efforts. These are an important, less resource intensive, more cost effective way to accomplish compliance monitoring goals for imports.

OIG Response to Recommendation 1: This recommendation is unresolved. In response to the EPA's comments on the draft report, the OIG has modified the wording of this recommendation in the final report to better clarify the intent of the recommendation. The OIG is recommending that OECA set an aspirational inspection frequency that is more in alignment with the resources available to EPA regions for conducting import inspections. In the EPA's supplemental response, the agency proposed a corrective action to identify opportunities for strengthening internal controls, establishing goals, and communicating progress specifically for non-inspection activities. However, this action does not meet the intent of the recommendation. The OIG sees weaknesses in how the EPA establishes aspirational inspection frequency and the agency's supplemental corrective action committed to identifying opportunities for strengthening internal controls for only non-inspection import-related activities.

<u>Recommendation 2</u>: Implement internal controls to monitor and communicate progress on regional goals.

OECA disagrees in part and agrees in part. To the extent this recommendation focuses on monitoring and communicating progress on regional *inspections*, OECA disagrees that current monitoring is inadequate. Developing and reporting annual commitments through the ACS process is part of an agency-wide effort that includes detailed guidance and procedures. However, OECA agrees with the OIG that there may be an opportunity to improve the Agency's internal controls to better track and monitor the other types of EPA activities, outcomes, and benefits of our imports compliance monitoring and enforcement program. Such improvement in tracking will allow OECA to better communicate the Agency's ability to effectively intercept and deter noncompliant and potentially harmful pesticide imports in our effort to protect human health and the environment. OECA therefore proposes as a corrective action that we consider opportunities for enhancement of current capabilities to improve tracking of import-related compliance assurance activities, allowing better communication of regional accomplishments.

This will build upon existing efforts to track, monitor and communicate progress on regional goals through ACS, through the two National Pesticide Meetings per year, and the annual FIFRA Enforcement Managers Meeting during which these specific issues are discussed. Existing efforts also include the internal monthly import calls as well as monthly pesticide calls with regional, OECA and OPP representatives in attendance. Further, import inspections conducted by state grantees are well-monitored because they are only performed at the request of EPA and the results are referred to EPA for enforcement response, if necessary.

OIG Response to Recommendation 2: This recommendation is unresolved. In both the EPA's official response and supplemental response, the proposed corrective action does not address monitoring of import inspections and sampling; it focuses on tracking non-inspection compliance and enforcement assurance activities. Since the proposed action does not also address monitoring and reporting of import inspections and sampling, it does not meet the full intent of the OIG recommendation.

<u>Recommendation 3:</u> Develop agency guidance and training on how EPA regions can use the Automated Commercial Environment System for regional targeting of importers, manufacturers and pesticide products.

EPA agrees with the recommendation that more training in this area will be helpful for the regions as they learn how best to use ACE for targeting. Therefore, OECA will continue its efforts in developing and providing guidance and training on how EPA regions can use the Automated Commercial Environment System. EPA has already been working closely with each region to ensure that all regions have staff with access to ACE and have been trained in the basic functions of the system, as well as the enhanced capabilities available through ACE in particular.

OECA conducted a training pilot before ACE was fully implemented in December 2016 to ensure that EPA regions set up group email boxes to receive email notifications from the ACE system for electronically submitted NOAs, and that each person responsible for the review and approval of NOAs had the proper training required by CBP in order to receive their ACE user access. EPA and CBP scheduled "war room" meetings with participating importers to conduct "live" runs of submissions of electronic NOAs. The "war room" sessions enabled EPA staff to learn: the steps to review labels submitted electronically in ACE, how to gather and download data about the importers and their import shipments, and how to electronically approve completed NOAs.

In addition, OECA has already conducted numerous regional, group, and one-on-one "live" webinar training sessions to provide an introduction on how regional staff can generate, modify and schedule ACE reports. OECA will continue to offer these training sessions and will also be available upon request on an individual basis. As the regional staff become more comfortable with the electronic system, trainings will be expanded to cover the more unique features of the system which will greatly enhance regional targeting capabilities.

The move from the old paper process to the ACE/ITDS electronic process will take time for both the trade community to make the transition and for the regions to become familiar with how ACE handles these filings, how to review the records in ACE, and how to utilize appropriate actions/messaging to the filer for each review. As the number of NOA filings in ACE increase, the number of inquiries from the trade community on how to use the system increase, as does the number of filing errors that require review and amendment. In addition, time and effort will also be spent utilizing relevant features in ACE as part of the regions' overall operational coordination with CBP. While several of the large importers are filing NOAs successfully in ACE, we expect the transition will take at least a year for the overall trade community to become proficient at filing NOAs electronically rather than on paper. Developing regional expertise with the ACE system will also take time.

OIG Response to Recommendation 3: This recommendation is unresolved. The agency's proposed corrective action does not address the full intent of the OIG recommendation to provide both guidance and training to all EPA regions. In the agency's supplemental response, the revised corrective action is responsive to regional training, but it does not address the issue of developing guidance that is included in this recommendation.

<u>Recommendation 4</u>: Direct each EPA region to develop guidance or protocols that define how the region will coordinate with local U.S. Customs and Border Protection offices on illegal pesticides that are imported without Notices of Arrival.

OECA agrees with this recommendation. OECA understands the OIG's concern that each region's relationship with CBP is specific to that region and may result in some inconsistencies in approaches nationally, and agrees with the OIG's observation, as stated in the Report, that new ACE capabilities with respect to processing NOAs provide an opportunity for the regions to have a more consistent and effective working relationship with CBP. OECA will commit to requesting each region to draft a functional protocol for how they coordinate with local CBP offices on illegal pesticides that are imported outside of the normal NOA process.

It is worth noting that as of May 18th for commonly identified pesticide products and potential devices, all filers must either file a NOA or indicate that they do not need to file a NOA (based on their understanding of FIFRA requirements). ACE will provide the ability for the EPA regions to periodically check the filings where the filers say they do not need to file a NOA to see if they in fact should have filed one. EPA regions have not had visibility into those who did not file NOAs in the past.

This new technical capability will allow CBP and EPA to become more effective at identifying unlawful importation of pesticides. Additional guidance and protocols will be considered as the new system is, over the course of this inaugural year, implemented and enforcement practitioners at both agencies learn the nuances of the program and the need for guidance or protocols.

OIG Response to Recommendation 4: This recommendation is resolved. The OIG accepts the proposed corrective action and scheduled completion date.

Not in Agreement

No.	Recommendation	Agency Explanation/Response	Proposed Corrective Action
1	Strengthen internal controls by establishing national compliance monitoring goals based on assessment and consideration of available regional resources.	Assessment and consideration of available regional resources is already conducted and is represented by the Annual Commitment System (ACS).	No further action proposed.
2	Implement internal controls to monitor and communicate progress on regional goals.	Existing internal controls regarding inspections exist through the ACS development and tracking process, National Pesticide Meetings, annual FIFRA Enforcement Managers Meeting, internal monthly import calls, monthly pesticide calls with regional, OECA and OPP representatives, and EPA-requested import inspections conducted by state grantees.	By September 30, 2019, consider opportunities for enhancement of current capabilities to improve tracking of non-inspection, import-related compliance assurance activities, allowing better communication of regional accomplishments.

In Agreement

No.	Recommendation	Agency Explanation/Response	Proposed
			Corrective Action
3	Develop agency guidance and training on how EPA regions can use the Automated Commercial Environment System for regional targeting of importers, manufacturers and	We can expand training efforts, working closely with the Office of Environmental Information (OEI) and the regions to implement the new ACE/ITDS system. Learning the system and how to use its new capabilities is considered critical for successful implementation of ACE/ITDS. OECA will continue this effort in group settings and one-on-one trainings.	Conduct at least two (2) new group training webinars and one-on-one personal trainings, upon request, by September 30, 2018.
	importers,	settings and one-on-one trainings.	

No.	Recommendation	Agency Explanation/Response	Proposed Corrective Action
4	Direct each EPA region to develop guidance or protocols that define how the region will coordinate with local U.S. Customs and Border Protection offices on illegal pesticides that are imported without Notices of Arrival.	Since each regional office deals with different US CBP District Offices which are uniquely managed, each region has established its own protocol for how EPA and CBP interact regarding pesticide imports. The issue concerning pesticide products being imported without filing an NOA is partly being addressed through the new ACE/ITDS system which will have the capability to identify products commonly identified as pesticides and require them to file an NOA or explain why they do not need to file an NOA. Regions will have the ability to check those non-filers to see if, in fact, they should have filed an NOA. Nevertheless, each region should have an established protocol providing guidance on how CBP and each region should interact to share information about illegal pesticide imports.	OECA will request each region memorialize a functional protocol for how they will coordinate with local CBP offices on illegal pesticides being imported without NOAs. Regions will be asked to have their protocols in place by September 30, 2018.

Agency Supplemental Response to Draft Report



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

AUG 1 6 2017

MEMORANDUM

OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

- SUBJECT: Supplemental Response to the Office of Inspector General Draft Report: "EPA Can Better Reduce Risks From Illegal Pesticide Imports," dated June 27, 2017, Report No. OPE-FY16-0025
- FROM: David Hindin, Director Davel Hunch Office of Compliance Office of Enforcement and Compliance Assurance

Susan Shinkman, Director Office of Civil Enforcement Office of Enforcement and Compliance Assurance

TO: Jeffrey Harris, Director Toxics, Chemical Management and Pollution Prevention Evaluations Office of Program Evaluation Office of Inspector General

On August 16, 2017, Jeffrey Harris, Ganesa Curley, and Steve Weber of the Office of Inspector General (OIG) met with managers and staff from OC and OCE. The parties discussed OECA's July 27, 2017 Response to the OIG Draft Report: EPA Can Better Reduce Risks From Illegal Pesticide Imports. Presented below are changes to the table in OECA's Response that the parties discussed would be acceptable for consideration in the OIG's final report:

No.	Recommendation	Agency Explanation/Response	Proposed Corrective Action	
1	Strengthen internal controls by establishing national compliance monitoring goals based on assessment and consideration of available regional resources.	Assessment and consideration of available regional resources for inspections are already conducted and is represented by the Annual Commitment System (ACS).	By September 30, 2019, for non- inspection import- related compliance assurance activities, identify opportunities for strengthening internal controls, establishing goals.	
2	Implement internal controls to monitor and communicate progress on regional goals.	Existing internal controls regarding inspections exist through the ACS development and tracking process, National Pesticide Meetings, annual FIFRA Enforcement Managers Meeting, internal monthly import calls, monthly pesticide calls with regional, OECA and OPP representatives, and EPA-requested import inspections conducted by state grantees.	establishing goals, and communicating progress of regional accomplishments.	
3	Develop agency guidance and training on how EPA regions can use the Automated Commercial Environment System for regional targeting of importers, manufacturers and pesticide products.	We can expand training efforts, working closely with the Office of Environmental Information (OEI) and the regions to implement the new ACE/ITDS system. Learning the system and how to use its new capabilities is considered critical for successful implementation of ACE/ITDS. OECA will continue this effort in group settings and one-on- one trainings.	Conduct at least two (2) new group training webinars by September 30, 2018.	
4	Direct each EPA region to develop guidance or protocols that define how the region will coordinate with local U.S. Customs and Border Protection offices on illegal pesticides that are imported without Notices of Arrival.	Since each regional office deals with different US CBP District Offices which are uniquely managed, each region has established its own protocol for how EPA and CBP interact regarding pesticide imports. The issue concerning pesticide products being imported without filing an NOA is partly being addressed through the new	OECA will request each region memorialize a functional protocol for how they will coordinate with local CBP offices on illegal pesticides being imported without NOAs. Regions will	

ACE/ITDS system which will have the capability to identify products commonly identified as pesticides and require them to file an NOA or explain why they do not need to file an NOA. Regions will have the ability to check those non-filers to see if, in fact, they should have filed an NOA.	be asked to have their protocols in place by September 30, 2018.
Nevertheless, each region should have an established protocol providing guidance on how CBP and each region should interact to share information about illegal pesticide imports.	

If you have any questions or concerns, please contact the OECA Audit Liaison, Gwendolyn Spriggs, at (202) 564-2439.

cc: Rosemarie Kelley, OECA/OCE Gregory Sullivan, OECA/OCE Lauren Kabler, OECA/OCE Ed Messina, OECA/OC Rochele Kadish, OECA/OC Gwendolyn Spriggs, OECA/OAP

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