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PESTICIDE SAFETY

Improvements Needed in EPA's Good Laboratory Practices Inspection Program

GAO Highlights

Highlights of GAO-14-289, a report to the Ranking Member, Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Pesticides used to control weeds, unwanted insects, and fungi contribute to agricultural productivity and public health by preventing crop damage and controlling pests. However, pesticides may also have adverse effects. EPA's OPP reviews applications for pesticide products and registers those that it determines do not have unreasonable adverse effects on health and the environment. EPA's OECA inspects laboratories where these pesticides are tested to ensure that the laboratories followed EPA's GLP regulations. FDA also conducts GLP laboratory inspections. GAO was asked to review EPA's GLP Compliance Monitoring Program. This report examines the extent to which EPA (1) inspects for GLP compliance laboratories that test pesticides and the challenges EPA faces in doing so, (2) uses the information obtained through GLP inspections in its pesticide decision-making process, and (3) collaborates with FDA on GLP inspections. To conduct this work, GAO reviewed relevant agency documents and data, conducted a nongeneralizeable survey of 20 laboratories, and interviewed EPA and FDA officials and laboratory and other stakeholders.

What GAO Recommends

GAO recommends, among other things, that EPA assess its authority and need for a fee-based inspection system for the GLP Program, determine why the database information to prioritize laboratories is incomplete, and that EPA and FDA develop a process to collaborate and share information on planned and completed inspections. EPA and FDA agreed with GAO's recommendations.

View GAO-14-289. For more information, contact John Neumann at (202) 512-3841 or neumannj@gao.gov

What GAO Found

The Environmental Protection Agency (EPA) inspects few laboratories that test pesticides for Good Laboratory Practices (GLP) compliance and faces challenges in selecting laboratories to inspect. For fiscal years 2009 to 2013, EPA's Office of Enforcement and Compliance Assurance (OECA) GLP Compliance Monitoring Program inspected from 51 to 80 laboratories annually from an estimated 1,400 that conducted studies used to support applications for pesticide registrations. During the same period, EPA reduced OECA's GLP Compliance Program budget and staff by about half. Laboratory and other stakeholders told GAO that not having GLP inspections can negatively affect a laboratory's business domestically and abroad. OECA prioritizes laboratories for GLP inspections using criteria that reflect, among other things, how long it has been since the last inspection and the number of studies the laboratory has conducted that have been submitted to EPA's Office of Pesticide Programs (OPP) in support of a pesticide registration application. However, GAO found that some laboratory information in the OECA database used to prioritize inspections was either inaccurate or incomplete, making it difficult to target laboratories for inspections. GAO also found that OECA is considering ways the GLP program could be run more efficiently given its recent budget cuts and concerns of stakeholders about the infrequent GLP inspections. For example, OECA officials have informally discussed the possibility of charging user fees that may be used to fund the GLP program, as the U.S. Food and Drug Administration (FDA) and many other countries do, but the agency has not conducted a formal evaluation of user fees. Without formally assessing the need for such fees, EPA cannot determine whether charging and retaining the fees would be possible and whether such fees could help make the inspection program self-sustaining.

EPA rarely uses GLP inspection results in making its initial pesticide registration decisions. An OPP official said that this is because most inspections occur after decisions have been made. OPP officials said they have not denied or revoked any pesticide registrations based on OECA GLP inspections during the past 5 years, but OPP has taken other actions, such as requiring that a study be repeated because of subsequent laboratory inspection information. According to EPA officials, OPP and OECA have communicated on an informal basis about OPP's inspection priorities before a pesticide registration has taken place.

EPA and FDA do not regularly collaborate on laboratory inspections and may be duplicating each other's work at some of these laboratories. In 1984, EPA and FDA entered into an agreement to collaborate on GLP inspections and met quarterly to discuss upcoming inspections; the agreement ended in 2004 although meetings continued until 2007. From fiscal year 2005 to 2012, EPA and FDA conducted a total of 170 GLP inspections of the same 37 laboratories. In 38 of 170 inspections, the agencies inspected the same laboratory during the same fiscal year. EPA and FDA have independent but similar sets of GLP regulations. Officials from both agencies said it would be useful to know which laboratories the other agency was planning to inspect and to have those inspection results, since each agency can only inspect a certain number of laboratories each year. Absent collaboration and information sharing with FDA on planned and completed GLP inspections, EPA will have difficulty efficiently using its limited resources to increase the number of inspections it conducts.