Improvements Needed in EPA's GLP Inspection Program

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GAO Report on EPA's GLP Program

- *Pesticide Safety: Improvements Needed in EPA's Good Laboratory Practices Inspection Program.* GAO-14-289
- Published in May 2014
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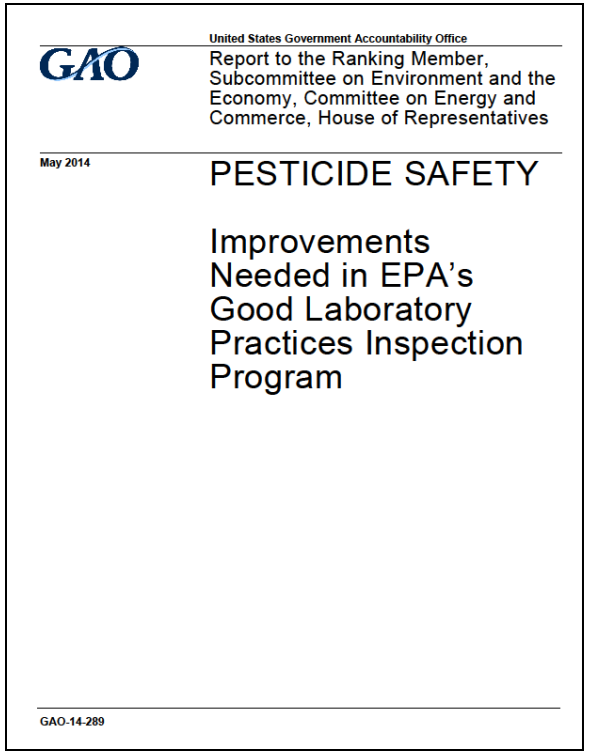

United States Government Accountability Office

Report to the Ranking Member, Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

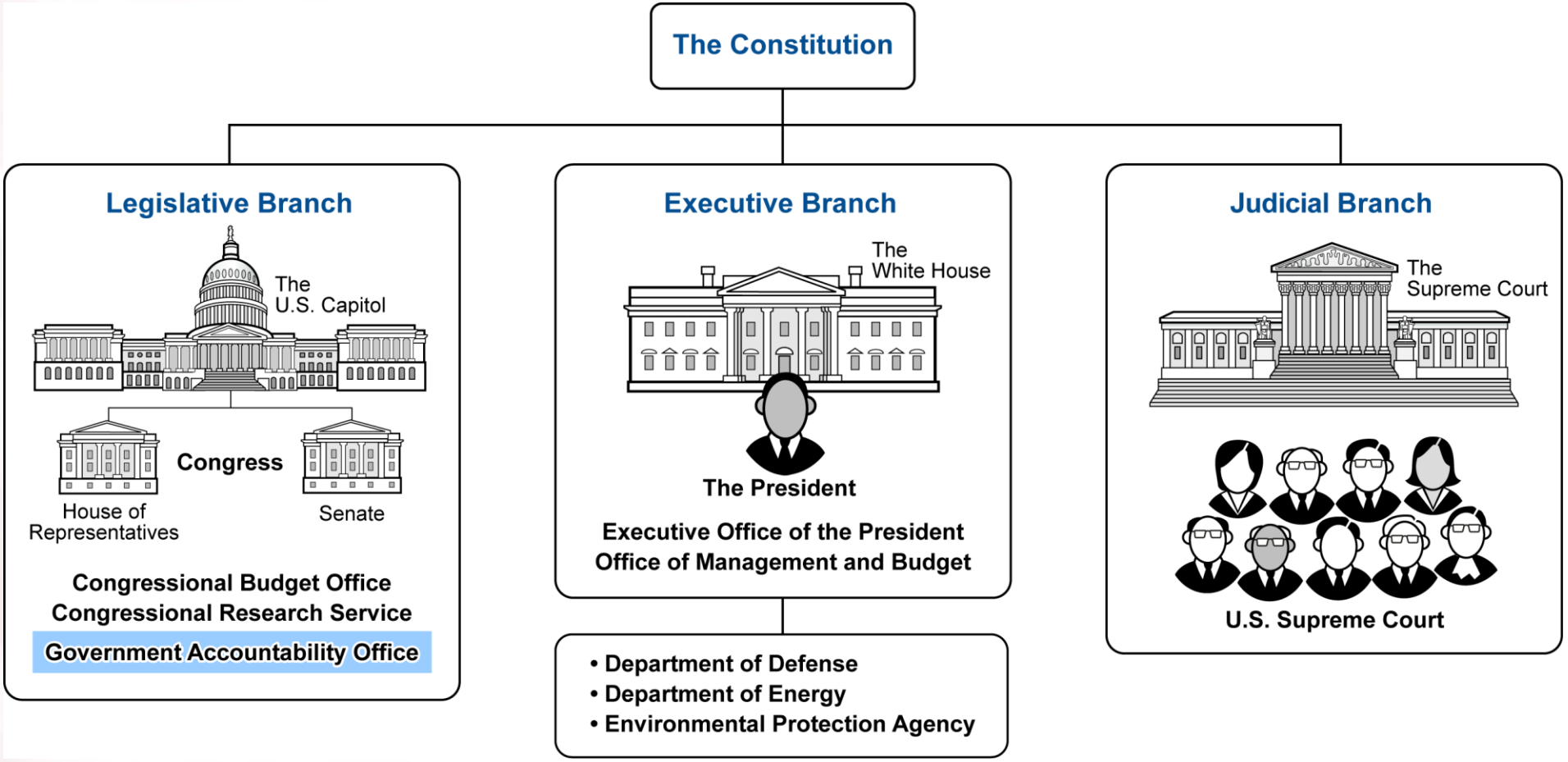
May 2014

PESTICIDE SAFETY

Improvements Needed in EPA's Good Laboratory Practices Inspection Program

GAO-14-289

Background


The Constitution
Legislative Branch
The U.S. Capitol
Congress
House of Representatives
Senate
Congressional Budget Office
Congressional Research Service
Government Accountability Office
Executive Branch
The White House
The President
Executive Office of the President
Office of Management and Budget
• Department of Defense
• Department of Energy
• Environmental Protection Agency
Judicial Branch
The Supreme Court
U.S. Supreme Court

Background

- GAO-14-289 done at the request of Congressman Paul Tonko (*Ranking Member, Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives*)

- Environmental and other groups have raised concerns about EPA's pesticide registration program. Pesticide manufacturers have expressed concern about how infrequently EPA conducts Good Laboratory Practices (GLP) inspections.

Research Objectives

- GAO's report examined the extent to which:

  1) EPA inspects pesticide testing labs for GLP compliance and the challenges, if any, EPA faces in doing so;

  2) EPA uses the information obtained through GLP inspections in its pesticide decision-making process; and

  3) EPA and FDA collaborate on GLP inspections

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Methodology

- Time Frame for Audit: November 2012 to May 2014

- Reviewed relevant laws, regulations, agency guidance
- Analyzed EPA and FDA lab and inspection data
- Visited four labs
- Surveyed labs whose studies were submitted to EPA
- Interviewed EPA and FDA officials
- Interviewed 25 representatives from laboratories, pesticide manufacturing companies, trade associations and foreign government GLP programs

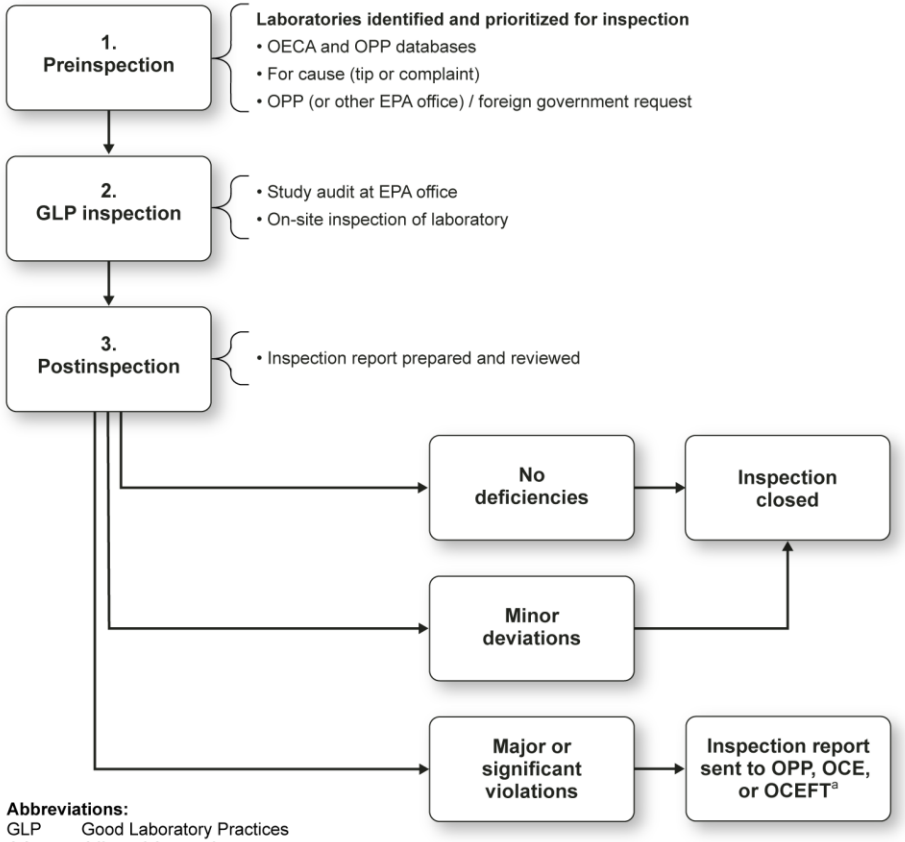
EPA's GLP Inspection Process

- EPA Offices Involved:
  - Office of Enforcement and Compliance Assurance (OECA)
  - Office of Pesticide Programs (OPP)

EPA's GLP Inspection Process

- 3 Stages

1. Preinspection
2. GLP Inspection
3. Postinspection



Abbreviations:
GLP Good Laboratory Practices
OCE Office of Civil Enforcement
OCEFT Office of Criminal Enforcement, Forensics and Training
OECA Office of Enforcement and Compliance Assurance
OPP Office of Pesticide Programs

Source: GAO analysis of EPA documents.

EPA's GLP Inspection Process

1. Preinspection Stage

   a) Neutral Scheme Targeting Module used to identify labs to inspect. Most labs selected via this method.
      - Numerical weights on set of criteria such as:
        - Length of time since last inspection
        - Severity of previous inspection findings
        - Number of studies conducted by the lab

   b) Other ways EPA selects labs for inspection:
      - Requests from OPP or foreign government
      - For cause inspection based on anonymous complaint

EPA's GLP Inspection Process

2. GLP Inspection Stage
   a) Study Audit: OECA inspectors conduct study audits and evaluate lab studies submitted to OPP
   b) On-Site Inspection: OECA inspector travels to the lab for an on-site inspection

3. Postinspection Stage
   - OECA inspectors prepare an inspection report

Objective 1

- Research Objective 1: The extent to which EPA inspects pesticide testing labs for GLP compliance and the challenges, if any, EPA faces in doing so.

- Finding: EPA has inspected few labs for GLP compliance and faced challenges in selecting labs for inspections.

Objective 1

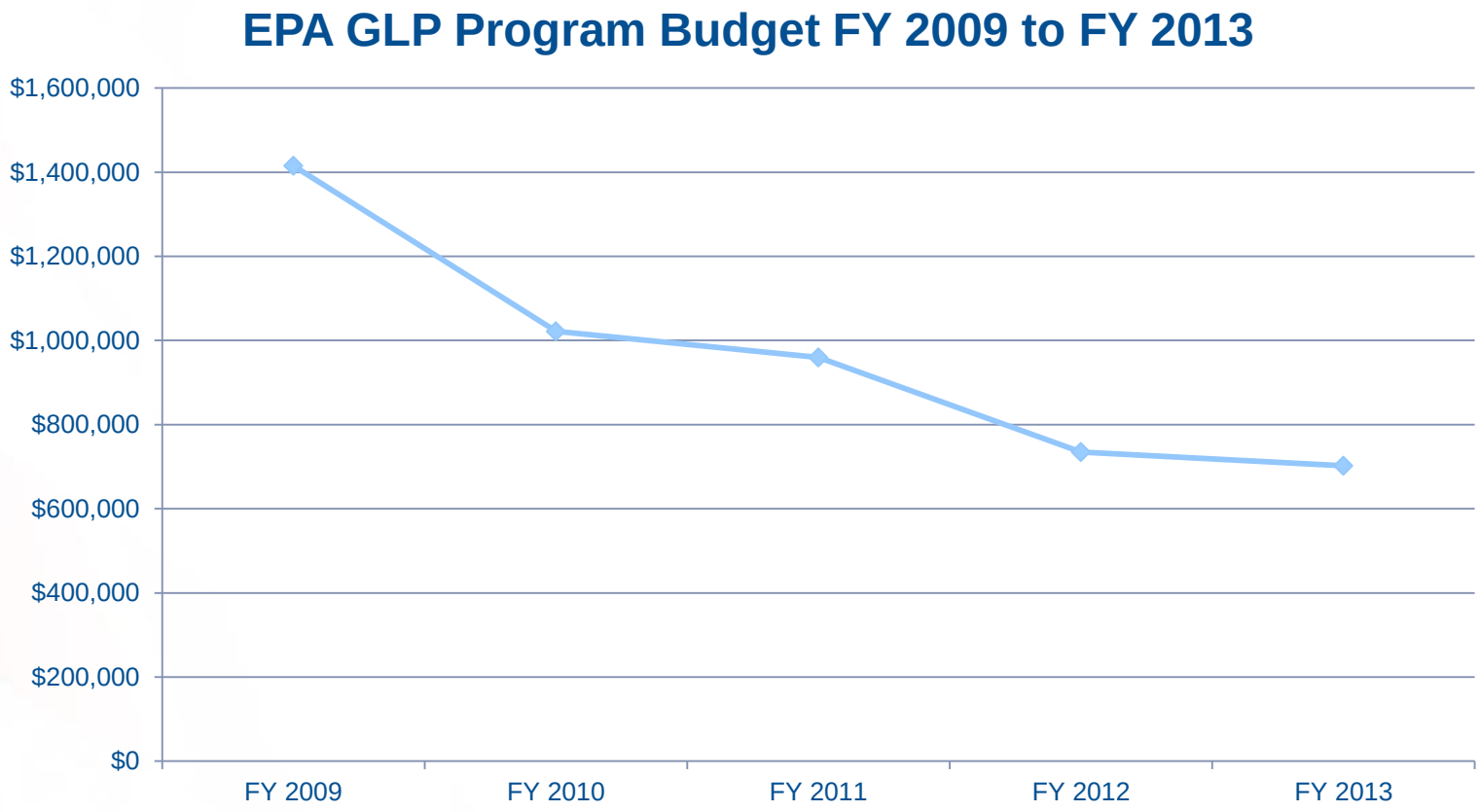
- Approximately 1,400 labs eligible for GLP inspection
  (based on data FY 2009 through FY 2013)
- EPA inspected about 4% to 6% of the eligible labs
- Average of 69 inspections annually
  (based on inspection data from FY 2009-2013)

Objective 1

- Negative effect of infrequent GLP inspections according to stakeholders and international officials we interviewed:
  - If labs can’t prove GLP compliance, their business can be negatively affected.
  - Example of a U.S. study rejected by the Netherlands in 2011 because contractor lab had not been inspected by EPA.

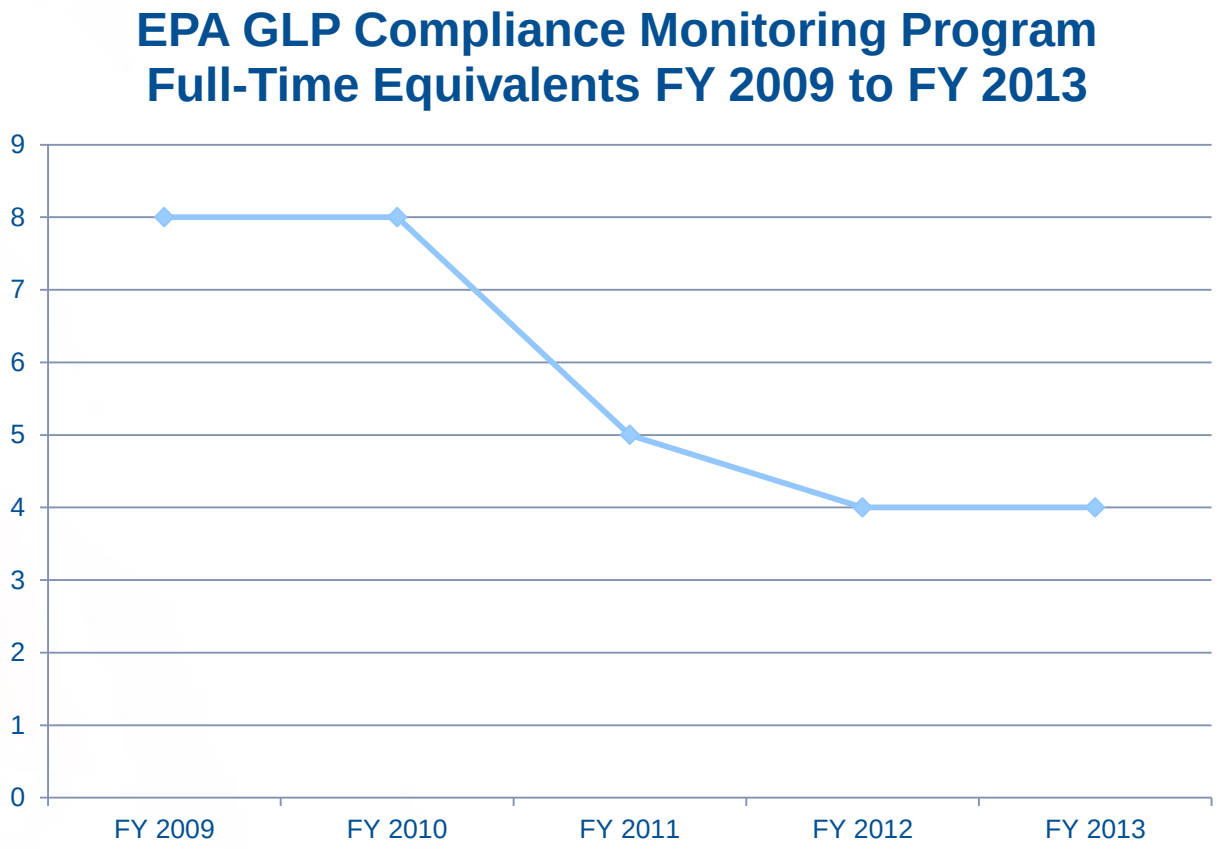
Objective 1

- Reduction in GLP Program Budget



Objective 1

- Reduction in Number of GLP Staff



Objective 1:

- Data Challenges
  - Labs' information in databases was sometimes incomplete or inaccurate.
  - Negative effect is that inspectors may not be able to efficiently or effectively identify the labs needing inspection.

Objective 1

- EPA has tried to respond to some of these challenges and industry concerns.
- EPA made changes in FY 2012:
  - Started to cluster GLP inspections by labs' geographic proximity to each other
  - Audits studies at EPA offices rather than on-site at a lab to reduce the amount of time spent inspectors spend at a lab

Objective 1

- EPA was considering other ways to increase the number of GLP inspections

  1. Third parties to conduct GLP inspections

  2. User fees to fund GLP inspections
     - EPA has discussed the possibility of user fees
     - FDA and some OECD member countries charge user fees for GLP inspections

Objective 1: Recommendations

Based on these findings, GAO recommended that EPA:

1. Assess the authority and need for a fee-based inspection system, and if such a system is warranted, establish a user fee system, seeking additional legislative authority, if necessary, to make the laboratory inspection program self-sustaining.

2. Direct OECA and OPP to ascertain the exact causes of inaccurate and incomplete data in its databases and take action to ensure that the data, such as identification of performing laboratories and inspection history, are accurately recorded.

Objective 2

- Research Objective 2: To what extent does EPA use the information obtained through GLP inspections in its pesticide decision-making process?

- Finding: EPA rarely used GLP inspection results in initial pesticide registration decisions but sometimes used them for later reexamination.

Objective 2

- Most GLP inspections occur after pesticide registration decisions are made
  - Statutory requirements for pesticide registration decisions to be made within 3-24 months of receipt of the pesticide application.
  - GLP staff can't always set up and conduct inspections of many of these labs involved within these time frames.

Objective 2

- If GLP inspection reveals deficiencies, OPP staff will review studies to see if it affects findings.
- OPP staff said they have not denied or revoked a pesticide registration based on a GLP inspection

- Communication and coordination between OPP and OECA is
  - Informal
  - Not documented in procedures

Objective 2: Recommendation

- GAO Recommended that
  - The EPA Administrator direct OECA and OPP to develop documented procedures to coordinate and prioritize labs for inspections.

Objective 3

- Research Objective 3: To what extent do EPA and FDA collaborate on GLP inspections?

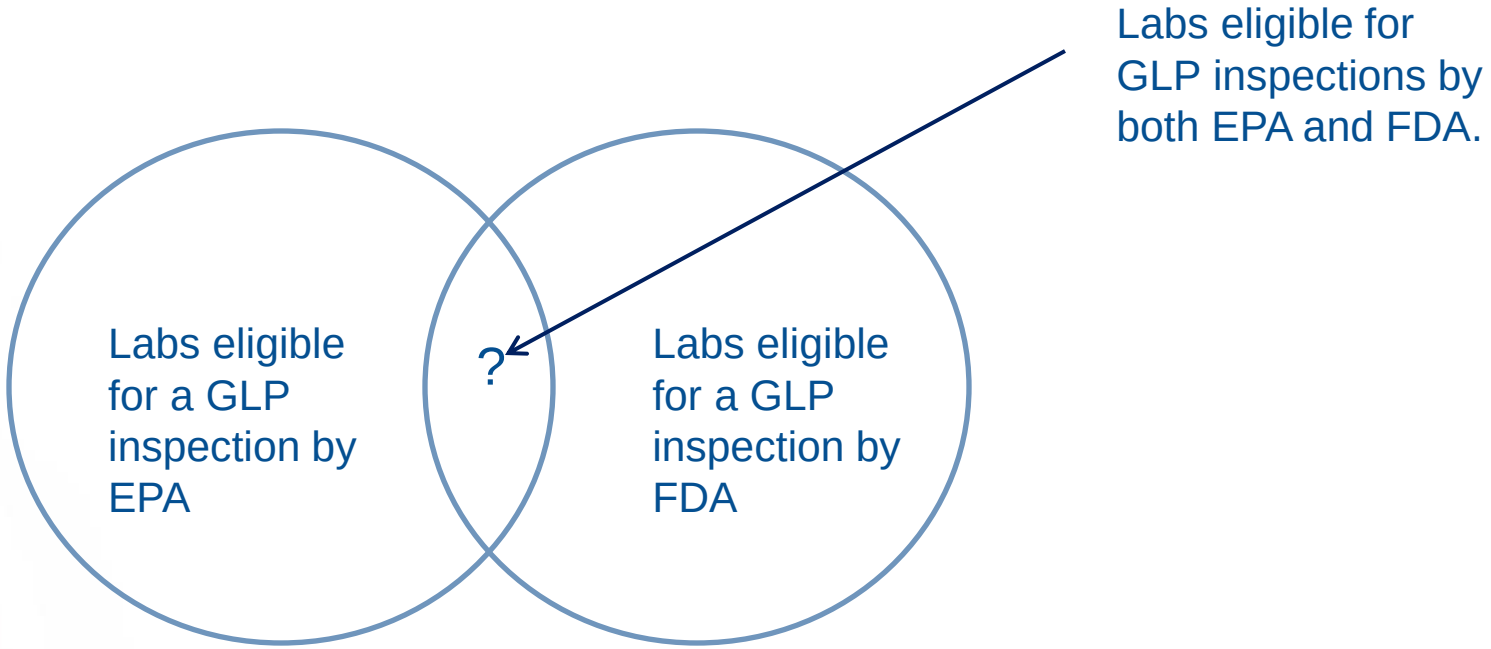
- Finding: EPA and FDA do not regularly collaborate on lab inspections and may be duplicating each other's work.

Objective 3

- FDA also inspects labs for GLP compliance
- EPA's and FDA's GLPs are similar, according to EPA and FDA officials
- EPA's and FDA's GLP inspections are comparable, according to senior OECA official and officials from three labs inspected by both agencies

Objective 3

- There are labs eligible for inspection by EPA and FDA (most likely in toxicology labs)



Objective 3

- EPA and FDA's 1984 interagency agreement
  - Agreed to collaborate on GLP inspections
  - Met quarterly
  - FDA used to send EPA a list of labs it planned to inspect.
  - FDA performed 9 inspections for EPA
  - Regular collaboration and communication ended by 2007; occasional communication since that time

Objective 3

- Inspections of Same Labs
  - FY 2005-2012, EPA and FDA conducted a total of 170 GLP inspections of the same 37 labs.
  - In 38 of 170 inspections, the agencies inspected the same lab during the same FY.

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Objective 3

- EPA and FDA do not regularly share inspection results or information about planned future GLP inspections.
- Officials from both agencies said it would be useful to know which labs the other agency was going to inspect and to have inspection results.
- Negative Effect: Agencies are not leveraging their inspection resources and missing opportunities to increase the annual number of GLP inspections.

Objective 3: Recommendation

- GAO Recommended that EPA and FDA:

  develop a formal written agreement, such as a memorandum of understanding, that outlines how the two agencies plan to regularly collaborate and share information on GLP inspections and avoid duplication of inspections so that EPA can more efficiently use its limited resources.

Next Steps

- GAO issued a four recommendations to EPA pertaining to its GLP Monitoring Program

- GAO will follow up with EPA annually to learn what actions the agencies may have taken in response to our recommendations.

References

Pesticide Safety: Improvements Needed in EPA's Good Laboratory Practices Inspection Program. GAO-14-289: May 15, 2014.

Other Relevant GAO Reports:

- *Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations.* GAO-15-38: Oct 7, 2014.
- *Pesticides: EPA Should Take Steps to Improve Its Oversight of Conditional Registrations.* GAO-13-145: Aug 8, 2013.

Reports are available online at www.gao.gov