Message

**From**: Sullivan, Greg [Sullivan.Greg@epa.gov]
**Sent**: 7/19/2018 7:14:06 PM
**To**: Teter, Royan [Teter.Royan@epa.gov]
**CC**: Werner, Jacqueline [Werner.Jacqueline@epa.gov]
**Subject**: RE: Importance of the GLP Audit and Inspection Program

Catherine told me she was working on it.

---

**From:** Teter, Royan
**Sent:** Thursday, July 19, 2018 2:51 PM
**To:** Sullivan, Greg <Sullivan.Greg@epa.gov>
**Cc:** Werner, Jacqueline <Werner.Jacqueline@epa.gov>
**Subject:** RE: Importance of the GLP Audit and Inspection Program

We'll proceed with checking in with OPP. It would be a good OD, particularly if there is going to be a push to move the program back to OCSPP. **Ex. 5 Deliberative Process (DP)**

---

**From:** Sullivan, Greg
**Sent:** Thursday, July 19, 2018 2:38 PM
**To:** Teter, Royan <Teter.Royan@epa.gov>
**Cc:** Werner, Jacqueline <Werner.Jacqueline@epa.gov>
**Subject:** RE: Importance of the GLP Audit and Inspection Program

Susan didn't ask for a response – but it seems we should check in at least on where OPP is on the program, and its continuing relevance to registration process. Please check in with them, **Ex. 5 Deliberative Process (DP)**

---

**From:** Teter, Royan
**Sent:** Thursday, July 19, 2018 2:32 PM
**To:** Sullivan, Greg <Sullivan.Greg@epa.gov>
**Cc:** Werner, Jacqueline <Werner.Jacqueline@epa.gov>
**Subject:** RE: Importance of the GLP Audit and Inspection Program

They make some interesting points about the importance of GLP inspections to registering products in other countries. However, the program was/is intended to inform domestic registration decisions. While more conversation with OPP is prudent, what we've heard so far is that the GLP program has less relevance in today's registration process because modern technology removes much of the opportunity for faulty data. **Ex. 5 Deliberative Process (DP)**
**Ex. 5 Deliberative Process (DP)**

---

**From:** Sullivan, Greg
**Sent:** Thursday, July 19, 2018 1:04 PM
**To:** Teter, Royan <Teter.Royan@epa.gov>
**Cc:** Werner, Jacqueline <Werner.Jacqueline@epa.gov>
**Subject:** FW: Importance of the GLP Audit and Inspection Program

---

**From:** Bodine, Susan
**Sent:** Thursday, July 19, 2018 12:07 PM
**To:** Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>

**Cc:** Starfield, Lawrence <Starfield.Lawrence@epa.gov>; Traylor, Patrick <traylor.patrick@epa.gov>
**Subject:** FW: Importance of the GLP Audit and Inspection Program

---

**From:** Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
**Sent:** Thursday, July 19, 2018 9:49 AM
**To:** Bodine, Susan <bodine.susan@epa.gov>
**Cc:** Starfield, Lawrence <Starfield.Lawrence@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Sharpe, Kristinn <Sharpe.Kristinn@epa.gov>; janet collins <jcollins@croplifeamerica.org>; Jay Vroom <JVroom@croplifeamerica.org>; Allison Jones (allisonjones@naicc.org) <allisonjones@naicc.org>
**Subject:** Importance of the GLP Audit and Inspection Program

Ms. Bodine:

On behalf of Crop Life America (CLA) and the National Association of Independent Crop Consultants (NAICC), we want to follow up the CLA visit with you on May 10 with more detail on the importance of the Good Laboratory Practice (GLP) Audit and Inspection program to the crop protection industry. We would welcome the opportunity to continue this conversation. I am taking the liberty of copying other EPA leaders with a stake in this program.

- We are concerned about a loss of vision within the management at the Environmental Protection Agency (EPA) regarding what the GLP program should do and be and accomplish.
- The GLP inspection and audit program is being starved of resources and personnel. In 1994, when the program was under the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), there were 19 inspectors, 6 support staff, and a contractor supporting the GLP program. Currently in the Office of Enforcement and Compliance Assurance (OECA) there are 4 inspectors and no support staff.
- A reasonable frequency of audit and inspection of the individual labs and facilities is necessary to assure EPA of the quality and integrity of the data supporting pesticide product registrations, as required by law, regulation, and international agreement.
- There are some 1400 laboratories, facilities, and field sites in the US participating in GLP research on pesticides. With current staffing of the audit and inspection program, keeping up with that number of facilities seems like an impossible task.
- By comparison, the burden of other GLP audit and inspection programs is more balanced, for example: US-FDA (300 labs, 75 inspectors); Canada (40 labs, 23 inspectors); UK (100 labs, 8 inspectors); Germany (160 labs, 53 inspectors). Many of these inspectors in other programs are part time.
- If inspections are not conducted with sufficient frequency, registrants may feel obligated to take their research to foreign contract research organizations (CROs), leading to loss of business for US laboratories.
- The US is obligated as a member of the Organization for Economic Cooperation and Development (OECD) to comply with requirements of formal OECD Decisions regarding GLP and audits and inspections. This has a direct bearing on the ability of US industry to operate internationally. Among other things, these requirements cover:
    - The nature and frequency of audits and inspections;
    - Providing statements of such audits and inspections to foreign governments in a timely manner.
- Historically, US has had a preeminent role in the development and management of the GLP and Mutual Acceptance of Data (MAD) programs under OECD. In recent years, EPA participation in the OECD GLP Committee and other international forums has been curtailed, resulting in loss of leadership, where the US should be in the forefront. The US should maintain active engagement in moulding and shaping the future direction of MAD.
- Because the EPA does <u>not</u> issue compliance certificates to GLP facilities, the inspection closure letters from EPA are vital in the registration submission process to many other countries, to assure studies have been conducted

in a GLP-compliant facility. Lack of the closure letter creates a significant barrier to acceptance of US studies by other countries.

- Registrants experience delays in registrations when they have to obtain a closure letter from the laboratory to send to the monitoring authority in the foreign government. The current practice is to obtain the closure letter in advance to include with the study report in the registration application, and not wait for the monitoring authority to make a request.
- New CROs have a hard time breaking into the business, because of lack of inspections and lack of the ability to be inspected.
- The industry – both registrants and CROs – have a great deal of confidence in and respect for Francis Liem who has led the audit and inspection effort for many years. The Agency must maintain this level of experience and expertise.
- Interaction of audit and inspection staff with industry has been curtailed. We depend on frequent interaction with them in meetings and conferences to keep up to date on the latest developments in GLP.
- The prospect of additional funding authorized by the Pesticide Registration Improvement Act (PRIA) to bolster the GLP program is heartening. It is the clear intent of PRIA legislation that this additional funding supplement, and not replace, current funding from appropriations. It is essential that the new funds set aside for this purpose be spent exclusively on the GLP program.
- In 2016 there was serious consideration of moving the audit and inspection program to the Office of Chemical Safety and Pollution Prevention (OCSPP). We felt then and still feel now that this would be a very positive step for the program.
    - The GLP program began in OPPTS {now known as OCSPP), and was located there until the mid 1990s.
    - The principle purpose of EPA's GLP program is to support the registration decisions made by the Office of Pesticide Programs (OPP) within OCSPP.
    - With such an organizational change, the GLP program could be more responsive to the audit and inspection needs of OPP for specific studies and facilities.
    - Administration of funds from product maintenance fees under PRIA for the GLP program would be simpler and more straightforward in OCSPP, which administers all other PRIA funds.
    - The GLP program does not audit or inspect research performed by OPP, so the organizational connection would not represent a conflict of interest.
    - OCSPP can maintain the appropriate organizational structure to assure independence of the GLP program.
- A robust GLP program in full compliance with the OECD MAD requirements demonstrates to all stakeholders the integrity of industry-supported and generated data that underpin pesticide registrations in the US and around the world. The EPA has a significant responsibility to vigorously defend its Pesticide Programs, and the GLP program should contribute in that regard.

Ray S. McAllister, Ph.D.
Senior Director, Regulatory Policy
CropLife America
202-872-3874 (office)
202-577-6657 (mobile)
ray@croplife.us

Allison Jones
Executive Vice President
National Alliance of Independent Crop Consultants (NAICC)
901.861.0511
AllisonJones@NAICC.org
www.NAICC.org

CC:

Larry Starfield, Principal Deputy Assistant Administrator, OECA
Jeff Morris, Director, OPPT; chief US Head of Delegation to OECD on Chemicals
Nancy Beck, Acting Assistant Administrator, OSCPP
Louise Wise, Deputy Assistant Administrator, OSCPP
Rick Keigwin, Director, OPP
Ed Messina, Acting Deputy Director, OPP
Daisy Letendre, Smart Sectors Program
Kristinn Sharp, Smart Sectors Program