Laws Surrounding GLP’s (FIFRA, FFDCA, PPA, and OECD requirements)

NAICC Meeting - Thursday, January 17, 2019

*Back to the Basics – QA Session*

Savannah, GA

Chair: Angela Dawson, EPL Bio Analytical Services

**Presenter:** Sandy Daussin, RPI, Apex, NC
TOPICS
Presentation and Discussion

I. Legal Landscape

II. Administrative Law

III. Rulemaking Process

IV. How GLPs Fit
Balance of Power

**Article I – Legislative Powers**
- Provides the enumerated list of powers of Congress
- Power to make statutes
- Power of the purse

**Article II - Executive Powers**
- President’s function is to fulfill the will of Congress
- Congress has delegated some power to the Executive Branch

**Article III - Judicial Powers**
- Federal courts have limited jurisdiction
- State courts have general jurisdiction
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Sources of Law

Statutes (e.g., FFDCA, FIFRA)

Administrative Law (e.g. GLPs)

Common Law and Case Law

Enabling Statutes (Empower Executive Branch)

Promulgate Regulations (Administrative Courts)

Interpretation of Laws (e.g. stand by things decided)
“The Fourth Leg Law”

Administrative Law (e.g. GLPs)

- Have same power as federal laws
- Cover topic areas that are too complex and dynamic to be regulated by Congress
- Agencies can only act within defined scope of enabling statute

Executive Branch

- 15 Executive Departments
- Numerous Independent Agencies
  - Constitutionally part of the executive branch but are not executive departments
# Statues with Data Quality Regulations

<table>
<thead>
<tr>
<th>Statute (Passed by Congress)</th>
<th>GLP Regulation (Promulgated by Agency)</th>
<th>Agency</th>
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</thead>
<tbody>
<tr>
<td>Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)</td>
<td>40 CFR Part 160</td>
<td>EPA</td>
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<tr>
<td>Plant Protection Act (PPA)</td>
<td>None</td>
<td>USDA</td>
</tr>
<tr>
<td>Federal Food, Drug, and Cosmetic Act (FFDCA)</td>
<td>21 CFR Part 58</td>
<td>FDA</td>
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Organization for Economic Co-operation and Development (OECD) and the MAD Agreement
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Administrative Rulemaking Process

1. **Congress delegates authority** by passing a law.
2. **Agency drafts the proposed rule.**
3. Draft proposed rule is reviewed/approved by **Agency.**
   - If significant, draft rule reviewed by Office of Management and Budget (OMB).
4. **Notice** of new rule is published in the **Federal Register** as required by Administrative Procedures Act (APA).
5. **≥30 day public comment period.**
6. **Agency reviews comments, drafts final rule.**
7. **Agency approves final draft of the rule.**
8. Draft final rule is reviewed and approved by OMB (if significant).
9. **Final rule is published in the Federal Register; Codified in C.F.R. Rule is now “Promulgated.”**
10. **Guidance documents issued.**
11. **Administrative Judges interpret law.**
Administrative Rulemaking Process

2 Main Publications

- **Federal Register**
  - Published daily (every business day, excluding holidays)
  - Organized chronologically
  - Citation: Vol. # FR Page # (e.g., 68 FR 7778)

- **Code of Federal Regulations**
  - Published annually (e-CFR daily)
  - Organized by subject area
  - Citation: Title # C.F.R. Part # (e.g., 40 C.F.R. Part 160)
Regulations in Action - Advisories

Example: ADVISORY 83

“This interpretation is official policy and should be followed by all GLP inspectors.”

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GLPs compared to Common Law Negligence

Four Elements of Negligence

1. **Duty** not to cause harm.  What is the actor’s duty? (Compare to GLPs)
   - Must exercise care of a reasonable prudent person (RPP)
   - If Risk > Burden then there is a duty. (Risk = Probability x Injury)

2. **Breach** of duty
   - Unexcused violation of a statute is breach, negligence *per se*.
   - Exception: Liability *even if there is an excuse* when selling adulterated food (e.g., case law from 1930’s interpreting the Pure Food and Drug Act).

3. **Causation** of harm.
   - Actor’s act must be the “but for” cause.

4. **Harm** results.
More on Common Law Negligence

**Standards for burden of proof**

1. Preponderance of evidence
   - e.g., ordinary negligence in a civil case
2. Clear and convincing evidence
   - e.g., aggravated negligence in civil case
3. Beyond a reasonable doubt (criminal standard)

**Evidence**

1. Examples of evidence
   - Testimony, documents, things
2. Hearsay generally not allowed
   - One exception, business records are allowed (must be authenticated)
   - Compare to GLP
More on Common Law Negligence

Spoliation
- Negligent or intentional destruction of a document or information could result in liability, including a presumption the lost document is unfavorable, or default judgement in favor of the opponent.
- Compare to GLP Master Schedule requirements.

What about respondeat superior (“let the master answer“)?
- In general, if employee is operating within the scope of their employment, the employer is vicariously liable.
  - What is the scope of employment?
  - What about aggravated / gross negligence (reckless)?
- Compare to GLPs, roles and responsibilities.
What happens during litigation?
Last thoughts ...

“There can be wise, amazed, temperate and furious, loyal and neutral, in a moment? No man.”

*Macbeth*, W. Shakespeare