

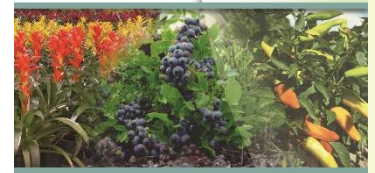


IR-4 Advisories

**Van Starner – IR-4 HQ, Assist. Director,
Research Planning & Outreach**

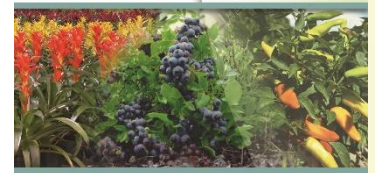
and Chair, IR-4 Education & Training Comm. (E&TC)

2017 National Education Conf.
Orlando, FL (2/28 – 2:45 p.m.)



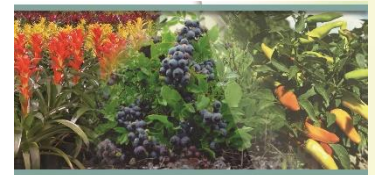
IR-4 Advisories

- **Purpose and Background**
- **EPA GLP Advisory example**
- **Process to establish an IR-4 Advisory**
- **Advisories approved/published**
- **Where are they?**



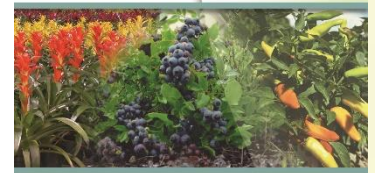
Purpose & Background

- **To serve as a tool to communicate resolution of issues/questions raised by anyone in the IR-4 Project**
- **Resolution could be valuable for many within IR-4**
- **Based on EPA's system of GLP Advisories, that were developed to interpret the regulations in light of specific questions/issues raised by the regulated community (registrants, IR-4, etc.)**



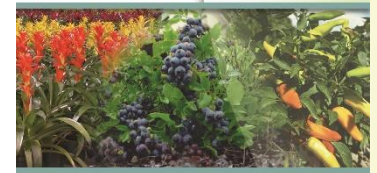
Example EPA GLP Advisory

- **EPA Advisory No. 58 (Jan. 15, 1993)**
IR-4 specifically asked: “Does compliance with GLPs apply to pesticide registrants when IR-4 sponsors studies and submits final reports to EPA?”
- **EPA response in Advisory No. 58:**
“When IR-4 acts as a testing facility and/or sponsor, it is responsible for compliance with GLPs, including provisions for retention of records.”



IR-4 Advisory Process

- **Proposed by the E&TC to IR-4 Project Management Comm. (PMC) in 2002**
- **PMC approved the recommended procedure, which was then incorporated into the IR-4 Handbook**
- **The process** (typically takes 8-10 weeks; Chair of E&TC is “gatekeeper”):
 - **an issue/question is raised by anyone in IR-4, to the Chair of the E&TC**
 - **decision is made if Advisory is the most appropriate means to address this topic**
 - **an Advisory is drafted**



IR-4 Advisory Process

- **Advisory format:**

IR-4 Advisory #2003-05 (Dec. 9, 2003)

Title: Weighing Field Trial and Processing Trial Residue Samples

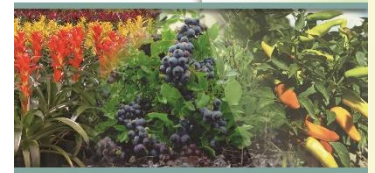
Issue/Question: Do the scales/balances used to establish estimated weights of in strict adherence to GLP?

Background: In two EPA inspections of IR-4 field test sites

IR-4 Protocols generally require a “minimum”

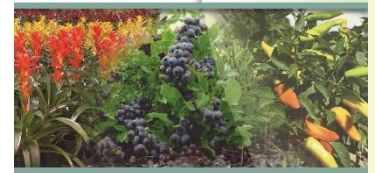
Resolution: It is IR-4’s assessment that field trial and

- 1) IR-4 protocols will
- 2) Part 1C of field data books will
- 3) In Part 7B of field data books
- 4) Compliance statements



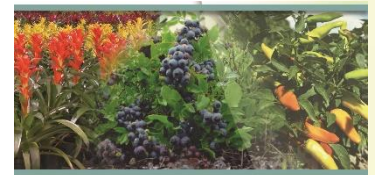
IR-4 Advisory Process

- **The process (cont'd):**
 - **draft Advisory given to E&TC for 2-week review/
comment period**
 - **suggested revisions are incorporated, and revised
draft Advisory goes out more broadly (to RFC,
SD, FRD, QA, E&TC) for a second 2-week
review/comment period**
 - **any new edits are incorporated, and the draft
Advisory is sent to PMC for a 2-week review**



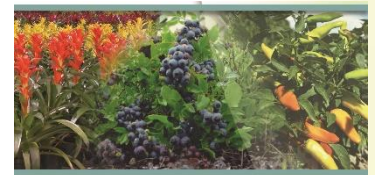
IR-4 Advisory Process

- **The process (cont'd):**
 - upon favorable review by PMC, the Advisory is finalized and “published” in the IR-4 Advisories/Training area of the website
 - the new Advisory is also distributed electronically throughout IR-4
 - the Advisory is now part of IR-4 policy, and helps govern IR-4’s adherence to the GLP regulations



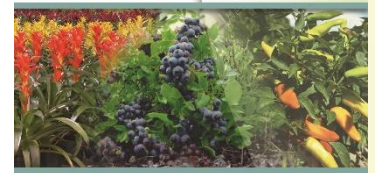
Does Every Draft Get Published?

- **During this entire multi-week process, if any serious concerns arise from anyone, these concerns must be fully addressed before the Advisory moves forward to the next step in the review process.**
- **If a legitimate concern is serious enough, the Advisory can be terminated at any point.**



Current Advisories

- **Since the first Advisory was approved in 2003 (IR-4 Advisory #2003-01), a total of 13 have been [published](#).**
- **If you are not familiar with any of these, you need to review them and understand their impact on your work, ASAP!**





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IR-4 Advisories

- [#2015-01 Storing and Maintaining Adjuvants \(Spray Additives\) for Use in IR-4 Field Residue Studies \(Amended September 10, 2015\)](#)
- [#2014-01 Maintaining Freezer Storage Systems at IR-4 Field and Laboratory Research Sites](#)
- [#2007-01: Shipping with Dry Ice and Training/Certification Guidance](#)
- [#2006-01: Inventory and Transfer of GLP Raw Data and Other Records to IR-4 Headquarters \(HQ\)](#)
- [#2005-02: Field Research Director Disposal of Field Data Book Copies](#)
- [#2005-01: Test Substance Container Disposal Website Approval Procedure \(Amended Nov. 21, 2008\)](#)
- [#2004-02: IR-4 Application Type Definitions](#)
- [#2004-01: Foliar Broadcast Spray Swath vs. Plot Width](#)
- [#2003-05: Weighing Field Trial and Processing Trial Residue Samples](#)
- [#2003-04: Test/Reference Substance Container Labels - Required Information](#)
- [#2003-03: Conflicting Chemistries in IR-4 Studies](#)
- [#2003-02: Test Substance Container Disposal](#)
- [#2003-01: Responding to FDB QA Findings](#)

Training

- [IR-4 Education and Training Committee \(TC\)- objective, composition, membership responsibilities](#)
- [Phoenix Proceedings February 2006](#)
- [GLP Training Opportunities](#)
- [San Antonio Workshop Results](#)
- [Operational Handbook](#)
- [2004 Southern/North Central Region GLP Training Session](#)
- [IR-4 Field Data Book \(FDB\) Guidance Document](#)
- [Laboratory Guidance Document](#)