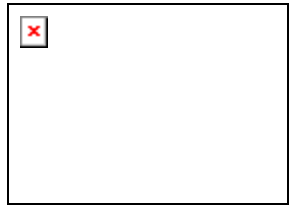




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FIFRA Data Reliance/Compensation Scheme: Actives and Inerts

James P. Rathvon
202-799-4381
james.rathvon@dlapiper.com



Presentation Outline

- **FIFRA Data Reliance/Compensation Scheme**
- **EPA Regulations Implementing Scheme**
- **Issues in Data Compensation Disputes**
- **Data Protections for Inert Ingredients/Endocrine Disruptor Screening Program**

Key Features of FIFRA Data Reliance/ Compensation Scheme

- **Registration of all pesticide products**
- **Protections for data required for registration: exclusive use, compensation, confidentiality**
- **Mandatory right to data reliance, conditioned on “irrevocable” offer to pay**
- **Binding arbitration to resolve compensation disputes**
- **EPA forfeiture of registration/compensation rights if noncompliance**
- **All of the above required by statute**

Pertinent Statutory Provisions

- FIFRA § 3(c)(1)(F): Data required to obtain registrations
- FIFRA § 3(c)(2)(B): Data required to maintain registrations (data call-in provision)
- FIFRA § 3(c)(7): Authority to grant conditional registrations, conditioned on future submission or citation of data
- FIFRA § 3(c)(2)(D): Exemption from (most) data requirements for formulators (formulator's exemption)
- FIFRA § 10: Qualified confidentiality protections

FIFRA § 3(c)(1)(F) [formerly 3(c)(1)(D)]

- **Data required to obtain registration (or amendment requiring data, e.g., adding new use)**
 - Keyed to Part 158 data requirements
- **10-year “exclusive use” period for data on new a.i.**
- **15-year data compensability**
- **Data reliance: citation of data/“offer to compensate”/ binding arbitration to resolve compensation disputes**
 - Use “cite-all” or “selective” method (discussed later)
- **EPA enforcement: power to deny/cancel registration or revoke compensation rights**

FIFRA § 3(c)(2)(B): Data Call-In Provision

- Data required to maintain registrations in effect
- EPA issues Data Call-In (DCI) to all current registrants of pesticide(s).
 - Fill “data gaps”
 - Address new risk concerns
- “Offer to jointly develop or cost share”/binding arbitration/ EPA enforcement
- No exclusive use protection
- 15-year data compensability

FIFRA § 3(c)(7): Conditional Registration

- **Registration conditioned on applicant satisfying data gaps/outstanding DCIs at same time as existing registrant(s).**
 - FIFRA LH: Intended to cure “double standard” whereby follow-ons subject to more stringent requirements than existing (basic) registrants.
- **Generic product must be substantially similar to existing product registration.**

FIFRA § 3(c)(2)(D): “Formulator’s Exemption”

- **Exemption from requirements under § 3(c)(1)(F) to**
 - Submit or cite data
 - Issue offer to pay (OTP) for cited data
- **Extended by EPA to DCIs (§ 3(c)(2)(B))**
- **Applicant/registrant must purchase registered pesticide from another:**
 - e.g., registered technical to produce EP
 - cannot switch to unregistered technical w/o amendment/OTP
- **Rationale: data costs included in purchase price of registered product; avoids formulator paying “twice” for data required for registration.**
- **Exemption highly efficient: data requirements only on suppliers; removes burden on customers/formulators.**

FIFRA § 10: Confidentiality Protections

- **EPA prohibited from disclosing data to foreign or multinational pesticide producers.**
- **EPA prohibited from disclosing to any third party:**
 - Manufacturing processes
 - Methods of testing
 - Identity and percentage of any deliberated added inert ingredient

Legislative History – 1972 Amendments

- **Pre-1972: USDA/EPA freely considered previously submitted data to grant follow-on registrations**
- **1972: Comprehensive amendments to FIFRA**
 - Section 3(c)(1)(D): mandatory data reliance scheme
 - Section 10(b): “Trade secret” data not subject to mandatory reliance, nor could EPA disclose data to public
- **“It was decided that fairness and equity require a sharing of the governmentally required cost of producing the test data used in support of an application by an applicant other than the originator....” S. Rep. 92-838 at 72-73 (1972).**

Legislative History – 1978 Amendments

- **Concerns leading to 1978 Amendments:**

- “logjam of litigation” resulting from “controversies over data compensation and trade secret protection.”
- “registration and reregistration process [has] ground to a virtual halt.”

S. Rep. No. 95-334 at 3 (1977).

- **EPA OPP Study (1977) “FIFRA: Impact on the Industry”**

- Broad trade secret claims “drastically changed” the competitive landscape
- Small producers being forced out of the market
- Market tending toward monopolization

Legislative History – 1978 Amendments

- **Eliminated trade secret protection for data (except as provided in FIFRA § 10(d)).**
- **Shifted jurisdiction over data compensation disputes from EPA to private arbitrators**
- **Data compensable for 15 years from submission**
- **10-year exclusive use for data submitted in support of first registration of product containing new ai**
- **Added data call-in authority (§ 3(c)(2)(B))**
- **Added formulator's exemption (§ 3(c)(2)(D))**
- **Added conditional registration (§ 3(c)(7))**

Legislative History – 1996 Amendments (FQPA)

- **Extended exclusive-use protections as reward for registering minor uses**
- **Granted data protections to inerts**

Drilling Down on FIFRA § 3(c)(1)(F)

Two Parts

- **Exclusive Use**
- **Mandatory Data-Licensing**

§ 3(c)(1)(F): Part 1 - Exclusive Use

- **10-year exclusive use rights** for data re: active ingredients first registered after Sept. 1978
- **FIFRA LH: To promote pesticide innovation w/o effectively extending patent protection**
- **10-year period begins on date of first registration of product containing new a.i.**
- **Does not apply to “defensive” (DCI) data**
- **Does apply to data to register new use(s) (but only for balance of 10-year period)**

§ 3(c)(1)(F): Part 1 - Exclusive Use

FQPA Amendments (1996)

- **Extends 10-year exclusive use period up to 3 years as reward for registering a.i. for “minor uses” w/in first 7 years of period.**
 - One more year for every 3 new minor uses registered
- **Provides separate 10-year exclusive use period for data submitted to support amendment adding minor use *after* expiration of 10-yr exclusive use period.**

§ 3(c)(1)(F): Part 2 - Mandatory Data-Licensing

- Applicants have mandatory right to rely on any data not subject to exclusive use without submitter's permission
- Data submitters have right to compensation for EPA's use of their data to approve generic registrations
- Data compensable for 15 years from date of original submission; thereafter, use is free [compare with exclusive use periods in example on previous slide]
- Fixing of compensation independent of EPA's approval of generic's registration
- No explicit compensation standard or formula
- FIFRA LH: Scheme intended to cure "free rider" problem, while promoting generic competition and discouraging duplicative data development

§ 3(c)(1)(F): EPA Implementing Regulations

40 CFR Part 152, Subpart E

- Cite-all and selective methods of data support
- Formulator's exemption
- Petitions to deny/cancel to protect data submitter's FIFRA data rights

Petitions to Deny or Cancel

40 CFR 152.99

- **Authorizes petitions to protect data submitter's FIFRA compensation/exclusive use rights**

Grounds:

- Inadequate selective data citations
 - Invalid OTP (1-year limit)
 - No OTP
 - Ineligible for formulator's exemption
 - Product not substantially similar
- **FIFRA also authorizes petitions by data “reliers” to have EPA forfeit data submitters' rights**
 - Failure to negotiate/arbitrate
 - Failure to comply with agreement or award

FIFRA Arbitration Scheme

- **Binding arbitration mechanism created in 1978:**
 - FIFRA § 3(c)(1)(F): compensation for reliance on previously submitted data
 - FIFRA § 3(c)(2)(B): cost-sharing for Data Call-In data
 - *Either* party may initiate arbitration
- **Arbitration authority vested in Federal Mediation and Conciliation Service (FMCS), a federal agency**
- **FMCS delegated most of its authority to the American Arbitration Association (AAA), a private entity**
 - FIFRA Arbitration Rules: 29 CFR § 1440.1, App.
- **Private arbitration scheme upheld in *Thomas v. Union Carbide*, 473 U.S. 568 (1984)**

Key Data Compensation Issues

- 1. Which are the compensable data?**
- 2. What costs should be assigned to compensable data?**
- 3. What share of the compensable data costs should the follow-on pay?**
- 4. Should the award include additional compensation for early entry, risk or other factors?**

FQPA (1996) Amendments to FDCA

- **FFDCA § 408(i): Extension of compensation rights to data submitted in support of tolerances:**

“Data and information that are or have been submitted ... in support of a tolerance or exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent as provided by [FIFRA] sections 3 and 10 ...”

- **Applies to both active and inert ingredients in food use pesticides.**
- **Tolerances are published in Federal Register/CFR; not tied to particular registrations/registrants.**
- **Poorly conceived; EPA has struggled mightily to implement.**

FQPA (1996) Amendments to FDCA (con't)

- **FDCA § 408(p)(1), (p)(3): EPA must develop endocrine disruptor screening program (ESP) for all pesticide chemicals (both active and inert)**
- **FDCA § 408(p)(5)(A): EPA must issue ESP test orders to registrants and manufacturers/importers**
 - Provision does not require joint data development
- **FDCA § 408(p)(5)(B): EPA must minimize duplicative testing and develop procedures for equitable sharing of test costs “to the extent practicable”.**
 - Provision does not create compensation rights, but statutory goals call for compensation/cost-sharing scheme

Reminder: Key Features of FIFRA Data Reliance/ Compensation Scheme

- Registration of all products
- Protections for data required for registration: exclusive use, compensation, confidentiality
- Mandatory right to data reliance, conditioned on “irrevocable” offer to pay
- Binding arbitration before FMCS/AAA to resolve compensation disputes
- EPA forfeiture of registration/compensation rights if noncompliance
- All of the above required by statute

Implementation Challenges

- Inerts are not separately registered. Therefore, FIFRA data reliance scheme not directly applicable to inert suppliers.
- Inerts are registered as part of end-use formulations, but end-use registrants should be exempt ... but no formulator's exemption in FFDCA §§ 408(i) or 408(p).
- Identity of inerts in formulations generally confidential.
- Some inerts/blends are trade secret.
- So ... What does “to the same extent” mean without inerts registration system and public information about use of inert ingredients?

Implementation Challenges (con't)

- **Non-food inerts do not trigger tolerance requirements, therefore (problematic) FFDCA § 408(i) not even applicable.**
 - EPA: data for non-food inerts must be submitted by a pesticide registrant to be compensable.
- **Because no registration, no offer to pay requirement.**
- **No binding arbitration mechanism, no registration forfeiture sanction, etc., etc.**
- **Some actives, and many inerts, are also used in non-pesticide products. Are suppliers to non-pesticide products/uses subject to ED requirements?**

EPA Statements & Interpretations on Inert Ingredient Data Compensation

- **2000 Federal Register Notice: EPA sought comment on possible interpretations of § 408(i):**
 - It is new law and should be given independent meaning to create new rights in data submitted by manufacturers of inert ingredients; or
 - It doesn't modify existing FIFRA “triggers” for data protection and is therefore simply a Congressional ratification of EPA's existing treatment of “tolerance-related” data.

EPA Statements & Interpretations on Inert Ingredient Data Compensation

- **2003 “White Paper”**: EPA announced its interpretation of 408(i) and sought comment on its implementation scheme:
- EPA interprets 408(i) to establish rights in “inerts data” that are submitted by inert ingredient manufacturers to support tolerance actions.
- The scope of data compensation and exclusive use rights mirror protections in FIFRA (except they are tied to the establishment and maintenance of a tolerance or tolerance exemption).
- Protection of inert data rights must be incorporated into FIFRA process.
- Data Submitters List must be modified to include inert ingredients.

EPA Statements and Interpretations (cont.)

- **EPA's April 2009 EDSP Policy Statement**

- **Outlined approach EPA generally intends to follow to ensure protection of rights in data on both active and inert ingredients subject to ED test orders.**

- **Relies on FIFRA process & issuance of “catch-up” orders to protect inerts data.**
- **Calls for creation of an inert ingredient data submitters list that includes both data submitters and other manufacturers and distributors that have offered compensation to data submitters.**

Approach in most respects mirrors proposal from coalition of registrant trade associations.

- **EPA intends to take a similar approach for other data submitted by inert ingredient manufacturers, although the approach for addressing “non-food-use” inerts data is unique to the EDSP program.**

Issues, Concerns with EPA Program

- **Difficulties identifying inert suppliers/test order recipients.**
- **Difficulties policing inert suppliers who have not made offers to pay.**
- **Difficulties policing formulator's exemption claims.**
- **Uncertain sanctions for non-compliance by inert suppliers.**
- **Offers not statutorily required; not same as FIFRA "irrevocable" offer to pay; enforcement disputes likely.**
- **Standard of compensation – strict cost-sharing?**
- **Uncertain enforcement of arbitration awards.**
- **Administrative/cost burdens on EPA and end-use formulators.**