PESTICIDE REGISTRATION

Registration: Pesticide product registration is the central mechanism for regulating United States pesticide sales and use.

- # Under FIFRA (7 U.S.C. § 136 *et seq.*), EPA makes an individual registration determination for every product based on a separate application for registration.

- # To issue a registration, EPA must determine, among other findings, that the product:

  - ➢ Will function without "unreasonable adverse effects on the environment"; and

  - ➢ When used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment.

- # Generally, EPA issues conditional registrations under FIFRA Section 3(c)(7)(A), provided:

  - ➢ The pesticide and proposed use are identical or substantially similar to a currently registered pesticide;

  - ➢ Registration would not significantly increase the risk of any unreasonable adverse effect on the environment; and

  - ➢ Registrant commits to satisfy any data gaps.

Reregistration: EPA is in the process of "reregistration" -- a long-term effort to update the databases that support all product registrations.

- # End result of this process -- publication of a reregistration eligibility decision (RED) for every registered pesticide active ingredient.

- # Reregistration process is far from complete.

REGISTRATION DATA REQUIREMENTS

New Registrants: Pesticide registrations include extensive data requirements for EPA to evaluate the environmental effects, health effects, and safety of the product.

- Data requirements (set forth at 40 C.F.R. Part 158) vary but can include product chemistry, mammalian toxicity, environmental toxicity and fate, and residue chemistry, reentry exposure, and spray drift.

- Efficacy studies generally are not required to be submitted, expect for certain antimicrobial pesticides, but must be submitted upon EPA's request.

Current/Existing Registrant: FIFRA Section 3(c)(2)(B) authorizes EPA to require additional new studies from current registrants "to maintain in effect an existing registration of a pesticide."

- A "Data Call-In" (DCI) is directed to affected registrants and specifies the additional tests that EPA requires.

- Registrants may individually submit, jointly develop, or share in the cost of developing those data.

Exclusive Use: Under FIFRA Section 3(c)(1)(F)(i), data submitters are given a ten-year period of exclusive use for data submitted in support of a registration for: (1) a new pesticide chemical; or (2) new uses of an already existing pesticide.

- Applies to data on an active ingredient registered after September 30, 1978.

- Registrant may not rely on exclusive use data without data owner's consent.

- Ten-year exclusive use period begins on date of first registration of new active ingredient.

- No exclusive use rights for data submitted in response to a DCI.

- FQPA extended exclusive use time periods for minor uses and extended exclusive use protection to data in support of a tolerance or tolerance exemption.

SATISFYING DATA OBLIGATIONS

An applicant can meet data requirements in one of several ways.

- **Conducting Studies**: Applicants can conduct a full battery of tests using the active ingredient or formulated product.

- **Data Citation**: Where EPA has data pertaining to a substantially similar or identical product, FIFRA Section 3(c)(1)(F) allows the new or "follow-on" registrant to "cite" data rather than repeat such data. Two methods of data citation are:

  - **Cite-All**: An applicant may cite to "all relevant data in the Agency's possession that would satisfy any applicable data requirements." *See* 49 Fed. Reg. 30884, 30889 (Aug. 1, 1984); 40 C.F.R. § 152.86.

  - **Selective Cite**: An applicant may "selectively [identify] one or more studies to satisfy each individual data requirement." *See id.*; 40 C.F.R. § 152.90.

- **Joint Development**: For data required under FIFRA Section 3(c)(2)(B), EPA authorizes registrants to individually submit, jointly develop, or share in the cost of developing those data.

- **Data Compensation**: FIFRA Section 3(c)(1)(F) requires applicants citing certain data (including Section 3(c)(2)(B) data) to offer to pay compensation to the original data submitter for reliance on such data.

- **Formulator's Exemption**: FIFRA Section 3(c)(2)(D) provides an exemption from data citation and compensation requirements.

  - To qualify, the applicant must purchase another registrant's pesticide product.

  - Rationale for exemption -- data costs are included in the product's purchase price.

COMPENSATION FOR EXISTING DATA

Negotiations/Arbitrations: FIFRA Section 3(c)(1)(F) requires a follow-on registrant to compensate the original data submitter for reliance upon data.

- Follow-on registrant must provide an "offer to pay" compensation.
- If no agreement on the amount and terms within 90 days of the submission of an offer to pay, the parties can enter into binding arbitration.
- Arbitrations are conducted by the American Arbitration Association (AAA) under the FIFRA Arbitration Rules at 29 C.F.R. Part 1440.
- No requirement to agree on amount and terms of compensation prior to EPA's issuance of the follow-on registration.
  - If EPA determines original data submitter has failed to participate in data compensation procedures, submitter forfeits right to compensation.
  - If EPA determines follow-on registrant has failed to participate in data compensation procedures, EPA can deny or cancel registration.

Data Compensation System/Standard: The United States Supreme Court has twice upheld the constitutionality of the data citation system. *See Ruckelshaus v. Monsanto Co*., 467 U.S. 985 (1984), and *Thomas v. Union Carbide Agric. Prods. Co*., 473 U.S. 568 (1985).

- Cases do not squarely address what standards should govern compensation decisions.
- *Thomas* stated that the "data-sharing provisions [were] intended to streamline pesticide registration procedures, increase competition and avoid unnecessary duplication of data-generation costs." 473 U.S. at 571.
- Court further noted the scheme provides "an added incentive beyond statutory patent protection for research and development of new pesticides." *Id*. at 572.
- Public arbitration decisions resolving compensation disputes also provide some guidance on how the amount and terms of data compensation have been awarded.

COMPENSABLE DATA

Types of Compensable Data: Arbitrations determine what data are compensable.

- FIFRA provides that compensation is required if: (1) the study was submitted after December 31, 1969; and (2) the follow-on registrant cites it within 15 years of its submission to EPA.

- EPA's regulations provide that a cite-all follow-on registrant is citing: "the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA." 40 C.F.R. § 152.86(d)(2)(ii).

- Where EPA has issued a RED applicable to the product being registered, compensable data almost certainly would include any that satisfy that standard.

DATA COSTS AT ISSUE IN ARBITRATIONS

Data Costs: Once compensable data are identified, arbitrations determine the costs of such studies. Costs can be calculated by:

- The costs incurred by the original data submitter (*i.e.*, actual invoices, contract laboratory costs); or
- The costs avoided by the follow-on registrant (*i.e.*, estimating how much it would cost the follow-on registrant to generate the data).

Study Management Costs: Arbitrations generally award administrative overhead costs associated with the studies the original data submitters managed. These costs, ranging from 15 to 20 percent of data costs, cover the:

- Cost of supervising studies carried out by the original data submitter; and
- Cost of monitoring studies conducted by independent laboratories under contract with the original data submitter.

Interest Costs: Data compensation decisions uniformly have awarded interest on data costs and overhead or have adjusted awards for inflation, to compensate for the lost use of funds expended in producing the original data.

OTHER ISSUES IN ARBITRATION

Cost Allocation: Arbitrations determine how costs are apportioned between the parties. The two principal ways are:

- **Per Capita**: Data costs apportioned on an equal, "per capita" basis.
- **Market Share**: Data costs are apportioned based on the relative sales (market share) achieved by the follow-on product.
- Some decisions have discounted the award since follow-on registrants do not always obtain equal rights to the data (*i.e.*, no "hard copies of the data"; cannot obtain international or California registrations).

Additional Compensation: Arbitrations determine whether additional compensation is warranted under one of the following theories:

- **Early Market Entry**: Compensation for the benefit gained by a follow-on registrant by its ability to enter the market in less time by citing rather than conducting the necessary studies. More recent decisions have rejected any compensation based on early market entry.
- **Lost Opportunities**: Compensation for lost profits of the data owner for investing time and resources in registering its product. Difficulty is proving a data owner could have made more had the money been invested elsewhere.
- **Risk Premium**: Compensation for the regulatory and commercial risks the data owner undertook and the follow-on registrant avoided so that the follow-on registrant does not get a "free ride" on these avoided risks. Risks include:
  - Risk of study failure or rejection;
  - Risk that EPA may expand or modify study requirements or study performance guidelines; and
  - Risk that sales volume or price will be inadequate to recover data costs.

JOINT DATA DEVELOPMENT

FIFRA Requirements:

- Section 3(c)(2)(B) authorizes EPA to require registrants to submit additional data, and authorizes registrants to: (1) develop jointly those data; (2) share in their cost; or (3) develop their own.

- Since Section 3(c)(2)(B) deals expressly with sharing data costs, rather than compensation, less ambiguity surrounds the determination of obligations under Section 3(c)(2)(B) than under Section 3(c)(1)(F).

- FIFRA provides for binding arbitration to determine the amount and terms of joint data development if the parties cannot reach agreement.

Costs That Must Be Shared:

- Costs to be shared include:

  - The direct cost of developing the required data and compiling and submitting the data to EPA;

  - The cost of study management/administrative overhead; and

  - Interest.

- Decisions refuse to award compensation beyond these core costs (*i.e.*, risk premium claims).

Cost Allocation: First arbitration panel to address this question held that there are no statutory requirements for a per capita or a market share allocation.

- Decisions have allocated costs under the market share and per capita approaches.

- Arbitrations have also discounted awards for lack of hard copy access and inability to obtain registrations abroad or in California.

NEGOTIATED DATA COST SHARING ARRANGEMENTS

Companies involved in the joint production of data generally establish a "task force" for study sponsorship.

- Section 3(c)(2)(B) expressly sanctions such joint efforts among competitors, essentially serving as a limited exception to the United States antitrust laws.

- Companies exercise care in structuring these arrangements to avoid over-expansive interpretations of the breadth of this "exemption."

Task forces are established pursuant to a written agreement. Provisions are geared to avoid any suggestion of anti-competitiveness and eliminate any incentive for companies to delay entry into the agreement.

Provisions in the typical task force agreement reflecting issues unique to -- or, at least, uniquely influenced by -- the FIFRA scheme include:

- **Cost Sharing Formulas**: Majority of agreements provide for an equal ("per capita") sharing of costs. Can also allocate depending on differing roles of participants or product-specific considerations.

- **Data Rights**: Most agreements provide all signatories with equal rights -- generally, full ownership of studies produced under task force sponsorship.

- **Confidentiality**: Typically, signatories are required to commit to take steps to assure that any studies sponsored by the group are maintained as confidential.

- **Interest**: Late joiners typically are required to make an initial payment equal to whatever amounts would have been due from the late joiner if it had participated in the task force from its inception, plus interest.

- **Premium**: Most agreements require that a late joiner pay a "testing risk assessment" (*i.e.*, 50 percent of the amounts that otherwise would be due from a late joiner).

- **Data Compensation**: Since data submitted in response to Section 3(c)(2)(B) may be cited and subject to Section 3(c)(1)(F) compensation requirements, FIFRA requires that task forces identify an agent for purposes of obtaining compensation.