



At A Glance  
*FIFRA Data  
Compensation*

## Overview

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The Federal Insecticide Fungicide and Rodenticide Act (FIFRA) governs the regulation, sale, distribution, and use of pesticides in the US. Under FIFRA, registering a pesticide requires that the US Environmental Protection Agency (EPA) determine that the pesticide will perform its intended function without unreasonable adverse effects on human health or the environment. To make that determination, the EPA relies on costly studies, tests, and other data produced and funded by third parties.

To balance the incentives to conduct R&D for new, improved pesticides with entry considerations, a company seeking a new registration may cite data (via a cite-all or a selective citation method) that appear in the public literature and/or were previously submitted to the EPA by another data submitter. If a prospective registrant relies on another submitter's data in support of its pesticide registration, FIFRA requires the prospective registrant to offer to compensate the original data submitter. If the parties are unable to reach a voluntary agreement on the compensation amount, a binding arbitration under the procedures of the Federal Mediation and Conciliation Service may be initiated by either party to resolve the dispute.

FIFRA does not explicitly define compensable "costs," and it does not provide a standard formula for determining the compensation a prospective registrant should pay for citing or relying upon data generated by another entity in support of its application. Prior FIFRA arbitrations are not binding precedents; they only provide guidance as to how some arbitration panels have resolved the issue of cost sharing in a given data compensation dispute.

## Our Capabilities

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Given the nature of the pesticide regulatory process and FIFRA data compensation, resolutions are rarely straightforward matters of accounting. The unique facts and complex circumstances of each matter are critical in determining the relevant components of a compensation amount.

NERA economists have a keen understanding of the economic intent of the FIFRA data compensation provisions: maintaining the incentive for further innovation and streamlining the pesticide registration process to avoid unnecessary duplication of data generation costs. We have extensive hands-on experience applying that understanding on behalf of clients throughout the process.

We have experience:

- Providing strategic economic advice to corporate clients and outside counsel during the negotiation or arbitration of a FIFRA data compensation claim.
- Developing accurate and defensible data compensation claims in arbitration proceedings under FIFRA.
- Determining the most reliable, comprehensive, and contemporaneous business records such as accounting statements to use in measuring the costs of generating pesticide data.
- Overcoming hurdles of limited or incomplete accounting records.
- Assessing the appropriate adjustments allowed under FIFRA for factors such as inflation, interest, and a premium.
- Applying rigorous analytical tools and techniques to formulate approaches to issues such as cost allocation and measurement of risk and/or risk avoidance based on the fact patterns of an individual case.
- Providing rigorous economic analysis, guidance on responses to data and other requests, comprehensive expert testimony, and critical analysis of documents produced by clients and other experts.

## About NERA

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NERA Economic Consulting ([www.nera.com](http://www.nera.com)) is a global firm of experts dedicated to applying economic, finance, and quantitative principles to complex business and legal challenges. For nearly half a century, NERA's economists have been creating strategies, studies, reports, expert testimony, and policy recommendations for government authorities and the world's leading law firms and corporations. We bring academic rigor, objectivity, and real world industry experience to bear on issues arising from competition, regulation, public policy, strategy, finance, and litigation.

NERA's clients value our ability to apply and communicate state-of-the-art approaches clearly and convincingly, our commitment to deliver unbiased findings, and our reputation for quality and independence. Our clients rely on the integrity and skills of our unparalleled team of economists and other experts backed by the resources and reliability of one of the world's largest economic consultancies. With its main office in New York City, NERA serves clients from over 20 offices across North America, Europe, and Asia Pacific.

## Contacts

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