

Protection of Regulatory Data

Background

When basic pesticide manufacturers decide to market a molecule or a genetic trait (such as herbicide tolerance) that they have discovered, they file a patent application to assert 20 years of exclusive rights to their discoveries. However, patent protection is not available for the regulatory data required by the Environmental Protection Agency (EPA) to register pesticide products.

To generate the regulatory data required for a registration, pesticide companies must perform up to 100 studies specified by federal regulations, including mammalian toxicity, re-entry exposure, and environmental fate and toxicity studies. All of the studies must be performed in accordance with Good Laboratory Practices, which increases their costs.

All told, the studies to support a registration can cost as much as \$10 million, and require nine to 10 years to complete. In addition, EPA may require additional regulatory data to maintain the registrations for existing uses.

When the regulatory data from a pesticide study is submitted to EPA, the data is said to enter the "public domain" because the Agency is a public entity. But, that does not mean that the data is freely available to the public. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA is required to disclose health and safety data, but the Agency is prohibited from releasing regulatory data to multinational pesticide companies.

EPA is prohibited from releasing the data to multinationals because they could benefit from the information in countries without FIFRA data protections. But this is just one of the protections provided by FIFRA for regulatory data. The key protection provided by FIFRA is a 10-year period of exclusive use for data submitted in support of a registration for new pesticides, and for data submitted to maintain those registrations.

During the 10-year period of exclusivity, data owners may, at their discretion, sell the data to a generic company. When the 10-year period expires, data owners are provided with a five-year period of limited exclusivity, during which a generic company may cite original data if it has offered to pay for the data and informs EPA of its offer. (Disputes over the value of the data are settled in arbitration.)

Our international trading partners have acknowledged the importance of regulatory data protection. For example, most of the 30 nations which are members of the Organization for Economic Cooperation and Economic Development, and all of the signatories to the Central America Free Trade Agreement, provide 10-year exclusivity for original regulatory data;

In addition, the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which is administered by the World Trade Organization (WTO), directs (but does not obligate) the 151 members of the WTO to protect original data against "unfair commercial use" and "disclosure." (Under TRIPS, data disclosed for public health protection must still be protected against "unfair commercial use.")

TRIPS does not, however, specify any periods of data exclusivity, leaving the decisions on exclusivity periods up to individual governments.

Position

- CropLife America strongly endorses a minimum 10-year exclusivity and five-year compensation period for crop protection chemicals.
- CropLife America believes that regulatory data protection is vital to the promotion of innovation in the pesticide industry. Without this protection, companies would not have any incentive to research novel molecules and genetic traits.
- The TRIPS Agreement Article 39 recognizes that the creation and submission of regulatory data by companies requires considerable effort and that, therefore, the data deserves strong protection.
- Without strong, international data protection rules, pesticide markets could be swamped with counterfeit or poorly manufactured products that would have an adverse effect on agricultural activity and production.