

Safeguarding Innovation

Protecting Regulatory Data



The protection of regulatory data is essential for agricultural innovation. The research required for a product to be registered is very detailed and demands significant resources. The data created and submitted for regulatory approval remain the sole property of the creator. It is thus important that regulatory data are not unfairly used commercially or disclosed in an inappropriate manner.

A strong regulatory framework for the protection of data fosters confidence and stimulates investment in research and development, making it possible to develop new crop protection products for sustainable agriculture.

What are regulatory data?

Regulatory data are the research and test results generated by plant science companies to prove the safety and efficacy of a product. They are required by a governing authority to allow companies to place their product on the market. Some of the data are confidential in nature and are communicated to government authorities with an obligation of non-disclosure.

Why should regulatory data be protected?

The generation of regulatory data requires a considerable effort on behalf of the innovator, and the data which are produced through that effort are the exclusive property of the innovator. The purpose of regulatory data protection is thus to protect companies' property and investments by preventing a third party from obtaining any unfair competitive advantage from the data submission.

Additionally, poor quality products sometimes enter markets through reliance on proprietary data. These products may be permitted for sale without passing 'international equivalency standards' which take into account safety standards for follow-up registrants. Without effective rules and enforcement, these markets could find that they are swamped with substandard products which could have an adverse effect on safety and agricultural production. Each product should be judged on its own merit, based on the application made by the registrant. Safety and efficacy data should not be compromised.

Protecting data needed for marketing authorization is not only recognition of the resources involved in bringing a new product to market, but is also a tool for increasing investment and competitiveness in emerging markets.

How should regulatory data be protected?

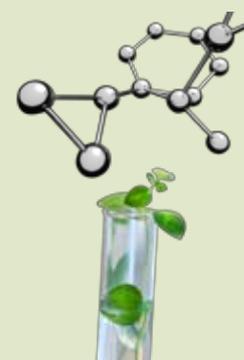
Regulatory agencies should strongly guard safety and efficacy data from inappropriate disclosure which may lead to any unfair commercial use. The plant science industry strongly endorses a minimum exclusivity period of 10 years for crop protection chemicals, such as is currently provided or exceeded by the vast majority of OECD Member States.

Once the exclusivity period expires, the data should not enter the public domain and must remain protected against inappropriate disclosure even if, under certain conditions, the data may be relied on for bringing copy products to the market. To ensure user, consumer, and environmental safety, companies seeking to register copy products must be required to demonstrate their product is truly equivalent to the original, as per the standards defined by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

The importance of data protection is acknowledged in the World Trade Organization's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement Article 39, which stipulates that regulatory authorities "shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use".

GENERATING REGULATORY DATA: A CONSIDERABLE EFFORT

- Producing data and gaining regulatory approval accounts for a significant amount of the time spent between discovery and commercialization of crop protection product.
- The development of a new agrochemical costs in excess of \$200 million, according to a study published in 2000.
- It takes over nine years from discovery to first market entry of a new product.
- Only one in approximately 140,000 molecules studied by the agrochemical industry makes it from the laboratory to the field.
- Over 120 tests are performed on each new product entering the market for safety and efficacy.



About CropLife Asia:

CropLife Asia promotes the benefits and responsible use of crop protection and plant biotechnology products, as well as sound regulatory frameworks in support of sustainable agriculture in the Asia Pacific region. As a regional unit of CropLife International – a global federation of the plant science industry in 91 countries – CropLife Asia supports the work of 15 member associations and is led by member companies at the forefront of crop production research and development.

www.croplifeasia.org

This publication is produced by CropLife Asia (S975S0018F). Copyright of the materials contained in this publication belongs to CropLife International. Nothing in here shall be reproduced in whole or in part without prior written consent of CropLife International. Views expressed are not necessarily those of CropLife International or CropLife Asia and no liabilities shall be attached thereto.

© 2009 CropLife Asia. All rights reserved.

Printed on recycled paper