



Position Paper

ON THE PROTECTION OF SAFETY AND EFFICACY DATA FOR EXISTING AND NEW CROP PROTECTION CHEMICALS

15 January 2008

CropLife International supports legislation which provides effective and adequate protection of regulatory data submitted for the registration of new and existing crop protection chemicals against unfair commercialization. The plant science industry strongly endorses a minimum ten-year exclusivity period for new chemicals, to the titleholder of the studies (beginning from the date of market approval of the innovative product in the country where the product is approved). Any data summaries released for the purposes of transparency are not to be treated as a disclosure to the public domain, and are still subject to full protection. Additionally, reliance on original data submitted for regulatory approval following the exclusivity period should only be permitted when internationally accepted equivalence standards (as described below) are met.

Introduction

The generation of safety and efficacy studies required by national authorities for the market approval/registration or re-registration of agrochemical products requires a significant investment of time and resources. The approval process is the essential assurance to farmers and consumers that agrochemicals meet established regulatory requirements for safety, efficacy and quality. Safety and efficacy data for crop protection chemical registration are provided to regulatory agencies at the expense of the manufacturer and are developed for a product with a specific chemical profile, including any impurities it may contain.

The studies are provided to regulatory agencies on the understanding that they are considered as proprietary data and so cannot be disclosed to or relied upon by third parties for their own regulatory submissions. Studies regarding new chemical entities are protected against any unfair commercial use pursuant to Article 39 of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which precludes third parties from unfairly relying on proprietary data for commercial purposes (for example, obtaining marketing approval). In the case of agrochemicals CropLife International considers the TRIPS minimum standard on the protection of safety and efficacy data to be applicable to both new and existing chemicals/products.

Effective protection of proprietary safety and efficacy studies from unfair commercial use requires:

- Ensuring a minimum ten-year exclusivity period for new chemicals, to the titleholder of the studies (beginning from the date of market approval of the innovative product in the country where the product is approved).
- Providing five years of protection for additional information required to extend the label (new uses) and/or maintain the market approval (re-registration).

- Authorizing the market entry of a copy product following the expiry of the ten-year exclusivity period based on safety and efficacy data provided by the first registrant — provided the copy product registrant demonstrates that the chemical profile of the copy product is equivalent to the original product, and therefore does not represent an unacceptable risk to users, consumers, or the environment.
- Establishing that any publication of data summaries for the benefit of transparency; does not represent disclosure to the public domain and the loss of protection.

An exclusivity period during which no third party may enter the market without filing its own safety and efficacy data – unless it has the approval of the titleholder of the data – is a widely adopted mechanism to protect regulatory data against unfair commercial use.

This minimum ten-year exclusivity period is similar to the protection currently offered by many OECD countries including the United States and European Union member states. Providing an inconsistent period of protection between trading partners creates market distortions and an uncertain regulatory environment for investment.

Summary approval procedure

Summary approval procedures allow registrants of copy agrochemical products to obtain market approval for products without filing the corresponding safety and efficacy studies. Registration or re-registration approval is granted based on the established safety and efficacy of a chemical entity which has previously been evaluated via the studies filed by the first registrant (normally the innovator).

In some cases, the copy product need only to indicate that it contains the same chemical entity as the original innovative product to gain registration approval, regardless of impurities in the content, which may represent an unacceptable risk to users, consumers and the environment. International regulatory and legal standards require that summary approval procedures are only granted for substances and products which: have obtained legitimate access to the supporting studies; and meet the equivalence standards defined and described in the *Manual of Development and Use of FAO and WHO specifications for Pesticides*. Approval granted to non-equivalent formulated products (those not meeting FAO/WHO standards) potentially jeopardize crop safety, the environment, and human health.

Summary approval procedures place all the risk and cost associated with studies which permit the marketing of the chemical entity on the first registrant (innovator). Summary approval procedures which do not meet these international standards promote illegitimate profiting from the innovator's effort and constitute an unfair commercial use of the studies. This conclusion is entirely supported in the history of negotiation of TRIPS Article 39.

TRIPS Article 39

TRIPS Article 39 creates obligations to protect safety and efficacy studies against both unfair commercial use and disclosure into the public domain.

The obligation to protect against unfair commercial use is typically limited in time by a predefined exclusivity period. Exclusivity periods are implemented to provide an adequate balance between protecting the efforts of the generator of the regulatory data and preserving the market entry of generic products, without requiring the independent duplication of safety & efficacy studies.

The obligation to protect against the disclosure of the data persists even after the expiration of the exclusivity period. Expiry of exclusivity for regulatory data does not constitute the release of the information into the public domain. On the contrary, the information continues to be the sole property of the submitter and must continue to be protected against disclosure.

The partial disclosure of data for noncommercial purposes (e.g. in order to allow third parties to consult and discuss the results of the studies) permitted under TRIPS Article 39 does not imply that the protection against unfair commercial use is lost. Test data are viewed as a whole, and revealing a part of the data does not imply that the complete studies have been placed in the public domain, nor that protection is lost. Likewise, data does not lose protection against unfair commercial use when, after it is filed with the authority, it becomes necessary to disclose test data results in the public interest. Therefore safety and efficacy studies remain *de jure* undisclosed, notwithstanding the fact that summaries or abstracts of them are published.

TRIPS Article 39 establishes the possibility of disclosing the data “when it be necessary to protect the public,” provided that the necessary measures are taken to guarantee their protection against unfair commercial use.

The obligation to maintain the exclusivity of undisclosed data applies equally to all of the national authorities (i.e. Ministry of Agriculture, Environmental Affairs, Health, Institutes in the Agro Sector, etc) that take part in the different stages of the application process for registration of agrochemical products. Thus, although only one agency may be the competent entity to issue the marketing license or market registration, all are obliged to preserve the proprietary nature of the data.

R&D Costs for Agrochemicals

Effective implementation of an adequate protection period permits the agrochemical industry to continue the costly development of new crop protection products and to maintain existing approvals.

Only one in approximately 140,000 molecules studied in the agrochemical industry makes it from the laboratory to the field. Because of their chemical nature and the wide variety of organisms potentially affected by their use, crop protection products are subject to a variety of safety and efficacy tests. Over 120 of these tests are performed on each new product entering the market and may need to be repeated depending on varying crops, pests, agronomical practices, climate conditions and terrains.

According to an industry analysis (year 2000), the development of a new crop protection chemical costs in excess of about \$180 million, and takes over 9 years from discovery to first commercialization. Producing data and gaining regulatory approval accounts for a significant amount of the time spent between discovery and commercialization. Extensive laboratory and field testing ensure the safety, efficacy and quality of crop protection chemicals with specific chemical profiles for use in the environment and the food supply. Data used by regulators to assess a new product is only available after the investment in dozens of complex tests required for product registration.

Conclusion

The protection against unfair commercial use of undisclosed safety and efficacy test data filed for the approval of new agrochemical products must not be lower than 10 years of exclusivity and 5 years protection for any additional documentation required to extend the label and/or maintain existing approvals.

The effective enforcement of these provisions is vital for agricultural innovation, to ensure confidence and stimulate research and development investment, making it possible to develop newer and safer agrochemical products for sustainable agriculture.