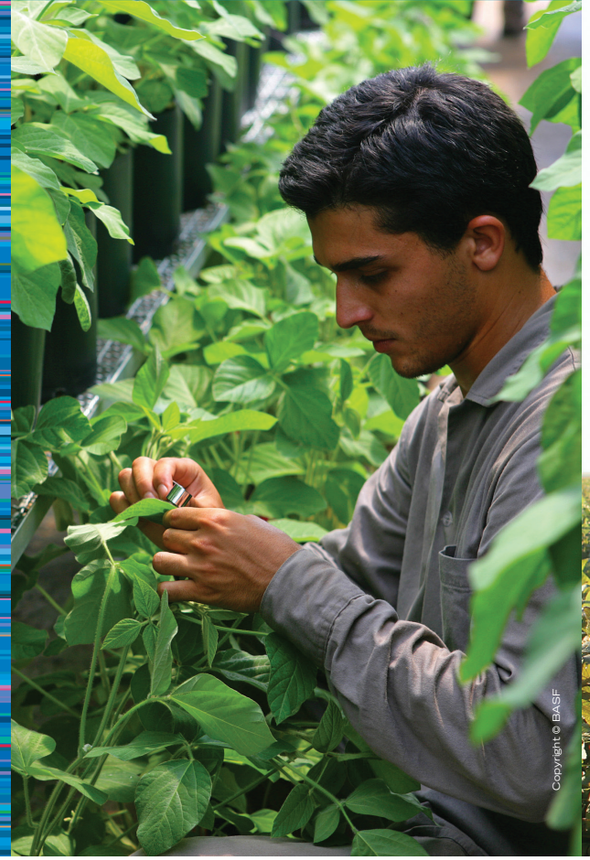
CropLife INTERNATIONAL

Meeting Challenges in a Growing World

Protection of Regulatory Data

Today, farmers, consumers and the environment all benefit from plant biotechnology. In the coming decades, as we are faced with increasing populations and the impact of climate change such as extreme growing conditions and shortages in natural resources, new innovations in plant biotechnology will play a critical role in helping farmers grow a greater amount of safe, nutritious and affordable food for our world's increasing population. The use of plant biotechnology can increase the productivity of land already cultivated, reduce the need to bring additional land into agricultural production, and thus contribute to the conservation of biodiversity and preservation of natural resources.



Conclusions

Protecting regulatory data and intellectual property is essential to supporting continued innovation in plant biotechnology. Every year, plant science companies invest a great deal to develop and improve the technologies and products that help farmers grow the food our rising world population needs. To enable and encourage innovation and investment to come up with new and better ways to feed our world's growing population, we need regulatory frameworks that ensure the protection of regulatory data.

It is vital we continue to invest in plant science innovation to meet the forthcoming challenges. Intellectual property is at the heart of encouraging this essential investment and ensuring innovation and technological advances. Protecting the data that are used as part of the regulatory review and authorisation process of plant biotechnology products is an essential part of encouraging on-going investment in plant science innovation and stimulating continued research and development.

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What are Regulatory Data?

Prior to entering the marketplace, technology developers must submit applications to regulatory authorities that contain data collected from comprehensive testing and research of a plant biotechnology product. The data accompanying the application are called "regulatory data" and are generated from rigorous and controlled scientific experiments. Regulatory data have significant economic value for the developer that generated them, due to the time and money he invested. Therefore, they must be considered exclusive and protected from unfair commercial use, as it is the case in other regulated industries (e.g., pharmaceutical and agrochemical industry). Technology developers, or applicants, have a long history of working with regulatory authorities to protect regulatory data.

Generating Regulatory Data: a considerable effort

Generating regulatory data requires considerable cost, time and effort by applicants.

The development of a biotech plant costs US$136 million (Phillips McDougall, 2011). The generation of regulatory data and the approval process represents about 26% of the total costs (i.e., US$35.6 million). The time taken from research to product commercialisation is typically about 13 years; the generation of product safety data and the regulatory review of these data prior to approval represents about 37% of the total time, nearly five years.

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Data generation continues even after regulatory approvals have been granted, involving significant subsequent costs. This is due to requirements for periodic review of regulatory approvals, request for post commercial monitoring data and/or additional data on product safety and changes in regulatory systems.

What is Protection of Regulatory Data?

As a significant investment in time and resources is devoted to the collection of the regulatory data required by regulatory authorities to commercialise plant biotechnology products, regulatory data must be protected from misuse.

Both Article 39 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Article 21 of the Cartagena Protocol on Biosafety provide protection against the disclosure and unfair commercial use of regulatory data. There are two types of protection for regulatory data.

1. Confidential Business Information (CBI). It is information that, if disclosed, could cause harm to the applicant's commercial interests.

2. Data Exclusivity. It is a legal right granted by governments, which protects regulatory data from unfair commercial use for a specific period of time (i.e., an exclusivity period). During the exclusivity period, the regulatory data – or the evaluation written by regulatory authorities based on the applicant's data – cannot be used for regulatory purposes by a secondary applicant (unless duly authorised by the applicant). When the exclusivity period ends, secondary applicants can use the original applicant's regulatory data to register follow-on products.

Safeguarding CBI

Regulatory data are submitted to regulatory authorities with the understanding that CBI will be protected by confidentiality rules and will not be disclosed at any time. CBI is information that is exempt from public disclosure by regulatory authorities, unless the applicant provides prior approval. If disclosed without permission, it could be detrimental to a technology developer's business interests or to the safety and privacy of researchers. Similar to the violation of patents and trademarks, disclosure of CBI can lead to the significant loss of potential revenue, and failure to adequately protect CBI discourages the research and development of innovative products by the plant science industry.

Ensuring the non disclosure of CBI can be difficult due to a lack of uniform understanding of what qualifies as CBI in the plant biotechnology industry. In order to ensure the protection of CBI, it is essential that applicants and regulatory authorities alike clearly understand what constitutes CBI, how it should be identified within applications, how the information should be stored, and how evaluations should be written by regulatory authorities in a way that does not disclose this protected information.

Safeguarding Data Exclusivity

Regulatory transparency can help support public acceptance of plant biotechnology products. However, it is essential to maintain a balance between transparency and protecting regulatory data from misuse, thereby protecting the data owner's rights. CropLife International believes that government

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policies that promote increased transparency around product safety information and regulatory decision-making have to be consistent with policies that contain strong data exclusivity provisions. In fact, strong data exclusivity rules can actually promote greater transparency as concerns related to unfair commercial use of disclosed information are mitigated. The publication of evaluations written by regulatory authorities based on applicant's data can help to build public confidence in the review process, as long as they do not include CBI information. The information contained in these evaluations should not be used by other technology developers as part of their product applications, unless secondary applicants can prove legitimate access to the proprietary data on which the evaluation is based. During interagency evaluations it is also critical that all regulatory agencies involved in the evaluation process prevent unauthorised disclosure of this protected data.

In several countries, regulatory information is made available for non-commercial purposes to the public through a reading room facility. CropLife International supports the use of a reading room facility and recommends that a legally enforceable agreement should be established by anyone seeking access to regulatory data to ensure that they will not use the information for commercial purposes in any other jurisdiction.