GENERATING REGULATORY DATA: A CONSIDERABLE EFFORT

Generating regulatory data requires considerable cost, time and effort on the part of the innovator:

• Development of a new agricultural chemical costs in excess of $250 million
• Development time exceeds 9 years
• Only 1 out of 140,000 molecules makes it from laboratory to field
• Over 120 tests are performed on each new product entering the market to ensure safety and efficacy. Some countries require that these tests be repeated under different agro-climatic conditions (or regions) in the country, depending on varying crops, pests, agronomic practices, climate conditions and terrains.

• Data generation continues after marketing approval, involving significant subsequent costs. This is due to requirements of periodic review, possible requests for additional data from regulatory authorities, and changing standards of scientific and technical knowledge.
• The role of providing information on the correct dosage/use of agricultural chemicals is being taken on by companies, who, after introducing the chemical in the market, do extension services and product stewardship for several years. For example, product stewardship in India includes door-to-door contact with farmers in villages to educate farmers on the use of new crop protection products.

REGULATORY DATA PROTECTION – A Win-Win for All

Farmers around the world face daunting challenges, ranging from climate change to growing populations and changing diets. The plant science industry invests in research and development (R&D) to bring forward new tools and technologies to produce food sustainably and help address these challenges.

Regulatory data protection is one of the essential elements for stimulating investment in research and development of agricultural crop protection products. This protection provides benefits to all stakeholders – from farmers to consumers – ultimately contributing to the economic development of industrialised and developing countries alike.

What are regulatory data?

The term “regulatory data” refers to test and other data generated by a plant science company to prove that its agricultural chemical products are safe and effective. More specifically, once a new product is created by a company, that company must obtain approval from government regulatory authorities to place that product on the market. To obtain this approval, the company must demonstrate the safety and efficacy of that product to these authorities through presentation of comprehensive test and other data. The data is the result of extensive research and testing in residue efficacy, ecotoxicology, toxicology and environmental safety. If these data meet certain criteria, such as being undisclosed at the time of submission, governments are required to protect the most sensitive information from disclosure, and all of the documentation from “unfair commercial use.” The requirement to protect data from disclosure and “unfair commercial use” is recognised under Article 39 of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
Protection of regulatory data provides benefits for all

1. BENEFITS FOR INNOVATORS
• Regulatory data protection is an incentive for innovation. Regulatory data protection provides plant science companies with an opportunity to recoup their investments in costly research and development of new and beneficial products for sustainable agriculture by protecting certain test and other data associated with those products. Thus, companies are encouraged to engage in their research and development of those innovative products.
• There are two types of protection for regulatory data. Protection consists of:
  i. governments maintaining the confidential business information (CBI) that is submitted; and
  ii. governments preventing competitors of the innovator plant science companies from using the regulatory data submitted by the innovator for a set period of time, i.e., an “exclusivity period.”
• At the expiration of the exclusivity period, a competitor is permitted to rely on the innovator’s regulatory data to register safe and effective generic copy products without competitions having to invest in the development of new safety and efficacy data.
• The period of exclusive use balances the dual objectives of providing continued strong incentives for investment in the development of novel crop protection chemicals, while also allowing generics to enter the market at a predictable point in time. Generics may rely on innovator’s data after the expiration of the exclusive period.
• Regulatory data protection provides an added incentive for companies to register their products in different markets, resulting in a broader range of product choice available to farmers.

2. BENEFITS FOR FARMERS & THE ENVIRONMENT
• Regulatory data protection facilitates the introduction of newer agricultural chemical products into the market, which benefits farmers by improving the yield and quality of their crops.
• Research shows that the number and variety of agricultural chemical products available for farmers is higher in countries that provide longer periods of regulatory data protection. Further, the availability of agricultural chemical products reduces agricultural losses to pests and improves harvest yield (Figure 1).

3. BENEFITS FOR DEVELOPMENT
• Regulatory data protection provides incentives that are an important part of a national innovation strategy and can contribute to economic development and poverty reduction in developing economies.
• Regulatory data protection benefits domestic innovators in developing countries. It acts as a domestic incentive to invest in R&D in agricultural chemical products, as it protects national companies from unfair commercial use and disclosure of test data submitted to the regulatory authorities.
• Protection of regulatory data also helps attract higher foreign direct investment (FDI), as countries providing data protection will be the preferred destinations for R&D cooperation and investment.
• A recent OECD study highlighted the positive relationship of intellectual property reform to trade, foreign direct investment, technology transfer and innovation. The OECD study highlighted the “clear tendency for the strengthening of IPR protection in recent decades to be associated with increased inflows of FDI.”
• Strong IP protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original invention, creating a “win-win” situation to spur further collaboration between developed and developing countries.
• Protection of regulatory data encourages plant science companies to import (or manufacture locally) new crop protection products, which benefits the local market.
• Protection of regulatory data will help countries spur innovation, attract investment and build countries’ R&D base.

Regulatory data protection is thus a win-win for all.

FIGURE 1: BENEFITS OF AGRICULTURE CHEMICALS PRODUCTS

Primary benefits
- Improved yields, quality, safety, shelf life, retailer networks
- Reduced drudgery and fuel use for weeding
- Reduced soil disturbance

Secondary benefits
- FARMING COMMUNITIES
  - Farm revenues
  - Nutrition and health
  - Food safety and security
  - Life expectancy
  - Labour freed for other tasks
- NATIONAL
  - Agricultural economy
  - Food safety and security
  - Export revenues
  - Nutrition and health
  - Human productivity
  - Reduced soil erosion and moisture loss
- GLOBAL
  - Assured safe food supply
  - Diverse produce
  - Less pressure on unspoilt land
  - Less greenhouse gas
  - Fewer pest introductions
  - Biodiversity conserved

Source: Jerry Cooper and Hans Dobson