

### Executive summary

The generation of safety and efficacy studies filed before national authorities for approval of new agrochemical products or for re-approval of existing chemicals involves a considerable effort that should be protected. This principle is supported by TRIPS' Article 39.3, which precludes third parties from unfairly relying on studies regarding new chemical entities for commercial purposes (for example, obtaining marketing approval). This position paper covers both new and existing chemicals/products.

In line with United States and European Union law, the plant science industry considers that the best way to protect innovators is to:

- Ensure a minimum ten-year exclusivity period for new chemicals, followed by five years of compensation 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)
- Ensure a five-year protection for additional documentation requested by the authorities to maintain market approval

### Protection against unfair commercial use:

- During the exclusivity period 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.
- During the compensation period, the competent national authority may grant a marketing license (market registration) to a copy product, with an obligation on the part of the copy applicant to compensate the titleholder for relevant studies.
- Once these periods have expired, the competent national authority may grant registrations through a summary approval procedure, but it remains under the obligation to protect the studies against disclosure (a principle supported by TRIPS' Article 39.3).

### Protection against disclosure

- The obligation to protect against the disclosure of the data persists even after the expiration of the exclusivity and compensation periods. The principle is that the complete studies must not be placed in the public domain: therefore safety and efficacy studies remain "undisclosed" notwithstanding the fact that summaries or abstracts of them are published.

The great majority of legislations worldwide have accepted the difference between pharmaceuticals and agrochemicals, regulating the protection of the respective safety and efficacy data in a different manner.

### Vision Statement

Working together for sustainable agriculture

### Mission Statement

As a global network, CropLife International acts as an ambassador for the plant science industry, encouraging understanding and dialogue whilst promoting agricultural technology in the context of sustainable development

### Values & Beliefs

#### Respect

- We will respect the views and values of others and act with honesty, humility and humanity.
- We will seek the respect of others for our values and beliefs.

#### Openness

- Communication will be a fundamental priority in all our activities.
- We will act with openness in all our dealings with stakeholders and actively engage in dialogue, exchanging opinions and facts, in order to increase society's understanding of our industry and our understanding of society.

#### Commitment

- We will commit to serve our members and stakeholders operating to the highest possible standards of professionalism ensuring the effective and prudent management of our resources.

#### Technology

- We believe in the benefits that technology brings to human development and progress, and to sustainable agriculture.
- We believe in the complementary and synergistic nature of technologies developed and offered by the plant science industry.
- We believe in science as the engine of innovation and the core principle of regulatory decision-making.

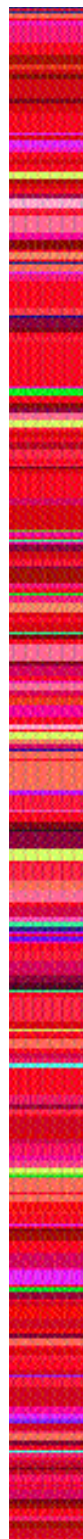
#### Sustainability

- We are committed to promoting full and effective stewardship (the responsible and ethical management of a plant protection or biotechnology product throughout its life cycle) to the field level, and recognise that the appropriate management and use of our products is an important element underpinning sustainable agriculture.
- We will strive to work together with others to achieve a proper balance between all dimensions/pillars of sustainable development.
- We will strive to maintain a healthy, ethical and viable business environment for the plant science industry.

# Position Position Paper Paper

## On the Protection of Safety and Efficacy Data for Existing and New Crop Protection Chemicals

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## Introduction

The generation of safety and efficacy studies filed before national authorities for approval of new agrochemical products or for re-approval of existing chemicals involves a considerable effort that requires a significant investment of time and money. Studies regarding new chemical entities are protected against any unfair commercial use pursuant to TRIPS' Article 39.3<sup>1</sup>, which precludes third parties from unfairly relying on them for commercial purposes (for example, obtaining marketing approval). In the case of agrochemicals CropLife International considers its position on the protection of safety and efficacy data to be applicable to both new and existing chemicals/products.

The plant science industry considers that the best way to protect the industry adequately from the unfair commercial use of proprietary safety and efficacy studies is to:

- Ensure a minimum ten-year exclusivity period for new chemicals, followed by five years of compensation 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)
- Ensure a five-year protection for additional documentation requested by the authorities to maintain market approval

This period is similar to the protection currently offered under United States<sup>2</sup> and European Union<sup>3</sup> law, and provides a reasonable time frame in which to recover the investment made by the innovator. A shorter period of protection would be completely inadequate and would foster a discriminatory obstacle to trade, not only between the countries which form a particular free trade area, but also between the free trade areas themselves, creating unacceptable market distortions.

## Summary approval procedure

Summary approval procedures to obtain market registration for agrochemical products exempt an applicant for the registration for a copy<sup>4</sup> product from filing the corresponding safety and efficacy studies. The rationale for summary approval procedures is based on the understanding that the safety and efficacy of a chemical entity has already been evaluated as a result of the studies filed by the first registrant (innovator), provided that equivalence<sup>5</sup> between the copy product and the innovative product is shown.

This procedure forces the innovator, the generator of these data, to assume all the risk and the cost (in time and money) of the studies which permit the marketing of the chemical entity, while a third party, relying on the innovator's studies, can enter the market with the same chemical entity without ever sharing any part of the effort or risk. Such unjust profiting from the innovator's effort constitutes an **unfair commercial use** of the studies, a conclusion that is entirely supported in the history of negotiation of TRIPS' Article 39.3.

## Data protection mechanisms in use

The preferred mechanism adopted worldwide to protect these data against unfair commercial use is 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.

Additionally, and subsequent to the exclusivity period, many legislations provide for a compensation period, during which the competent national authority<sup>6</sup> may grant a marketing license (market registration) to a copy product, with an obligation on the part of the copy applicant to compensate the titleholder for relevant studies.

Once these periods have expired, the competent national authority may grant registrations through the summary approval procedure, but it remains under obligation to **protect the studies against disclosure**.

## TRIPS' Article 39.3

Pursuant to the double purpose of TRIPS' Article 39.3, the obligation to protect the safety and efficacy studies against unfair commercial use is complemented by the obligation to protect them **against disclosure**.

The obligation to protect against unfair commercial use is typically limited in time by predefined exclusivity and compensation periods, in order to reach an adequate balance between the need to protect the efforts of the generator of the data while preserving the market entry of generic products, without requiring that they generate their own studies.

The second obligation, to protect against the disclosure of the data, persists even after the expiration of the exclusivity and compensation periods, **as this expiration does not mean that this information is released into the public domain**. On the contrary, the information continues to be the property of the submitter and must continue to be protected against disclosure.

Similarly, the fact that TRIPS 39.3 allows for the partial disclosure of data for non-commercial purposes (e.g. in order to allow third parties to consult and discuss the results of the studies) does not imply that the protection against unfair commercial use is thereby lost. The requirement that the data be **undisclosed** rests on the principle that **the complete studies must not be placed in the public domain**. Therefore safety and efficacy studies remain "undisclosed" notwithstanding the fact that summaries or abstracts of them are published.

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, the data does not lose its protection against unfair commercial use when, after it is filed with the authority, it becomes necessary to disclose the results of the test data for reasons of public interest. This is why TRIPS' Article 39.3 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.

It must be borne in mind that unlike industrial secrets, the basis of which is derived from the confidentiality of the information, the protection over safety and efficacy data is derived from **the need to protect the generators' effort**. Thus, the criteria by which data are judged to be protected against unfair commercial use are higher for safety and efficacy test data than the basic judgment of confidentiality used for industrial secrets.

The clear distinction between both protections (against unfair commercial use and against disclosure) reveals the particular nature of the protection of studies against unfair commercial use. It seeks to prevent third parties from entering the market in an unequal and unfair way by profiting from an effort undertaken by another. Such unfair commercial use could result despite the fact that the studies themselves are not revealed or disclosed to the party in question during the summary application procedure. For the unfair commercial use to occur, it is enough if, during the protection period of the test data (exclusivity and/or compensation periods) the competent national authority accepts that another applicant is totally or partially exempt from filing their own test data.

<sup>1</sup> The following countries have a specific regulation for pesticides, establishing a special exclusivity period: European Union (10 years for initial data, 5 years for additional data in Annex 1 of European Directive 91/414/EEC). Other countries regulate the protection for pharmaceutical and agrochemical sectors in the same way. In the case of Guatemala, a 10 years protection period is provided for agrochemicals and 5 years for pharmaceuticals, pursuant to the legislation approved in March 2003. Japan awards a permanent protection for both sectors. [From: <http://www.croplifeamerica.org/public/issues/intel/wtodata1.pdf> ]

<sup>2</sup> See, generally, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).

<sup>3</sup> According to a study by the Tufts Center for the Study of Drug Development. Tufts University, November 30, 2001. At: [www.tufts.edu/med/csdd](http://www.tufts.edu/med/csdd)

<sup>4</sup> Data from independent Report for ECPA and CropLife America, published 2003 (exchange rates are those in 2000 when the study was carried out).

## Data protection for pharmaceuticals and agrochemicals

In spite of the fact that the general protection over safety and efficacy studies in Article 39.3 applies to the pharmaceutical as well as the agrochemical industry, the differences between these industries are well known, and their requirements are quite diverse. The great majority of legislations worldwide have accepted this difference, regulating the protection of safety and efficacy data in a different manner<sup>7</sup>.

While in the United States the exclusive protection period for the safety and efficacy studies in the pharmaceutical industry has been limited to only 5 years as a result of a negotiation in which an extension in the duration of pharmaceutical patents was awarded<sup>8</sup>, the protection for new agrochemical products consists of a 10-year exclusivity period from date of registration and 15 years of compensability from date of submission.

Likewise, the protection given to the studies for agrochemical products in the European Union is from 10 years of exclusivity for initial data and of 5 years for additional data, again differing from that accorded to pharmaceuticals.

## R&D costs for agrochemicals

The effective implementation of an adequate protection period allows the agrochemical industry to face the particular circumstances and high risk investments associated with the development of new crop protection products and to maintain existing approvals.

While in the pharmaceutical sector one of every 5000 molecules investigated is approved by the FDA for marketing<sup>9</sup>, in the agrochemical sector only one in approximately 140,000 studied molecules makes it from the laboratory to the field. Because of their chemical nature and the wide range of organisms potentially affected by their use, agrochemical products must pass more than 120 different safety tests. Additionally, efficacy tests must be repeated in each country, even in several regions of one country, due to differences in crops, pests, agronomical practices, climate conditions and terrains.

Because of the nature of the substances involved, the plant science industry faces a responsibility for environmental impact to which the pharmaceutical industry has little exposure. The average development cost for a new agrochemical in the year 2000 was € 200 million (US\$ 184 million), and the average development time is over 9 years from discovery to first commercialisation<sup>10</sup>. This justifies the different treatment that the pharmaceutical and agrochemical sectors receive worldwide as to the term and form of protection of safety and efficacy studies.

## 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 followed by 5 years of compensation, and a five-year protection for additional documentation requested by the authorities.

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