

The Impact of Generics on Weed Management

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In a presentation to the 2001 annual meeting of the Weed Science Society of America, it was said, "When considering the role of a generic product it is important to understand that few herbicides are discontinued due to lack of efficacy. Newer products with a different spectrum of activity or more favorable environmental/toxicological properties replace some, but others fade for economic reasons because they no longer meet the commercial expectations of the registrant." While this very much remains the same, the case is being tempered by declining success from discovery and commercialization of new molecules.

To better understand the impact of generics, present and future, on weed management, it is important to consider factors having given rise to this group of products. It must always be remembered that generics are a commercial and not a technical evolution. Generic herbicides are not the result of a targeted development activity, but economic necessity.

World wide, agriculture is in recession with free market desires entangled with a variety of national and international subsidies. As a result, farmers in most areas are unable to maintain profitability considering the breadth of the gap between income and expense. As a result, in 2000, the Crop Protection Chemical (CPC) industry experienced a 12 to 15% reduction in value; in 2001, it may have been nearer a 25% loss of value. Keep in mind this loss was only partially due to reduced CPC product utilization, but more significantly due to reduced prices. With greater than 70% of currently registered CPC products off patent, pressure will continue to assure that competition drives pricing; but the big question is will this result in costs that are sustainable? Products will be lost forever once the threshold is crossed whereby value received will not sustain expenses required to maintain registrations and provide reasonable shareholder financial return. Other factors impacting the rise of generic herbicides include:

- 1) Cost of discovery of new CPC products increasing sharply as the rate of commercialization of new molecules declines.
- 2) All sections in the CPC industry are attempting to rationalize costs to deal with reduced profitability through consolidation at all levels.
- 3) Global manufacturing/supply is in change characterized by over capacity in regard to production.
- 4) Reduced CPC profitability is impacting funding available to support public research efforts.
- 5) Biotechnology has given rise to a variety of before unknown agricultural tools impacting the use of CPC products.

With these factors giving rise to significant change, what is this thing called a Ageneric herbicide?"

- 1) A product without an established trade name or a representative of a class.
- 2) A product with patent protection expired.
- 3) A commercially proven product remaining biologically active.
- 4) A product often presenting opportunity for modification of presentation form (e.g. Formulation).

Key to acceptance of a generic herbicide has been user or customer reaction. While acceptance of newly introduced products can be long and costly, generics are seen by users as a way to influence supply/demand by supporting the presence of competition within the market place. Generics are generally considered more cost effective than patented proprietary offerings. There is also concern among some users in regard to tactics employed by original suppliers when products were under patent protection. There is continuing concern as to the way prices decline so rapidly upon the entry of generic supplier(s). Utmost among factors causing users to accept generic products is Aconfidence@ based on use history. This is an interesting representation of selective memory as this knowledge is the direct result of activity funded while sold under patent protection.

To have generic herbicides, there must be a means by which they can be made available. While it is becoming more common for a generic supplier to have manufacturing capacity, excess manufacturing capacity around the world allows toll/contract market entry. Once supply is obtained, a product must be proven Asubstantially@ similar to currently/previously registered products to qualify for data citation in the registration process. While some specific data are required for any generic CPC product, proving substantial similarity, assures the opportunity to cite the data of other registrants under the FIFRA provision regarding Adata compensation." This all done, the public domain presents data relating to the product performance which serves to substantiate generic performance in creation of a use label.

Now we have created an opportunity to market a generic herbicide. Those who have registered generics have a huge challenge that may be new to most of them. It is becoming more common for the generic producer to become the primary registrant for a product with attendant responsibilities. Often there is a void in regard to adequacy of current environmental and toxicological data leading to the need for expensive testing. To complicate product issues in a very competitive business environment, it is not uncommon for the Arumored@ issues to have a greater impact on data requirements than the Aknown."

Now that we have some appreciation for what a Ageneric@ is, how it comes to be, and the factors that influence, what will a generic herbicide do? Technically, nothing that it did not do as a patented product, but economics have changed! The largest generic product in the USA is glyphosate; at a cost of \$3 to \$4 per acre, its use brought about by biotechnology has humbled pre-plant and pre-emergence herbicide use. The applied cost of this one product has set a pattern where low cost product delivery is more important than service and to a degree quality. Declining prices have been experienced across most major classes of herbicides with the trend expected to continue as other classes of products come off patent.

It was reported at the 2001 Brighton Conference that the following five herbicides make up over 75% of generic herbicide sales:

<u>Rank</u>	<u>Product</u>	<u>2000 Sales (Est. \$ Million)</u>
1	Glyhposate	3,100
2	Paraquat	470
4	Atrazine	320
5	Metolachlor	305
7	2,4-D	265

Further, a ranking of generic producers was given at Brighton:

<u>Company</u>	<u>2000 Sales (Est. \$ Million)</u>
Makhteshim-Agan	734
Nufarm	498
Griffin	406
Cheminova	255
Sipcam Oxon	229

Interestingly the two largest generic producers, Monsanto and Syngenta, were considered basic manufacturers for the purposes of the Brighton report.

What will a generic herbicide do for weed management? The cost reductions brought about by the rise of generic herbicides have created an opportunity for users to employ products/mixtures previously not cost effective. Generics have removed cost as a controlling factor in most herbicide management systems!