

Statement on Biotech Seed Industry Competition & Innovation

**American Farm Bureau Federation
American Soybean Association
National Farmers Union**

Our farmers are concerned about the need to maintain international regulatory approvals after a product goes off-patent. They are also increasingly concerned that there are no regulatory or industry-agreed processes in place to ensure that competition and innovation in the biotech seed industry are facilitated as trait patents near expiration. Our members are eager for our organizations to work with the technology providers, regulators, and others to resolve these issues in a satisfactory and timely manner.

We are pleased that the Biotechnology Industry Organization (BIO) has started work to address these concerns for products that are due to go off-patent.. Since our farmers have a significant stake in ensuring that a timely solution is realized, we wanted to share with you our thoughts on this subject. We believe any resolution must be delivered in a timely and enforceable fashion, and include the following components:

1. **A system for maintaining international regulatory approvals for generic traits after patent expiration in a way that enables generic single-trait products to be available for all farmers.** It has been a fundamental principle since the introduction of the first biotechnology traits that key export market approvals are necessary for commercialization, and this principle still holds after the patent has expired on a product. This goal could be satisfied in a number of ways, but it is critical that a method for dealing with this challenge be mapped out and agreed upon.
2. **A product development clause, such as a research exemption, to allow both private and public sector researchers to work with a trait under proper stewardship restrictions before its patent expires. A research exemption should allow seed breeders to access the data package in a timely manner before trait patent expiration in order to advance single trait or stacked trait breeding programs.** Researchers should not be allowed to bring products containing a patented trait to market before the patent expires, but they should be allowed to develop products under proper stewardship restrictions and seek export market approvals so that products can be brought to market as soon as patents expire.
3. **A compulsory system for obtaining a timely letter of access to use data collected by the patent holder for the regulatory process for ag biotech products.** Companies can currently negotiate such a letter of access with a patent holder in order to obtain export market approvals, but negotiations may not be successful or may drag on for extended periods of time. Fair compensation for data should be required and, in the event negotiations are not successful, the mandatory arbitration process outlined in FIFRA for the agrichemical industry is a model that may warrant a closer look.

Our organizations and our producers understand that these are major challenges to overcome but, given the profoundly negative implications for farmers of delaying a resolution, we must urge your companies to work to resolve them in a timely manner.