NCFC
National Council of Farmer Cooperatives

Tel: 202-626-8700
Fax: 202-626-8722
50 F Street, NW Suite 900
Washington, DC 20001
www.ncfc.org

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Regulatory Analysis and Development, PPD, APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

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Re: ***Docket No. APHIS-2014-0054; Environmental Impact Statement; Introduction of the Products of Biotechnology; Notice of intent to prepare an environmental impact statement; 81 Federal Register 6225, February 5, 2016.***

Dear Sir or Madam:

On behalf of the National Council of Farmer Cooperatives (NCFC), please accept the following comments on the notice of intent to prepare an environmental impact statement on the introduction of the products of biotechnology, published in the Federal Register on February 5, 2016.

Introduction
American agriculture is a modern-day success story. America's farmers produce the world's safest, most abundant food supply for consumers at prices far lower than the world average. Farmer cooperatives are an important part of the success of America's food agriculture supply chain.

Since 1929, NCFC has been the voice of America's farmer-owned cooperatives. NCFC members include regional and national farmer cooperatives, which in turn comprise over 2,500 local farmer cooperatives across the country. Farmer cooperatives – businesses owned, governed and controlled by farmers and ranchers – are an important part of the success of American agriculture. Like many in production agriculture, our members have had long and direct experience with biotechnology crops and have realized the many benefits they provide, including improvements in production efficiency while lessening the environmental impacts of food production.

Better seeds give farmers new choices to cope with new challenges, such as difficult weather conditions and plant diseases, and to increase productivity to help feed, clothe, and provide energy to a rapidly growing global population in an environmentally sustainable way. By improving crops and farm productivity, modern biotechnology delivers significant economic, environmental, health and consumer benefits.

The introduction in 1995 of modern biotechnology has made a significant contribution to meeting the global needs for food and feed, and to improving farmers' economic and environmental sustainability. Rapid adoption of this technology reflects farmer satisfaction, including more convenient and flexible crop management, lower cost of production, higher productivity and/or net returns per acre, and numerous health, social and environmental benefits, including decreased use of pesticides.

The development and adoption of these products, and the promise of new products makes possible the continued availability of safe food, feed, and fiber products to consumers in the U.S. and worldwide. We support the intent of the Animal and Plant Health Inspection Service (APHIS) to prepare an environmental impact statement of the regulatory approval process of new biotechnology traits and urge APHIS to focus any changes to the current process on facilitating innovation, maintaining a clear and unambiguous scope, and streamlining coordination with the approval requirements of the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).

Facilitating Agricultural Biotechnology Innovation

American agriculture has long been at the forefront of meeting the world's ever expanding needs for food, feed and fiber. The availability of corn, cotton, soybeans, sugar beets, canola, alfalfa, and other crops enhanced through biotechnology will continue to assist the U.S. farmer in providing for the world's growing population.

NCFC supports policies that enhance the ability of producers to use new practices and technologies to produce their crops, so long as the practices are based on proven science, are economically and environmentally sound and ensure food safety. Additionally, we strongly support the safety and science-based risk assessments conducted as part of the regulation of biotechnology crops. Farmer cooperatives are stakeholders in the development, deregulation and commercialization of biotechnology crops, and the actions taken by government agencies on these crops have a direct and indirect impact on timely access to future traits now under development.

Crops enhanced through biotechnology currently on the market bring value to agriculture, consumers and the environment. For example, some of these plants have been engineered to allow the application of herbicides, such as glyphosate, over the top of crops growing in the field, reducing tillage and runoff. Others have been protected against harmful insect pests and diseases, thereby reducing the need for chemical spraying.

Breeders have a long history of developing new crop varieties that are more efficient and precise at producing the same desired characteristics that would normally occur through traditional breeding techniques, which require longer development time. Furthermore, these new varieties have a proven track record of health and safety for over twenty years. However, unknown costs, approval delays, and ambiguity of regulatory scope can stymie investments in agricultural innovation. In our modern agriculture system, time is critical to meeting the mounting pressures of global food insecurity and an array of environmental challenges, while maintaining competitiveness in the global marketplace. The U.S. government must establish a regulatory environment that facilitates efficient agricultural innovation to enable American farmers to overcome these serious hurdles.

Regulatory Scope

When considering changes to the regulatory approval process of biotechnology products, APHIS should focus its attention within the boundaries of its statutory authority. Narrowly, regulatory oversight should focus on the specific outcome of a trait, regardless of the process used to achieve it, and the level of risk to plant health, while maintaining a clear and unambiguous process.

APHIS has the authority to regulate the introduction of organisms and products of biotechnology that are, or could be, plant pests. Therefore, regulatory oversight should be applied only to the assessment of plant health risk posed to other plants as a product of the seed trait, not necessarily the process by

which a trait is achieved. The oversight of products using biotechnology to achieve a certain outcome should be consistent with oversight of products with similar outcomes generated by other means.

Furthermore, oversight of a specific trait should be proportional to the severity of risk it poses to other plants; oversight of products of biotechnology should be consistent with oversight of similar products created by other means that pose the same level of risk. It is critical that APHIS's regulatory scope is consistent and transparent before resource investments for innovation can take place.

Streamlined Agency Coordination
It is important to consider a broad range of perspectives in order to clarify, improve and modify, if necessary, the four regulatory alternatives the agency is considering before publishing a proposed rule. This systematic consideration will ensure that the final regulatory framework will be efficient, transparent, predictable and easy to implement, ultimately encouraging greater investment in innovation and strengthening our country's food and agricultural economy and the health of our environment.

In developing the final process of considering a new pre-market agricultural biotechnology trait approval system, APHIS should work closely with scientific experts, stakeholders, and with the other agencies responsible for U.S. biotechnology regulation, including FDA, EPA, and the U.S. Trade Representative to ensure harmonious definitions across U.S. regulation and international trade.

Definition of Biotechnology
The definition of biotechnology should only consider organisms that contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature. Furthermore, any definition adopted by APHIS should be compatible with those of other U.S. regulatory agencies and international trading partners.

New gene editing tools offer a precise alternative to mutagenic techniques, which have been safely used by plant breeders for almost a century, to create novel alleles of native genes. These novel alleles are indistinguishable from naturally occurring mutations that may be found fortuitously or through ECO-TILLING in adapted germplasm, landraces, or wild relatives. Recent advances in functional genomics have, and will continue to add tremendous new knowledge about gene function, thus informing the selection of target genes and gene edits for the creation of plants with novel traits and improving crop performance and/or quality.

Gene editing techniques offer the promise of significant opportunities for smaller acreage crops that have not been able to participate in the advances in crop improvement associated with traditional genetic engineering; incremental opportunities are also available to plant scientists employed in the public sector and by smaller companies.

We request that low-risk, simple gene editing – as defined in the APHIS scoping document as gene edits resulting in "modifications that could reasonably be expected to be obtained through mutagenic techniques," – be exempt in the definition of biotechnology and from the technologies requiring pre-market regulatory oversight.

Regulatory Alternatives
All approaches proposed should be clear and transparent enough to provide a predicable determination of what plants would and would not be regulated. NCFC believes that a clear, science-based definition of biotechnology will help inform any of the regulatory alternatives outlined in the NOI. Any regulatory system considered by APHIS should continue to focus on plant health risk posed by specific unique products and not the general process used to create it. APHIS should carefully consider whether and how to regulate products developed through precision breeding tools that are similar to or indistinguishable from products resulting from more traditional breeding tools.

Any new regulations should avoid creating new trade barriers or trade disruptions due to non-harmonious policies and practices. The U.S. government consistently supports and defends science-based regulatory regimes. In many international forums, U.S. policy is the standard for science and risk-based regulation. The interests of growers, businesses and consumers depend on trade agreements with countries that import commodities and products that we produce. The injection of non-science-based criteria into our government's regulatory process will only serve to undermine those international efforts.

Conclusion
In closing, we urge the Administration and this Committee to maintain the integrity of the regulatory process for the benefit of U.S. growers and our consumers. We must remember that we all are working toward the use of biotechnology in a manner that promotes continued opportunities for all farmers and consumers around the world.

NCFC appreciates the opportunity to comment at this important stage of your regulatory development process.

Sincerely,

Charles F. Conner
President & CEO
National Council of Farmer Cooperatives