NCFC
National Council of Farmer Cooperatives

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Regulatory Analysis and Development, PPD, APHIS
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Re: ***Docket No. APHIS-2015-0057-0001; Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms; Proposed Rule; Federal Register 2017-00858, January 19, 2017.***

Dear Sir or Madam:

On behalf of the National Council of Farmer Cooperatives (NCFC), please accept the following comments in response to the United States Department of Agriculture's (USDA) request for public input on revisions to biotechnology regulations (7 CFR part 340) contained in the proposed rule to regulate the Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms as published in the Federal Register on January 19, 2017.

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 are in turn composed of 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.

Facilitating Agricultural Biotechnology Innovation
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 safe, affordable food 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.

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 thirty 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.

Proposed Revisions
NCFC commends the USDA on its efforts to modernize regulatory oversight of biotechnology to ensure its policies are aligned with the best available science and reduce the burden of the regulatory process on new varieties that pose no plant pest or noxious weed risk. The new regulatory provisions proposed on January 19, 2017, take positive steps to ensure that innovation is met by a regulatory review process that is proportional to the actual risk of new technologies. We support the Department's approach to the exclusion of newer breeding techniques, such as gene editing, that result in plant varieties that are essentially indistinguishable from those resulting from traditional breeding techniques. Our membership believes this approach will help ensure that U.S. Agriculture remains as a leader in agricultural innovation.

Unfortunately, the regulatory proposal contains several inadequacies that could result in unintended outcomes preventing USDA from meeting its regulatory objectives. Therefore, NCFC is unable to fully support the regulatory revisions as they are proposed.

We oppose the following aspects of the proposed regulation:

- The proposal lacks transparency and clarity about the regulatory status of newly developed genetically engineered (GE) organisms which must undergo a complex and lengthy risk assessment process before fully understanding whether or not they will be subject to regulatory

oversight. This uncertainty puts researchers and developers at a disadvantage and ultimately stifles agricultural innovation.

- Risk assessments should not be conducted based upon the type of technology used to produce a new plant variety, but rather, the level of risk it poses to the environment.

- The proposal shifts the regulatory burden from the commercialization stage to the research and development stage of product innovation, requiring each new GE plant variety to undergo a complex risk assessment and public comment period before even beginning a field trial.

- According to the proposal, the process by which new plant varieties would undergo assessment puts a heavy load on the Department and its available resources, likely creating a situation where the scale of technology submissions would far exceed the Department's capacity to conduct assessments and review public comments, trapping technologies in regulatory limbo.

- The proposed regulation may not align with current USDA pest and weed regulations creating confusion and double standards. For example, the current proposal would broaden oversight of the authority given under Part 340 to encompass the regulatory process of assessing weed risk, currently authorized under Part 360 regulations. To combine these two authorities would create a more complex regulatory environment and innovation barriers. We encourage USDA to maintain the distinction between these two regulatory authorities.

- The significant changes to the current regulatory system may create an unintended misalignment with other regulatory agencies and international markets which could lead to possible litigation risks.

We believe these shortcomings would have negative impacts on the development of new plant technologies which aim to quickly solve regional and environmental challenges facing producers. Cooperatives that strive to solve these challenges for their farmer-owners through biotechnology innovation would be at a greater disadvantage due to the level of resources needed to proceed under this new regulatory proposal. For these reasons, NCFC recommends the Department reconsider the regulatory implications of this proposal and address these concerns by significantly revising the proposed rule.

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