June, 2017

Dr. Sidney Abel
Assistant Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
4700 River Road, Unit 147
Riverdale, MD 20737-1238

Docket No. APHIS-2015-0057 for "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms."

Dear Dr. Abel,

Thank you for accepting comments on the proposed regulations regarding genetically modified organisms. New genetic modification techniques, like genome editing, are revolutionary, and they carry the potential to speed the development of sustainable solutions to the most pressing agricultural challenges. To ensure the success of the incredible opportunities for sustainable intensification and environmental stewardship that such new technologies afford, appropriate regulation and federal guidance is necessary.

The American Society of Agronomy (ASA), Crop Science Society of America (CSSA), and Soil Science Society of America (SSSA) represent over 18,000 scientists in academia, industry, and government, 12,500 Certified Crop Advisers (CCA), and 781 Certified Professional Soil Scientist (CPSS). As such, we represent the largest coalition of professionals dedicated to the agronomic, crop, and soil science disciplines in the United States. The effects of APHIS's proposed regulations on the scientific community are significant, and so we are pleased to offer comments and suggestions.

APHIS's proposed regulations are a welcome acknowledgement that it is out of date and unscientific to base regulatory status on whether a plant pest was used in an organism's development. The Societies applaud APHIS for modifying its definition of a genetically modified organism and for undertaking the development of a regulatory system that is risk-based instead of method-based. However, certain requirements in this proposed plan need more clarity, and others may be overly burdensome to academic scientists running smaller-scale experiments with plants not intended for market. The following paragraphs detail a number of our concerns and include suggestions for remedying the proposal's shortcomings.

**Not all GE plants need a weediness evaluation.**

*Concern:* APHIS proposes that every new plant-trait combination, unless specifically exempted, would be subject to an APHIS weediness evaluation. Noxious weeds are, indeed, a risk factor that should be considered as new plants enter the United States, either from other countries or the lab, but just as new varieties of imported plants need not undergo a weediness evaluation upon entry, not all GE plants should either. It is contradictory and concerning that APHIS proposes a principle of risk-based evaluation but then, in practice, supposes that all GE plants are more likely to be noxious weeds because of the method of their creation.

*Suggestion:* APHIS should evaluate the weediness of GE plants in the same way it evaluates non-GE plants. Conveniently, APHIS already has criteria for defining noxious weeds, and the authority to regulate plants that meet them, in its noxious weed regulations (7 CFR 360). If there are plants that pose a noxious weed risk that would not be covered under APHIS's existing authority, then the risk factors for such a weed should be identified and incorporated into APHIS's existing noxious weed regulations. It is unclear why a separate risk assessment model for GE plants is necessary.

**APHIS should define weediness criteria upfront.**

*Concern:* APHIS proposes to create a list of plant-trait combinations to exempt from weediness review. Ideally, such a list would significantly reduce the number of evaluations that APHIS would need to perform. However, that list has little hope of ever being exhaustive, and while it may reduce the overall workload for APHIS, it shifts the burden of crops under evaluation to the broader range of new combinations that academic and research scientists are more likely to engage with and away from the large-scale, marketable commodities favored by industry. This will have a cooling effect on research and innovation as plant-trait combinations already on the list will be favored, and new ideas, regardless of actual weediness risk, will be avoided.

*Suggestion:* Instead, APHIS should provide clear criteria for determining if a new plant-trait combination is likely to be weedy. This will offer scientists a clear roadmap for the initial development of products unlikely to be regulated down the road.

**APHIS should specify a timeframe for weediness evaluations.**

*Concern:* It is unclear how long a weediness evaluation may take to complete. APHIS's example evaluations ranged from 40 to 90 pages in length even when they examined plant-trait combinations unlikely to be weedy. Such evaluations may take months to perform in the simplest of cases, especially considering that each evaluation is proposed to be open for public comment, presumably for a minimum of 30 days. Waiting an unspecified time to start a scientific experiment is an acute burden for an academic laboratory. If evaluations take many months or years, academic researchers may choose not to pursue an important line of research, and if no timeframe is given, researchers may expend precious resources on applications with no way of knowing whether they will be approved in enough time to perform the experiments in question.

*Suggestion:* APHIS should set a reasonable, maximum timeframe for the processing of these evaluations.

**A two-tiered system for permitting is valuable.**

*Concern:* If a plant-trait combination meets a published set of criteria for weediness, and, after an evaluation, APHIS determines that this crop should be regulated, it is nevertheless unreasonable that smaller, academic experiments or those using crops unlikely to be commercialized should be subject to the same permitting process, and have the same data requirements, as a crop that is intended for commercialization and widespread distribution.

*Suggestion:* We support the reinstatement of a two-tiered system for permitting. The new system need not use performance-based metrics, as the notification system does, if such metrics cannot be reconciled with OIG recommendations, and it need not be called a "notification" if that term has led to confusion. But it could include risk-based metrics and written protocols to prevent unintended release.

Such a system would preclude the need for a public comment period and extensive data collection, much of which would not be relevant for a small, academic study, and it would greatly speed and simplify the process of moving laboratory specimens across state lines, for example if scientists wished to collaborate or if a scientist were moving to a different institution. Current notifications for field trials or interstate movement take 15-30 days to process, and we propose that any new system not increase that timeframe.

**Conclusion.**

Our members stand ready to develop, commercialize, distribute, grow, and assess new, genetically engineered crops with both enthusiasm and a scientifically critical eye, and we look forward to a risk-based regulatory environment that does not place undue burden or uncertainty on the academic research that underpins the success of U.S. agricultural innovation.