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Docket No. APHIS-2014-0054
Regulatory Analysis and Development, PPD
Animal and Plant Health Inspection Service
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

To Whom It May Concern:

The US Canola Association (USCA) submits these comments in response to Notice of Intent published in the Federal Register on February 5, 2016, in which the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture indicates it will conduct a programmatic Environmental Impact Statement as part of a comprehensive study to examine alternative changes to 7 CFR Part 340. USCA is a non-profit commodity organization and represents canola producers on national and international policies important to the U.S. canola industry.

We commend APHIS for undertaking this initiative, and support the goal of updating regulations to reflect changes in the environment for the development and commercialization of the products of biotechnology. Any changes to the regulations should be tailored to address specific problems in a clear and transparent manner. The existing regulations were designed to address whether transgenic biotech products can pose a plant pest risk, as defined in the Plant Protection Act. Consistent with this authority, APHIS has used the best available science to review the safety of genetically engineered organisms.

In reviewing the four regulatory approaches proposed in the notice, USCA supports Alternative 2 because it is product-based, regulates only products that pose a documented risk, and is consistent with APHIS's authority and intent to modernize its regulations. We would note, however, that in implementing this approach, regulatory scope and oversight must be transparent, predictable, and proportionate to the actual risk posed. APHIS should also take into account the views and responsibilities of the Food and Drug Administration and the Environmental Protection Agency in regulating biotech products to ensure improved and ongoing communication. In addition, APHIS must consider the potential impact of changes in its policies on the international as well as the domestic regulatory and commercial environment for biotech products. Finally, the scope of APHIS's oversight must be limited to its authority to regulate transgenic products that pose a plant pest risk, and should not be expanded to include products that could otherwise be derived through conventional plant breeding techniques.

USCA is particularly concerned by the potential for changes in our regulatory system to disrupt international trade. The U.S. government and our industry are actively encouraging our foreign trading partners to adopt product-based regulatory review systems for biotech traits that are similar to our own. While progress has been slowed by asynchronous approvals in some countries, this approach remains the most viable way to move the technology forward by ensuring market acceptance. Any decision to change to a process-based system in the U.S. would cause other countries to question and possibly abandon the positive changes they are considering for their current regulatory systems.

This issue is critically important to U.S. canola producers, since North America – the United States and Canada combined – exports approximately half of its annual production and biotech traits are expressed in over 90 percent of the varieties planted. A sudden or unexpected change in our regulatory policy could prevent the introduction of new biotech products in the U.S as well as Canada, since nearly all countries have a zero tolerance for the presence of traits they haven't approved. This would effectively shut down the process for developing and introducing new products. We need ongoing access to innovative biotech products that enhance our ability to meet the world's growing food demand.

USCA is particularly concerned by the possibility that APHIS's regulatory review could broaden the scope of bioengineered products to include new plant breeding techniques. In the years since development of transgenic plants, scientists have developed methods for targeting precise changes within the genomes of specific plant species that can achieve many of the same results without introducing genes from another species. These techniques, including gene editing and cisgenics, represent an evolution of older plant breeding methods where the resulting product is indistinguishable from the original variety.

By limiting the definition of biotechnology to transgenic plants, APHIS can enable these new techniques and promote public acceptance. This, in turn, would allow many small companies and universities to participate in a much broader and modern plant breeding sector, and to develop superior plants for many smaller crops, including canola. It is imperative that APHIS continue to restrict the application of its authority to regulate plant pests and its definition of biotechnology to transgenic products.

Given the importance of this review to canola producers and to the broader agriculture community, we would appreciate the opportunity to attend stakeholder meetings with appropriate APHIS and USDA officials prior to publication of a proposed rule.

USCA appreciates the opportunity to comment on the proposed revision of APHIS's regulations under 7 CFR Part 340. If you have questions about our position on the above issues or require additional information, please do not hesitate to let us know.

Respectfully yours,



Jeff Scott
President, U.S. Canola Association