October 20, 2015

The Honorable John P. Holdren
Director, Office of Science and Technology Policy
Eisenhower Executive Office Building
Washington, D.C. 20504

The Honorable Howard Shelanski
Administrator, Office of Information and
Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

The Honorable Darci Vetter
Chief Agricultural Negotiator
United States Trade Representative
Washington, DC 20508

Ms. Christy Goldfuss
Managing Director
Council on Environmental Quality
Washington, DC 20503

Dear Dr. Holdren, Ambassador Vetter, Dr. Shelanski, and Ms. Goldfuss:

We are writing to express our appreciation for the guidance and opportunity for input provided by the Request for Information (RFI)[1] on the White House initiative to review and assess the Coordinated Framework (CF)[2]. We strongly support this one-year initiative and its objectives: to ensure public confidence in the regulatory system and prevent unnecessary barriers to future innovation and competitiveness, while continuing to protect health and the environment[3]. Meeting these objectives is critical, if the U.S. wants to maintain its position as the world's agricultural leader.

We agree that the primary need articulated in the RFI – the need for agencies to clarify their current roles, responsibilities and coordination mechanisms – will serve the initiative's two objectives. Clarifying their requirements and bases for decision-making will help people appreciate the rigor of the current U.S. regulatory process. Biotech crop varieties have been subjected to exhaustive study and analysis to verify food and environmental safety, and learning about the thoroughness of the testing process should instill public confidence in the safety of the biotech products on the market.

Clarity about agencies' authorities, data requirements, bases of decision-making and coordination procedures is also essential for product developers – both public and private. More clarity about current practices will serve the objective of preventing unnecessary barriers to innovation and competitiveness. Biotech crops, which were grown globally on over 450 million acres in 2014[4], have a sterling safety record, with no documented instance of harm to humans, animals or the environment. Even though certainty about biotech crop safety has increased, some agencies' regulatory requirements continue to expand. Escalating requirements, irrespective of a product's risk, have led to the scenario described in the PCAST report to the President[5]: the regulatory system has created an "innovation ecosystem that lacks diversity," by deterring developers and the public sector from developing products. Ever-increasing, unanticipated regulatory

[1] Federal Register Volume 80, Number 193 (Tuesday, October 6, 2015). To be clear, this letter to you is not a formal response to the RFI. Some of all of the organizations signing this letter expect to submit responses to the RFI by the response deadline, November 13, 2015.
[2] *The Coordinated Framework for the Regulation of Biotechnology*. http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
[3] *Modernizing the Regulatory System for Biotechnology Products*
https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf
[4] www.isaaa.org
[5] President's Council of Advisors on Science and Technology. December 2012. *Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise* https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_agriculture_20121207.pdf

requirements not only impede innovation, they also lead to regulatory delays. The RFI asks how the agencies can clarify their processes in order to minimize delays. We encourage the White House to look to USDA-APHIS, which has recently implemented process improvements that have significantly improved timeliness in their decision-making.

In addition to seeking input on how the agencies can clarify their regulatory scope, authorities, requirements and coordination mechanisms, the RFI asks stakeholders 1) to provide "relevant data and information, including case studies, that can inform the update to the CF," and 2) to share insights on "specific issues that should be addressed in the update of the CF." The responses you receive to these open-ended questions will be particularly useful for meeting the initiative's objective of preventing unnecessary barriers to future innovation and competitiveness.

Therefore, we ask that you encourage the agencies to spend this year not only clarifying how their systems work, both alone and together, but also listening to the responses to the RFI's open-ended questions as they consider ways to improve their regulatory processes. That input should inform any substantial changes proposed by an agency. Also, an agency moving forward with changes that would affect the structure of the U.S. regulatory system, during the review process, would make OSTP's role in interagency coordination much more challenging.

We look forward to working together to fashion a biotechnology regulatory system that continues to protect health and the environment but does not stigmatize new technologies or unnecessarily impede innovation. Achieving this will accelerate and broaden access to the many benefits that biotechnology can provide for consumers, the environment and the economy.

Sincerely,

Agricultural Retailers Association

American Farm Bureau Federation

American Seed Trade Association

American Society of Agronomy

American Soybean Association

American Sugarbeet Growers Association

Biotechnology Industry Organization

Crop Science Society of America

National Association of Wheat Growers

National Corn Growers Association

National Cotton Council

National Council of Farmer Cooperatives

Soil Science Society of America

CC: The Honorable Tom Vilsack, USDA
The Honorable Gina McCarthy, EPA
Dr. Stephen Ostroff, FDA