



Biotechnology Innovation Organization  
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May 4, 2022

The Honorable Tammy Baldwin  
Chair  
Subcommittee on Agriculture,  
Rural Development,  
Food and Drug Administration, &  
Related Agencies  
U.S. Senate Committee on Appropriations  
Room S-128 The Capitol  
Washington, DC 20510

The Honorable John Hoeven  
Ranking Member  
Subcommittee on Agriculture,  
Rural Development,  
Food and Drug Administration, &  
Related Agencies  
U.S. Senate Committee on Appropriations  
Room S-128 The Capitol  
Washington, DC 20510

Dear Chair Baldwin and Ranking Member Hoeven:

BIO represents 1,000 members in a biotech ecosystem with a central mission – to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity.

The value of science and agricultural innovation cannot be understated. The adoption of biotechnology in agriculture and the development of biobased technologies has already contributed to food security, sustainability, and climate change solutions. Over the past 25 years it has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits. At the same time, biotechnology has led to a dramatic paradigm shift in the production of fuels and chemicals facilitating modern biorefineries to convert domestic sources of renewable biomass, wastes, and residues into sustainable low carbon fuels, chemicals, and products.

BIO supports public policies centered on innovation to incentivize the adoption of cutting-edge technologies and practices to maintain America's leadership and benefit our rural economies. Further, it is crucial that the government establish risk-proportionate, transparent regulations in a timely manner that spur biological innovations and biobased technologies while protecting health and the environment.



As such, BIO urges the committee to actively support the following priorities as it develops the Fiscal Year 2023 (FY 2023) Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act:

### **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

**FDA Salary and Expenses and Buildings and Facilities:** In line with the Alliance for a stronger FDA, BIO supports the Administration's BA request of \$3.653 billion. This provides for an increase of \$318 million in BA salary and expenses and an increase of \$18 million in BA buildings and facilities.

**FDA Draft Guidance on Gene Edited Plants:** Innovations in agricultural biotechnology, including genome editing tools such as CRISPR, are crucial to ensure agriculture can sustainably produce the food, feed, fuel, and fiber needed for a growing world. FDA plays a critical role in the coordinated oversight of plant biotechnology. While both the U.S. Department of Agriculture (USDA) and the U.S. Environmental Protection Agency (EPA) have taken actions to modernize their regulations for plants produced using new biotechnology techniques, FDA has yet to issue its guidance on new plant varieties produced using the tools of genome editing.

BIO requests the Committee provides FDA with the necessary resources to support the issuance of guidance for industry on foods derived from plants produced using genome editing and to modernize and improve the timelines and predictability of the Plant Biotechnology Consultation Program under FDA's 1992 Statement of Policy – Foods Derived from New Plant Varieties.

**Center for Food Safety and Nutrition (CFSAN):** CFSAN provides numerous important food safety functions, including regulatory oversight of new biotechnology plant varieties intended for food use. BIO appreciates FDA's commitment to ensuring food safety through CFSAN and supports robust funding in FY 2023. We are concerned, however, that the timeliness of CFSAN consultations on products derived from biotech plants (conducted jointly with Center for Veterinary Medicine (CVM) has slowed significantly in recent years, therefore slowing the pathway to market for innovative products of agricultural biotechnology. BIO therefore urges Congress to ensure that FDA's reviews of new biotech plant varieties are not delayed due to competing priorities using the same appropriated funds.

**Center for Veterinary Medicine (CVM):** BIO requests appropriate funding in FY 2023 for FDACVM's Animal Drug and Feeds operations to oversee biotechnology-derived plant products



used as, or in, animal feed and traditional drugs that improve animal health. As with CFSAN, the timeliness of CVM reviews of products derived from biotech plants has slowed significantly in recent years, with concomitant impacts on commercialization of innovative products. We urge Congress to ensure CVM has adequate funding to timely complete reviews of new biotech plant varieties and that they are not delayed due to competing priorities.

In the past BIO has expressed concerns over CVM's oversight of biotech animals, which remains opaque and cumbersome, needlessly bureaucratic, and vastly disproportionate to actual risk. However, FDA's announcement in March that it had made a low-risk determination for the marketing of products, including food, from two genome-edited beef cattle and their offspring after determining that the intentional genomic alteration does not raise any safety concerns was a positive development.

BIO welcomes CVM's efforts to develop a more functional regulatory system for biotech animals – one that ensures the health and safety of animals, consumers, and the environment while also fostering innovation. Accordingly, we urge appropriators to provide FDA the sufficient support to implement an improved regulatory structure.

### **U.S. DEPARTMENT OF AGRICULTURE (USDA)**

**USDA Guidance for GE Microbes:** In May 2020, APHIS issued a final rule to update biotechnology regulations under Part 340 for biotechnology plants. However, USDA did not provide GE microbes with similar, clear next steps for obtaining permits and moving towards commercialization. This lack of predictability threatens the fast-moving pace of research, development, and commercialization for new breakthroughs for GE microbial technologies in the food and agriculture sector.

BIO urges the committee to include report language directing APHIS to take measurable steps to establish a predictable and science-based regulatory pathway, including guidance on categories or characteristics of microbes and install a formal, pre-notice consultation process to formalize the regulatory system for GE microbes.

**Biotechnology Regulatory Services (BRS):** BRS is a program within the Animal and Plant Health Inspection Service (APHIS) that plays an important role in regulating the field testing, movement, and importation of certain biotechnology-derived organisms, including microorganisms and plants. BIO supports providing BRS with sufficient resources to conduct predictable, science-based, and risk proportionate regulatory oversight for certain biotechnology-derived products. BIO supports USDA's efforts to modernize its regulatory



system and encourages Congress to provide BRS with adequate funding in FY2023 to implement the new regulatory structure.

**Section 9002: the Biobased Markets Program, or the BioPreferred® Program:** The Biobased Markets Program, or the BioPreferred® Program, directs federal agencies to increase their purchase and use of renewable chemicals and other biobased products. This program also establishes a labeling program for biobased products to accelerate commercialization. The BioPreferred® Program is driving growth of the biobased economy by helping consumers recognize biobased products. USDA is making it easier for consumers to identify biobased products with the USDA Certified Biobased Product label. There are currently more than 2,700 voluntarily labeled products: 1,700 of them are consumer goods, 400 are renewable chemicals, and 600 are industrial products. According to USDA, the biobased products industry contributed \$393 billion and 4.2 million jobs to America's economy.

Because of the vital economic benefit this program provides, BIO urges the Committee to provide \$3 million in mandatory funding along with the \$3 million in discretionary funding for the Biobased Markets Program FY 2022.

**Section 9003: Biorefinery Assistance Program:** This critical program provides loan guarantees for the development, construction, and retrofitting of commercial-scale biorefineries that produce advanced biofuels, biobased products, and renewable chemicals. This program has enabled companies to put steel in the ground for first-of-a-kind biorefineries. Programmatic improvements in the 2018 farm bill will ensure standalone renewable chemical and biobased manufacturers are eligible to qualify for loan guarantees without having to produce an advanced biofuel. This will provide new and innovative technologies the opportunity to secure funds to develop first-of-their-kind biorefineries, which will grow the biobased economy.

To ensure USDA can support new technologies now able to qualify under the Biorefinery Assistance Program, BIO urges the Committee to provide \$75 million in discretionary funding for the Biorefinery Program in FY 2023. Additionally, BIO requests that the Committee refrain from rescinding any unobligated balances from previous fiscal years that may otherwise be reprogrammed to continue financing loan guarantee commitments under the Biorefinery Assistance Program.

**Biotechnology and Agricultural Trade Program:** Section 3301 of the 2018 Farm Bill reauthorized \$2 million for FY2022 for USDA's Foreign Agricultural Service's (FAS) biotechnology and agricultural trade program, which USDA utilizes to mitigate and resolve nontariff trade barriers. At a time when agricultural export markets are significantly stressed, this



modest investment ensures resources and personnel are available to prevent disputes and keep markets open to hundreds of millions of dollars in U.S.-grown exports in the event of a dispute. BIO supports fully funding the program at \$2 million for FY 2023.

**Agricultural Biotechnology Outreach and Education Initiative:** Consumers face increasing challenges attaining quality, accurate information informing their food purchasing decisions, especially as it relates to biotechnology. BIO supports continued appropriations for the Agricultural Biotechnology Outreach and Education Initiative in FY 2023 to proactively engage the public on this issue and provide consumers with factual, science-based information.

**NIFA-AFRI:** Federal research programs under USDA's National Institute of Food and Agriculture (NIFA) Agriculture and Food Research Initiative (AFRI) have been fundamental to the applied research, extension, and education of food and agricultural sciences to improve environmental outcomes in agriculture, strengthen rural economies, and create new sources of energy. These programs have been essential for the foundational research and agricultural workforce development that complements and underpins large systems-level research, education, and extension activities needed to maintain America's global preeminence in food, agricultural, and bioenergy production.

Unfortunately, despite its benefits, agricultural research accounts for just 2 percent of total federal R&D spending, and AFRI consistently receives far more recommended projects than it has the resources to fund. Given the crucial role federal research agencies like NIFA AFRI will play in addressing the crucial issues of climate and food security and helping U.S. farmers and consumers adapt to a changing world, BIO urges the committee to provide AFRI the full \$700 million authorized in the 2018 Farm Bill.

**AgARDA:** Innovative breakthroughs in agriculture can reduce greenhouse gas emissions, from the field to consumer. New technologies can strengthen producers' resiliency to climate change while increasing production and help tackling hunger by bringing more nutritious offerings to all tables. Doing so will speed the transition of the U.S. economy to one that is more biobased and resilient.

Funding Agriculture Advanced Research and Development Authority (AgARDA) will support government efforts to invest in climate-smart agriculture which is needed to create, test, and scale up promising solutions that can supercharge progress and help us avoid the worst impacts of climate change on the nation's food system. BIO urges the committee to provide at least the \$4.9 million requested in the President's FY 2023 budget



Thank you for your consideration of this request. Should you have any questions or comments regarding these requests, please contact Erick Lutt, Senior Director of Federal Government Relations, at [elutt@bio.org](mailto:elutt@bio.org). We look forward to working with you throughout the appropriations process.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Michelle McMurry-Heath". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Michelle McMurry-Heath, MD, PhD