Biotechnology Innovation Organization

July 31, 2020

The Honorable Sonny Perdue
Secretary
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

Re: U.S. Department of Agriculture *Solicitation of Input from Stakeholders on Agricultural Innovations* (Docket No. USDA-2020-0003)

Dear Secretary Purdue,

The Biotechnology Innovation Organization (BIO) is pleased to respond to the U.S. Department of Agriculture's (USDA) *Solicitation of Input from Stakeholders on Agricultural Innovations*.[1]

BIO represents 1,000 members from the biotech ecosystem around a central mission – to advance public policy that supports a wide range of companies and academic research centers that are applying biology and technology to improve the lives of people and the health of the planet. Our members operate at the nexus of environmental, human, and animal health. They are developing biology-based technologies to enhance cultivation and food production and produce sustainable fuels, renewable chemicals, and biobased products. With our growing understanding of the plant, animal, and microbial worlds and supportive policies and regulations we can modernize agriculture, energy, and manufacturing.

These innovative breakthroughs can reduce greenhouse gas emissions throughout agricultural supply chains and strengthen producers resiliency to climate change while increasing production and help tackling hunger by bringing more nutritious offerings to all tables; and protect against this pandemic and the next by enhancing the response to public health emergencies and speed the transition of the U.S. economy to one that is more biobased and resilient. Already, innovative technologies have been widely adopted to increase productivity while reducing the footprint of agricultural production. Increasing use and acceptance of these technologies will enable U.S. agriculture to meet the Department's goal set forth in the Agriculture Innovation Agenda (AIA) of increasing agricultural production by 40 percent to meet the needs of the global population in 2050 while cutting the environmental footprint in half.

The U.S. has led the way in developing these innovations due to thoughtful, bipartisan public policy. This has created a favorable climate in which to undertake the lengthy and risky job of investing and developing the next biotech breakthroughs; allowed producers to use new technologies; and ensured a pathway to market for new products. However, America's continued success and leadership are not guaranteed, and it should not take its global leadership for granted. Foreign countries are taking overt steps to streamline regulatory systems and speed pathways to market, often with direct government support as part of national bioeconomy strategies.

[1] https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06825.pdf

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COVID-19 has also exposed the vulnerabilities and inequalities in how communities are disproportionately impacted, our capacity to respond to crisis, our ability to maintain our supply chains, and to withstand an economic downturn. These challenges will only grow more prevalent and damaging because of climate change. To ensure America is able to respond to future challenges in cleaner, more efficient ways, maintain its global leadership, and allow its farmers, ranchers, sustainable fuel producers, and manufacturers to have access to cutting edge technologies, the United State must invest in new technologies and have risk-proportionate regulations that spur biological innovations. The government should also focus on removing barriers and assisting beginning and socially disadvantaged farmers and ranchers in accessing and utilizing these technologies, so all producers can adapt to the challenges ahead. By accelerating and deploying innovation American agriculture can be resilient, self-sustaining, and drive our economic recovery.

Below are five key drivers for successful growth of the bioeconomy and to enable U.S. agriculture to meet the Department's goals set forth in AIA:

1. **Advance Modern Regulatory Approaches to Keep Pace with Innovation –** Innovative biotechnologies have allowed producers to increase crop yields, enhance food animal production, improve soil health, and provide biomass and waste feedstocks for sustainable fuels and biobased manufacturing. Expanding the adoption of innovative technologies and practices that reduce the environmental footprint of agriculture while combatting climate change will be necessary to provide the world with adequate food, feed, fuel, and fiber.

   As such, it is critical that the government establish risk-proportionate, transparent regulations that spur biological innovations while protecting health and the environment. Enabling regulatory systems to keep pace with advancements in biology is essential if society is expected to fully benefit from food, health, and industrial products developed using the very latest cutting-edge platform technologies; such as, gene editing, synthetic biology, cell culturing, and fermentation.

2. **Provide Robust Funding of Public and Private Sector Scientific Research –** We must foster an innovation ecosystem that unleashes the transformative potential of science and take steps to ensure the gains from these innovations are broadly shared for the benefit of humanity. This research and development will require the strong support of land-grant universities and Historically Black Colleges and Universities (HBCUs), to produce and develop young scientists and engineers critical to moving the industry forward.

   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 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.

Other federal government research and development programs have been essential to the development of clean energy technologies that strengthen the economy, protect the environment, and reduce dependence on foreign oil. While there has been increasing research and development in biotechnology platform technologies—such as gene editing, synthetic biology, cell culturing, and fermentation—increased federal funding and coordination between agencies will be critical to maintain America's leadership in an increasingly competitive race to generate breakthroughs. The new innovations unlocked from supportive scientific research and development will enable agriculture to increase production while reducing greenhouse gas emissions across agriculture, transportation, and industry.

3. **Modernize Infrastructure –** Ensuring farmers and ranchers can deploy innovative technologies that increase production to create a resilient bioeconomy while reducing pollution will also require important investments in infrastructure. This includes, but is not limited to increased lab capacity, widespread access to broadband internet technology, pipelines and distribution capacity for carbon dioxide and sustainable fuels. It will also require the government working with financial institutions and investors to promote access to capital for startups and scaleup in the biobased manufacturing sectors across agricultural, energy, and material products.

4. **Incentivize Farmers** – Supporting America's farmers, ranchers, and foresters who want to adopt new technologies and innovative practices will be critical to USDA achieving the goals set forth in the AIA. To foster sustainability and economic resiliency in agriculture and preserve America's rich environmental diversity all producers must have access to and benefit from new markets that reward practices for reducing the environmental impact of agriculture.

5. **Build Public Support and Increase Market Access for Innovative Technologies –** Innovation flourishes when science and consumer values are aligned and complement one another. BIO understands that consumers want more information about innovative biotechnologies; to know what is in their food and whether their food is safe. Moreover, it should be clear that biofuels and biobased products are sustainable. As such, the government must help build trust and foster an inclusive environment to address our most pressing societal, nutritional, and environmental concerns to achieve the goals put forward in the AIA.

The following comments expands on these principles, highlights existing and developing technologies describing how increasing the utilization of biological innovations will enable U.S. agriculture to meet the Department's goals set forth in AIA for the betterment of society.

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Advance Modern Regulatory Approaches to Keep Pace with Innovation

I. Food and Farm Applications

Plant Biotech – Plant Biotech Innovations Benefits

Biotech crops have already contributed to food security, sustainability, and climate change solutions. The acceptance of biotechnology has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits. No-till agriculture has been widely adopted due to the superior weed control from biotech crops that are able to tolerate the newer class of lower-impact herbicides. In addition, a reduction in plowing has also enabled farmers to significantly lower the consumption of fuel and decrease greenhouse gas emissions. No-till farming also leads to better conservation of soil and water and a decrease in soil erosion and soil compaction. Biotechnology has also made possible pest control measures that are more precisely targeted at specific problem pests while dramatically reducing impacts on non-target species. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA)[2] biotech-enhanced farming systems saved 452 million acres of lands from plowing and cultivation, and decreased use of pesticides by 8.2 percent since 1996.

Biotech has also enabled plants maintain yields in the face of drought and less water. While high-yielding biotech crops have a direct bearing on improved food security and poverty alleviation with increased production. As highlighted by the United Nations biotechnology can contribute to combating global hunger and malnutrition. Approximately 140 million children in low-income groups are deficient in Vitamin A. This situation has compounded into a public health challenge. The World Health Organization reports that an estimated 250,000 to 500,000 Vitamin A-deficient children become blind every year, half of them dying within 12 months of losing their sight. Golden Rice, a crop produced using the tools of biotechnology, contains three new genes that helps it to produce provitamin A.[3] Because of these benefits, 150 Nobel Laureates and 13,270 scientists and citizens wrote in support of crops and foods improved through biotechnology.[4]

As great as these developments have been towards enabling agriculture to increase production while reducing its environmental impact; developing and deploying new innovations in crop production will be critical in adapting to the challenges brought on by climate change

Future Plant Biotech Opportunities

Gene editing is a process scientists use to make targeted modifications to a plant's DNA to strengthen the plant. Gene editing is the most recent breakthrough in a continuum of breeding methods that have been used to develop more beneficial food, fiber, and fuel for centuries. Our growing understanding of DNA allows this to happen in years, rather than decades. In many cases, the changes made through gene editing could happen naturally

[2] http://www.isaaa.org/resources/publications/briefs/54/executivesummary/default.asp
[3] https://unchronicle.un.org/article/biotechnology-solution-hunger
[4] https://www.supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html

through an evolutionary process, making the gene-edited plant the same or very similar to products developed through other existing breeding methods.[5]

Gene editing can fast track genetic improvements in food, fiber, and fuel crops to keep pace with global warming and a growing human population[6] and enable growers to produce higher yields with lower fertilizer, water, and nitrogen inputs.[7] Environmental stressors cause $14 to $19 billion in plant losses every year. The single biggest cause of those losses is limited water, and that will likely get worse with climate change.[8] This technology can help us create more resilient crops able to withstand more variable weather events due to climate change by increasing plant tolerance to heat, floods, salinity, droughts and extreme cold.

Climate change will also exacerbate crop loss from insects by 10 to 25 percent because insect populations and their appetites surge in warm temperatures.[9] However, researchers are using gene editing to limit the threat to crops. Gene edited insects, like the genetically modified diamondback moths have the potential to reduce wild pest populations.[10] Gene editing hold great potential help plants become more resilient to a range of environmental stressors including pest and disease. As an example, the deadly fungus – *Fusarium oxysporum* Tropical Race 4 (TR4) –has decimated banana plantations in southeast Asia for 30 years and has made its way to Latin America.[11] However, gene editing is being used to create a banana resistant to TR4. Not only can this technology create disease-resistant varieties, it can also bring more genetic diversity to the fruit to mitigate future disease.[12]

Gene editing can also boost the nutrient levels of fruits and vegetables. Increasing the vitamin and mineral contents of plants, particularly staple crops, such as, potatoes, corn, soybeans, and wheat can address hunger issues globally and, in the U.S., where large portions of the population do not meet their nutrient requirements.[13]

Incentivizing the utilization of biotech in specialty crops can also help address the lack of fresh fruits and vegetables in food deserts in urban and rural communities. Consumers are already enjoying non-browning features in apples and potatoes. Extending the shelf life of produce can increase the availability of fruits and vegetables.

Not only will this innovation make nutritional food more available to consumers, it will cut down on food waste. According to USDA, in 2018 Americans threw away roughly 150,000 tons of food each day with fruits and vegetable accounting for 40 percent of that total.[14] Globally, the U.N. Food and Agriculture Organization (FAO)[15] estimates that worldwide, the amount of food wasted is enough to feed 2 billion people – more than double the number of people struggling with hunger. The global carbon footprint of all this wasted food was about

[5] https://innovature.com/basics
[6] https://www.nytimes.com/2019/06/17/science/food-agriculture-genetics.html#click=https://t.co/yb95Eso0kY
[7] https://innovature.com/article/dr-kasia-glowacka-plants-may-thrive-less-water
[8] https://www.nsf.gov/awardsearch/showAward?AWD_ID=0820126
[9] https://science.sciencemag.org/content/361/6405/916
[10] https://www.cnn.com/2020/01/29/us/genetically-engineered-moths-crop-protection-study-scn/index.html
[11] https://www.wired.co.uk/article/banana-disease-tr4-latin-america
[12] https://www.bio.org/blogs/bananas-are-brink-extinction-gene-editing-can-reverse
[13] https://innovature.com/article/dr-taylor-wallace-gene-editing-could-mean-healthier-foods-and-healthier-planet
[14] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0195405
[15] https://www.wfpusa.org/articles/8-facts-to-know-about-food-waste-and-hunger/

3.3 billion tons of carbon-dioxide equivalents, 7 percent of all global emissions.[16] Using technology to cut down on food waste can help us address hunger and tackle climate change.

Synthetic biology also has major potential to improve agricultural production. Using tools in the synthetic biology toolbox, scientists typically stitch together long stretches of DNA and insert them into an organism's genome[17].

Innovations like gene editing and synthetic biology hold tremendous potential to solve urgent challenges in agriculture which will only be compounded by climate change. Producers will need access to these innovative technologies to increase production while cutting down on their environmental footprint. Ensuring regulatory systems keep pace with these advancements will be essential for agricultural production to keep up with a growing population while reducing the environmental impacts.

Modernize Plant Biotech Regulations

A regulatory climate that fosters innovation is an important component to ensuring the development and deployment of tools producers will need for meeting the agricultural and environmental challenges in the future. A 2011 study found that between 2008-2012, bringing a new plant biotechnology trait to market cost $136 million and took approximately 13.1 years, with regulatory requirements accounting for more than one-third of the time required. The study also projected these costs and timeframes to increase in future years[18]. These costly barriers for market entry have historically prohibited the participation of many academics and small- and medium-sized businesses in this sector and has unfortunately limited the deployment of these innovations to crops where these significant costs can be recouped[19].

Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products (E.O. 13874)

BIO appreciates the Administration and USDA's efforts to create a predictable, streamlined, science-based regulatory system to spur investment in and deployment of innovative solutions. Last year's Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products (E.O. 13874)[20] set forth agency reforms that could facilitate the growth of technological innovation in agriculture for the foreseeable future. E.O. 13874 builds on calls to improve the regulatory process that has spanned multiple administrations.[21]

[16] https://www.washingtonpost.com/news/energy-environment/wp/2016/03/28/the-enormous-carbon-footprint-of-the-food-we-never-eat/
[17] https://www.genome.gov/about-genomics/policy-issues/Synthetic-Biology
[18] https://croplife.org/wp-content/uploads/pdf_files/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf
[19] https://www.cast-science.org/publication/regulatory-barriers-to-the-development-of-innovative-agricultural-biotechnology-by-small-businesses-and-universities/
[20] https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/
[21] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf

SECURE Rule

USDA's Animal and Plant Health Inspection Service (APHIS) Final Rule for biotechnology regulations, 7 CFR part 340, issued on May 14, 2020 also helps ensure that regulations keep up with innovation. Referred to as the SECURE rule[22], which stands for Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient, is the first comprehensive revision of APHIS' biotechnology regulations since they were established in 1987.
BIO, overall, supports the USDA's final revisions to its plant biotechnology regulatory system. USDA has an excellent track record regulating plant biotechnology based on science and risk. The final rule acknowledges a history of safe use of plant biotechnology and the similarity of many gene edited plants to those derived from conventional breeding techniques.[23]

Regulatory Barriers to Address

The SECURE rule is a meaningful step forward in fostering innovation, enabled by its use of exemptions for certain, familiar, and low-risk plants and adoption of a new, more efficient risk assessment system. However, the lengthy timeframe over which the new rules will be implemented, and relatively narrow exemptions will delay development and commercialization for many innovative products. Those issues will need to be resolved going forward to ensure that innovative products face a clear, risk-based timely path to market. Visibly absent from this rule however were any revisions to the part 340 regulatory systems for future advances relevant to non-plant GE organisms. Also, because the SECURE rule allows developers to self-certify exemption from USDA regulations without notifying the agency, the rule raises issues related to transparency about products entering the marketplace. As discussed in more detail later in our comments, BIO will continue to drive a process to develop an inclusive and impactful approach to transparency for biotechnology in food and agriculture.

Microbial Biotech – Benefits of Microbial Technology in Farm, Food, and Feed Applications

Farm

Synthetic biology can be used in a variety of ways to reduce agriculture's environmental impact. One example is through the development of soil microbes.[24] Globally 4 percent of greenhouse gases are attributed to making ammonia, nitrogen fertilizer. When applied, half goes to crops and half ends up in water due to runoff. This excess nitrogen runoff can lead to "dead zones" in our large lakes and oceans. [25] Plants like soybeans and other legumes have microbes in their roots that take on this chemical engineering process naturally fertilizing themselves. Corn, wheat, and rice, which make up half the global fertilizer usage do not have these microbes. Using synthetic biology you can take the DNA code from the microbes in soybeans, redesign it to work with the microbes in corn. [26] Then you apply it as

[22] https://www.usda.gov/media/press-releases/2020/05/14/usda-secure-rule-paves-way-agricultural-innovation
[23] https://archive.bio.org/sites/default/files/docs/toolkit/USDA_Part_340_Issue_Brief_FINAL.pdf?_ga=2.217235934.974532664.1591207008-377855674.1537910566
[24] https://www.bio.org/blogs/synthetic-biology-sustain-agriculture-and-transform-food-system
[25] https://www.bloomberg.com/news/features/2019-11-06/ginkgo-bioworks-ceo-wants-biology-to-manufacture-physical-goods
[26] https://onezero.medium.com/how-microbes-could-upend-americas-toxic-dependence-on-nitrogen-fertilizer-548451117a63

a seed treatment, and it will fertilize that crop so you can wean corn off fertilizer over time. By creating the right combination of microbes, scientists can make more resilient, efficient cropping systems.[27]

Plant biostimulants can improve a plant's natural nutritional processes, which results in enhanced tolerance to abiotic and other environmental stresses that improves overall plant health, growth, quality, and yield. In doing so, these products can increase the uptake and utilization of existing and applied nutrients. Plant biostimulants also can increase yield and quality without increasing applied fertilizer, water, or expanding planted acres, thus, sustainably enhancing the efficient use of these inputs and natural resources. Comprehensively, these technologies will not only result in a significant reduction in agriculture's climate and water-quality footprint, but it is a win-win for farmers, as the costs for their crop inputs and labor needs would decrease.

Food

Altering microbes with synthetic biology also gives us new ways to sustainably develop food ingredients. Vanillin—one of the most popular synthetic ingredients in the world—makes up 99 percent of vanilla flavoring consumed but relies on coal and oil mining to produce. Through synthetic biology we can make vanillin that is molecularly identical to the bean without burning fossil fuels.[28] Separately, using synthetic biology to edit brewer's yeast to produce hemoglobin is key to the development of new alternative proteins.[29] This is the base technology that makes product taste like meat, i.e. the high concentration of heme, gives meat its signature texture and is key to several alternative meats such as the impossible burger.

Using microbials and synthetic biology, we can boost nature's ability to grow more food on less land and create food ingredients without harming the environment.

Feed

Applications of biology-based innovation to animal feed holds potential for providing additional agricultural solutions. Enteric fermentation from ruminant animals – such as cows, sheep, goats, and buffalo are a major contributor of greenhouse gas emissions from agriculture. These animals, which use microflora to assist in the digestion of otherwise indigestible starchy plants, such as grasses, produce significant volumes of methane as a byproduct of the digestive process.[30]

Despite trends in plant-based protein, animal protein production is not expected to decrease any time soon. Not only has U.S. consumption of meat and poultry continued to increase,[31] but global animal protein consumption is expected to jump 15 percent by 2027, especially in areas with growing global middle classes with increased access to disposable income.[32] Due

[27] https://innovature.com/article/microbes-nourish-plants-naturally
[28] https://wholefoodsmagazine.com/columns/debates/synthetic-biology-key-to-a-healthier-planet-or-threat-to-organic/
[29] https://www.bio.org/blogs/synthetic-biology-sustain-agriculture-and-transform-food-system
[30] http://www.fao.org/in-action/enteric-methane/background/what-is-enteric-methane/en/
[31]: https://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/
[32] https://www.agri-pulse.com/articles/11933-plant-based-animal-protein-demand-shows-no-sign-of-letting-up

to methane's high, short-term global warming potential compared to CO_2, solutions are immediately needed to facilitate this expansion sustainably.

Existing innovations, such as feed additives for ruminant livestock, have been demonstrated to reduce methane levels in ruminant animals by up to 30 percent.[33] The addition of enzymes[34] to chicken feed promotes better protein digestibility, which helps reduce residual nitrogen emissions from manure. While probiotics[35] in animal feed help improve gut health of the animal. Using methanotrophs and other microorganisms, such as E. coli, have also demonstrated the feasibility of converting natural gas and methane into proteins for animal feed. Where feasible, anaerobic digestion can be applied to convert manure and other carbonaceous wastes into renewable natural gas. However, many of these post-excrement solutions are not practical for free range ruminates. Innovation in ruminant feeds and animal genetics will be critical to expand upon these environmental benefits as growth in animal protein continues.

Regulatory Barriers to Address

Barriers to Microbial Technologies

While the SECURE Rule will help streamline the deployment of innovative plant technologies, it has created uncertainty for microbial technology. Under the previous regulations. developers of innovative microbial products could confirm whether a particular product was subject to regulation using USDA's "Am I Regulated Process. The SECURE rule provides less certainty and fewer mechanisms for evaluating whether a product is subject to regulation, resulting in an unclear and uncertain regulatory process for microbial products of biotechnology.

BIO requested in its comments[36] on the proposed rule, *Movement of Certain Genetically Engineered Organisms*[37] develop, propose, and implement a plan to facilitate research, develop, and commercialize non-plant GE organisms, including microbes and insects. The comment noted failure to do so will create a significant competitive disadvantage for these products and delay their introduction to the market.

The SECURE rule is lacking a clear and predictable regulatory framework for non-plant GE organisms potentially subject to part 340. This uncertainty has significant potential to slow research, development, and commercialization of entire categories of innovative agricultural products with the potential to present novel lasting solutions to some of agriculture's most pressing challenges.

Accordingly, BIO urges APHIS to promptly develop and issue guidance for non-plant GE organisms' potentially subject to regulation under Part 340. Without guidance, developers of non-plant GE organisms will lack any semblance of clear, predictable, risk-based regulatory options. In the absence of leadership from USDA companies may choose to commercialize their product in countries with a more predictable regulatory framework and path to commercialization. APHIS, should ensure any movement restrictions imposed on non-plant organisms, whether microorganisms or invertebrates, should be based on the fact that the

[33] https://newfoodeconomy.org/feed-additive-methane-cow-burps/
[34] https://www.novozymes.com/en/news/news-archive/2017/03/more-from-one-acre-new-report
[35] https://www.novozymes.com/en/advance-your-business/agriculture/animal-health-nutrition/product/alterion
[36] https://www.bio.org/sites/default/files/2020-04/BIO%20Comments%20on%20340FNL%20080519.pdf
[37] https://www.federalregister.gov/documents/2019/06/06

organism itself poses plant pest risk and not on the fact that the non-plant is used to control plant pests.

Regulatory uncertainty with feed additives

As for feed additives, many of these new innovative products lack a suitable regulatory product category for timely approval of solutions that improve animal health without being veterinary drugs. For example, if a feed additive were to address methane emissions from cattle, that product would require one of three regulatory pathways. One is GRAS (Generally Recognized As Safe) notice to FDA, which will take an estimated two years for approval and limits the claims that can be made. Two is an Association of American Feed Control Officials (AAFCO) new ingredient definition submission, which may take between three and five years, and would limit the types of claims the feed producer could make. Three is a Food Additive Petition with FDA's Center for Veterinary Medicine (CVM), which may also take three to five years for approval and would also limit the claims the producer could make because it is not a full drug approval. None of these pathways offer the kind of quick assessment that is necessary to bring innovation to market to address climate change. Faster assessment route for these technologies will be critical in addressing emissions from livestock.

Animal Biotech

The outbreak of COVID-19 has brought to light the interconnectedness between human and animal health. Like the current coronavirus, scientists estimate that more than six out of every ten known infectious diseases in people can be spread from animals, and three out of every four new or emerging infectious diseases in people come from animals.[38] In addition to the dreadful health implications, the resulting economic costs of a pandemic are profound. The World Bank estimates that, between 1997 and 2009, the global costs from six zoonotic outbreaks exceeded $80 billion.[39] COVID-19 has already produced one of the sharpest economic downturns in U.S. history and is costing the U.S. treasury alone trillions of dollars.

The U.S. was woefully unprepared for this pandemic. We must employ modern approaches to be ready for future outbreaks. Improvement of animal genetics will also be a critical aspect to helping livestock producers around the world adapt to climate change, develop resiliency, and reduce emissions in milk and protein production.

Benefits of Animal Biotech

Human Health

Innovations in animal biotechnology can yield significant benefits to human and animal health, agriculture and food production, and the environment. Among these potential benefits is the ability to prevent, prepare for, and respond to outbreaks of infectious diseases such as coronavirus, Ebola, Zika, avian influenza (HPAI), and MERS, by creating more disease-resistant animals and providing disease treatments for humans.

[38] https://www.cdc.gov/onehealth/basics/zoonotic-diseases.html
[39] http://documents.worldbank.org/curated/en/612341468147856529/pdf/691450ESW0whit0D0ESW120PPPvol120web.pdf

Genetically designed cattle are being developed to produce fully human polyclonal antibodies to provide treatments for infectious diseases such as COVID-19. Scientists create a cow embryo with parts of human chromosomes, including human antibody genes, and turn off the animal antibody genes. Once grown, researchers inject a non-infectious part of the novel coronavirus into the cow, which produces human antibodies to the virus. Scientists draw blood from the cows, extract and purify the antibodies with the hope that these antibodies may treat the coronavirus in humans[40].

Similarly, scientists have developed a chicken that is resistant to contracting and transmitting avian influenza[41]. Other innovations in animal biotechnology may be able prevent, prepare for, and respond to outbreaks of infectious diseases by providing prevention strategies and treatments for humans. These breakthroughs are even more important given reports such as the swine flu strain with human pandemic potential increasingly found in pigs in China.[42]

Biotechnology can also strategically reduce and even eliminate the populations of insects that cause the greatest harm. Mosquitoes are not just a pest, but responsible for outbreaks of diseases like West Nile, Zika, and dengue. Genetically modified mosquitoes can be designed to help decrease and eventually diminish the overall population of mosquitoes. The U.S. Environmental Protection Agency (EPA) has granted permission to release these mosquitoes in parts of Florida and Texas. If the solution goes worldwide, we may be able to eradicate the number one killer of children in Africa, malaria.[43]

Animal Health

It is not just diseases transmitted between animals and humans that can have devastating consequences for the economy. In 2015, the outbreak of avian influenza devastated poultry producers in Minnesota. The outbreak infected more than 100 farms in the state, forced the destruction of millions of birds, and cost the state economy nearly $650 million[44]. Porcine Reproductive and Respiratory Syndrome (PRRS) is a disease that attacks the pigs' reproductive and respiratory systems, making it difficult for them to give birth and breathe. It can devastate an entire herd of 1,000 pigs in just two short months. African Swine Fever (ASF) has been devastating herds throughout Asia[45]. Researchers at Iowa State University (ISU) estimate an outbreak in the U.S. could cost up to $50 billion[46]. Gene editing can prevent these future outbreaks, as researchers are working to develop pigs with genetic resistance to PRRS[47], ASF[48], and Foot and Mouth Disease (FMD). These technologies can be used to make other animals resistant to disease, protecting farmers and the food supply.

Sustainable Animal Production

Precision breeding of animals to produce more meat or milk will allow for the reduction of the total number of animals in production, thus reducing the aggregate environmental

[40] https://www.bio.org/blogs/can-cows-help-treat-covid-19
[41] https://www.fooddive.com/news/gene-edited-chicken-cells-may-stop-the-spread-of-bird-flu/556976/
[42] https://www.sciencemag.org/news/2020/06/swine-flu-strain-human-pandemic-potential-increasingly-found-pigs-china
[43] https://www.bio.org/blogs/its-one-health-oclock
[44] https://www.mprnews.org/story/2017/03/08/bird-flu-outbreaks-elsewhere-worry-minnesota-farmers
[45] http://www.fao.org/ag/againfo/programmes/en/empres/ASF/situation_update.html
[46] https://www.card.iastate.edu/products/publications/synopsis/?p=1300
[47] https://innovature.com/article/agricultural-innovations-protect-your-favorite-foods
[48] https://innovature.com/article/gene-editing-could-protect-pigs-diseases

impact. For example, even though there are fewer than half the dairy cows in the United States today as there were in 1950s, average milk production per cow has nearly doubled, largely because of genetic improvements through traditional breeding.[49] While these improvements took over 60 years to accomplish, the use of technologies, such as gene editing, could allow us to make similar improvements in a fraction of the time.

The first bioengineered food animal approved to date, the AquAdvantage salmon, is a fish that can grow large and healthy with fewer resources, helping to reduce the environmental impact of raising fish. Through biotechnology the salmon grows to market-size using 25 percent less feed than traditional Atlantic salmon on the market today. This makes an already efficient protein producer even better because it requires fewer wild fish to be converted into salmon feed. Further by being developed in domestic facilities close to major metropolitan areas, it significantly cuts transportation distance from farm to table. Unlike imported salmon, this salmon has a carbon footprint that is 23 to 25 times less than for traditional farmed salmon.[50]

Improvement of animal genetics will also be a critical aspect to helping livestock producers around the world adapt to climate change. Globally, but especially in tropical and sub-tropical environments, protecting herds from increasing temperatures expected with climate change will be very important[51]. Research is currently being done to improve animal genetics, such as in cattle, to adapt to expected increasing temperatures.[52] The UN FAO has also reported that improving fertility, use of genomics and genetic improvement can play a significant role in reducing emissions from the livestock sector.[53]

Regulatory Impediments

Unfortunately, the current regulatory approach to these technologies is an impediment to innovation and commercialization. The Food and Drug Administration (FDA) uses its "new animal drug" authority under the Food, Drug, and Cosmetics Act to assess animal biotechnologies. Evaluating food animals under this pharmaceutical-based framework is essentially forcing a square peg in a round hole. Under this system, genetically engineered animals and their progeny could be considered "drugs" and farms and ranches could be regulated as "drug manufacturing facilities." For developers, the FDA's current evaluation process is time-consuming, opaque, unpredictable, and disproportionate to the actual risk posed by the products being evaluated.

FDA has announced that it plans to also regulate gene-edited animals under this system – even those products with edits that could have occurred naturally or through conventional breeding. This puts at risk an entirely new generation of technologies and threatens to drive research, jobs, and innovation overseas. Similar concerns were raised by a bipartisan group of members in the House of Representatives in a letter to FDA last year.[54]

In more than two decades, the United States has approved only one biotechnology food animal for production and sale. Fast action is needed, or the U.S. will be prevented from

[49] https://www.wpr.org/how-we-produce-more-milk-fewer-cows
[50] https://aquabounty.com/sustainable/
[51] https://www.bio.org/blogs/recombinetics-animal-gene-editing-could-transform-beef-industry
[52] https://futurism.com/scientists-want-to-genetically-engineer-heat-resistant-cows-to-survive-climate-change
[53] http://www.fao.org/3/a-i8098e.pdf
[54] https://www.bio.org/sites/default/files/2020-05/190726%20-%20EC%20Letter%20to%20FDA%20re%20Gene%20Editing.pdf

deploying this promising technology and risk losing our leadership position in livestock genetics and in global meat and dairy production and export. We are already out of sync with the rest of the world, including European authorities (and livestock breeders), who are increasingly characterizing such approaches simply as advanced breeding. Other countries, like China, Canada, Australia, and Brazil, will be deploying this technology with or without the guidance of the United States. They will also begin to become more formidable exporters of their beef, pork, poultry, and fish products[55].

As USDA rightly note in its *Task Force on Agriculture and Rural Prosperity,* federal regulations are limiting technological innovation in animal biotech[56]. To overcome these regulatory barriers, BIO supports USDA's[57] efforts to create joint agreement with FDA whereby the USDA leads regulatory oversight of biotechnology-derived food animals and the FDA leads oversight of non-food and biomedical animals. In addition, FDA should conduct a review of its process and implement specific process changes to improve its decision-making, transparency, and timelines for reviews. Developers and other stakeholders need confidence that FDA will be held accountable for approval timelines and ensure that the pathway to commercialization is predictable, clear, consistent, and based on risk.

Taking these steps will ensure America's farmers and ranchers have access to cutting-edge technologies to remain globally competitive and resilient to disease and climate change, the United States must have risk-proportionate regulations that spur biological innovations, while protecting health and environment.

One Health

In addition to technology, better coordination will ensure that our country is better prepared for the next pandemic. The One Health collaboration eliminates barriers that often exist between human health, animal health, and environmental health regulatory strategies to create smarter, multi-faceted and coordinated efforts. The bipartisan, *Advancing Emergency Preparedness Through One Health Act of 2019*[58], (H.R. 3771/S. 1903) would direct the U.S. Department of Health and Human Services and USDA to coordinate with other agencies and state and local leaders to advance a national One Health[59] framework to better prevent, prepare for, and respond to zoonotic disease outbreaks like COVID-19.

II. Sustainable Fuels

Benefits of Sustainable Fuels to Agriculture

The development of sustainable fuels enables agriculture to be a key contributor in addressing emissions from the transportation sector, which is the leading source of greenhouse gas emissions according to the EPA.[60] Not only is this one of the largest sectors of emissions, it is growing.

[55] https://thehill.com/opinion/energy-environment/373361-regulatory-restructure-of-biotech-is-critical-to-the-future-of-us
[56] https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf
[57] https://www.agri-pulse.com/articles/13210-perdue-says-mou-with-fda-could-be-solution-to-animal-biotech-regulation
[58] https://www.congress.gov/bill/116th-congress/house-bill/3771
[59] https://archive.bio.org/sites/default/files/OneHealth_Final.pdf
[60] https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100WUHR.pdf

Emissions Reductions

Biofuels and those produced using biological systems provide a strong and immediate solution to reducing emissions from all forms of transportation, including aviation, which has an immediate and long-term nee for liquid fuels. Development of sustainable fuels allow agriculture to play a crucial role in addressing climate change. It is critical that we recognize that these are solutions that are available today, and do not require a mass turnover in vehicles. It is commonly known that carbon emissions act much like compounding interest. Just in the way that a dollar saved today is better than a dollar saved tomorrow, limiting carbon emissions today is far more valuable than limiting the same or a greater volume of emissions at a later date.[61]

Because of biotech innovations, the production of biofuels is becoming more efficient and environmentally sustainable. Biocatalysts, such as enzymes, lower energy requirements, increase reaction rates, can reduce the number of process steps necessary to make chemical transformations. Enzymes are selective, specific, and have a high catalytic rate; they are more efficient, producing chemical products with higher purity and fewer byproducts or wastes. Enzymes are enabling biofuel producers to convert corn stover, wheat straw, wood chips, sawdust, waste, and sugarcane bagasse into fuel, and to collectively increase biofuel yield and energy efficiency throughout the sector. Biocatalysts (e.g. bacteria) are enabling production of fuels and chemicals from new waste and residue streams. New bio-boosting chemicals are increasing biomass yields while eliminating the need for antibiotics in feed bioproducts for livestock. Companies have commercialized enzymes for producing cellulosic ethanol from agricultural waste and are currently operating cellulosic biorefineries.[62]

We are already reaping the benefits of the development of advanced and cellulosic biofuels. The use of low-carbon biofuels, primarily used in passenger cars, has resulted in significant greenhouse gas reductions, with cumulative CO_2 savings of nearly 600 million metric tons (mmt) since the RFS was enacted.[63]

The greenhouse gas emission reductions and benefits will only expand with the utilization of new conversion technologies and the development of advanced and cellulosic biofuels across all transportation sectors. As USDA highlighted last year, greenhouse gas emissions from corn-based ethanol are about 39 percent lower than gasoline. The study also states that when ethanol is refined at natural gas-powered refineries, the greenhouse gas emissions are even lower, around 43 percent below gasoline.[64] Current federal policy supporting these fuels, the RFS, requires lifecycle greenhouse gas reductions of at least 50 percent versus the relevant petroleum-based alternative for a fuel to qualify as an advanced biofuel, and at least 60 percent for cellulosic biofuels.

Existing advanced and cellulosic biofuel technologies are far surpassing these requirements. As highlighted in an Environmental and Energy Study Institute (EESI) report, "according to Argonne's GREET model, an energy crop like miscanthus can have negative greenhouse gas

[61] Frank, Jenny. "Quantifying the Comparative Value of Carbon Abatement Scenarios Over Different Investment Timing Scenarios" National Biodiesel Board Conference and Expo, 28 January 2020, Tampa, Florida. Next Generation Scientists for Biodiesel
[62] https://www.bio.org/industrial-biotechnology-unique-potential-pollution-prevention
[63] https://ethanolrfa.org/wp-content/uploads/2019/02/LCARFSGHGUpdatefinal.pdf
[64] https://www.usda.gov/media/press-releases/2019/04/02/usda-study-shows-significant-greenhouse-gas-benefits-ethanol

emissions, meaning that over the crop's life cycle, carbon sequestration outweighs emissions. Argonne researchers show that, compared to gasoline, biofuel from energy crops can reduce emissions by 101 to 115 percent. Corn stover, a residue from corn, can reduce emissions by 90 to 103 percent."[65] As the industry improves its efficiencies and practices, the greenhouse gas reductions of approved advanced and cellulosic biofuels are likely to be substantially greater. Further, new technologies such as gas fermentation, provide alternative routes to advanced biofuels, including sustainable aviation fuel (SAF), from a variety of biomass residues.

The development and expansion of algae and aquatic plant cultivation has great potential for the development of advanced biofuels. Microalgae are aquatic plants that can be induced to rapidly accumulate lipids, often greater than 60 percent of their biomass, while consuming large amounts of carbon dioxide. They can be cultivated using closed loop systems, open ponds, and photo-bioreactors, using less land, energy, and water than land crops. The characteristics of algae biofuels include high flash point, biodegradability, and low or no aromatic or sulfur compound, so they are being used to produce a variety of biofuels such as bioethanol, bio-butanol, jet fuel, biodiesel, bio gasoline, green diesels, and methane.[66]

Air Quality Benefits

The environmental benefits of biofuels go beyond greenhouse gas reductions. The outbreak of COVID-19 has highlighted the importance of clean air to human health. Harvard University found that small increases in exposure to long-term levels of tiny particulate matter were linked to a big jump in the mortality rate for COVID-19. Each extra microgram of fine particulate matter per cubic meter that people were exposed to over the long-term was linked to an eight per cent increase in the mortality rate.[67] Similar results were found by the University of Cambridge which overlaid nitrogen dioxide (NO2) and nitrogen oxide (NO) levels from more than 120 monitoring stations across England with figures on coronavirus infections and deaths. They found a link between poor air quality and the lethality of COVID-19 in those areas[68].

As BIO stated in its comments to the EPA Scientific Advisory Board (SAB) *Review of COVID-19 Pandemic Scientific and Technical Issues to Inform EPA's Research Actives*[69], "our member companies offer several solutions that can not only help combat this pandemic, but also lessen the impact of a future pandemic by helping to establish a resilient, sustainable bioeconomy."

Harmful tailpipe emissions, including particulate matter (PM) from the transportation sector disproportionately affect areas comprised of minority populations. For example, according to a study by the Union of Concerned Scientists (UCS), African Americans and Latinos breathe in about 40 percent more particulate matter from cars, trucks, and buses than white

[65] https://www.eesi.org/articles/view/biofuels-versus-gasoline-the-emissions-gap-is-widening#:~:targetText=Argonne%20researchers%20show%20that%20compared,for%20the%20RFS%20from%202010.
[66] https://farm-energy.extension.org/algae-for-biofuel-production/
[67] https://www.researchgate.net/publication/340492612_Exposure_to_air_pollution_and_COVID-19_mortality_in_the_United_States_A_nationwide_cross-sectional_study
[68] https://www.medrxiv.org/content/10.1101/2020.04.16.20067405v5
[69] https://yosemite.epa.gov/sab/sabproduct.nsf//0/2996BA363B41C2598525854C0048EA69?OpenDocument

Californians[70]. Another UCS study found Northeast communities of color breath 66 percent more air pollution from vehicles[71].

According to the National Bureau of Economic Research, the United States saw fine particulate pollution increase 5.5 percent between 2016 and 2018. According to the American Lung Association, State of the Air report for 2019, more than four in ten Americans live in counties that have unhealthy levels of ozone pollution or particular matter.[72] Prior to COVID-19, the World Health Organization[73] found that 4.2 million deaths[74] every year occur as a result of exposure to ambient air pollution. Since then, numerous studies have found that long-term exposure to levels of tiny particulate matter were linked to a significant increase in the mortality rate for COVID-19[75].

Sustainable fuels represent a readily available solution to addressing air quality by reducing tailpipe emissions including particulate emissions, hydrocarbons, and carbon monoxide, which helps prevent the formation of ground-level ozone. Data from 222 EPA sensing sites show that ozone levels have fallen during the period in which ethanol blending increased.[76] Additional data from the University of Illinois-Chicago (UIC) show substantial reductions in particulate matter and benzene with the addition of biofuels.[77] The American Lung Association, Upper Midwest Region found higher volumes of biofuels can reduce ozone-forming pollutants and evaporative emissions.[78]

Such benefits are not unique to ground transportation; research has demonstrated that SAF reduce contrails, particulate matter and mass emissions compared to conventional fossil jet fuels, with the potential to improve air quality near airports and reduce the climate impacts of aviation at high altitude.[79] Additionally, sustainable fuels produced via microbial fermentation of industrial waste gases can limit the impacts of carbon pollution on human and environmental health locally. Sustainable fuels can be produced from the organic fraction of municipal solid waste (MSW), a much healthier option than MSW incineration which can contribute to air pollution.

As we begin to bring the economy back online, it is critical we do so with a cleaner, more resilient energy sector. Biofuels are an immediately available path toward decarbonizing the transportation sector and improving air quality while lowering fuel prices, driving economic growth, and creating jobs. However, this will require stable policies and regulations.

Stable Policies for Sustainable Fuels

Renewable Fuel Standard

When allowed to work, the RFS has enabled billions of dollars of investment in new technologies that have led to the rapid growth of the renewable fuels industry, the

[70] https://www.ucsusa.org/resources/inequitable-exposure-air-pollution-vehicles-california-2019
[71] https://www.ucsusa.org/about/news/communities-color-breathe-66-more-air-pollution-vehicles
[72] http://www.stateoftheair.org/key-findings/
[73] https://www.who.int/health-topics/air-pollution#tab=tab_1
[74] https://www.who.int/gho/phe/outdoor_air_pollution/burden/en/
[75] https://www.newscientist.com/article/2241778-are-you-more-likely-to-die-of-covid-19-if-you-live-in-a-polluted-area/
[76] http://www.ethanolrfa.org/2014/12/real-world-ozone-and-particulate-data-expose-fallacy-of-minnesota-study/
[77] http://www.erc.uic.edu/assets/pdf/UIC_Cook_County_Slides.pdf
[78] https://www.cleanairchoice.org/fuels/e85.cfm
[79] https://www.nature.com/articles/nature21420

development of new fuel technologies, and the biobased economy. The growth of the biofuels industry has bolstered our rural communities and provided agriculture producers stable commodity markets, benefitting our nation's economic and energy security.

Unfortunately, the demand destruction caused by the EPA's drastic expansion of small refinery exemption waivers or SREs has had a major impact on the industry, costing jobs, stifling investment in innovation, and undermining efforts to reduce greenhouse gas emissions in the transportation sector.

In January 2020, the U.S. Court of Appeals for the Tenth Circuit ruled in *Renewable Fuels Association v. EPA* that EPA had exceeded its authority in granting SREs under the Renewable Fuel Standard to three refineries in 2016 and 2017, and that moving forward, EPA may only issue SREs to refineries that have continuously received exemptions for every compliance year since 2011.

Despite this ruling, refiners have now filed at least 58 retroactive SRE requests[80]. This comes on top of another 27 SRE applications pending for 2019 and 2020. Unfortunately, rather than comply with the ruling in the 10th Circuit and immediately reject the retroactive requests it is perpetuating the uncertainty about the RFS by letting these pending applications linger.

Beyond SREs, innovative biofuel producers are also stymied by EPA's delays in the approval of new advanced and cellulosic biofuel pathways and petitions for production facilities. These delays are arbitrarily keeping advanced and cellulosic biofuels from reaching the marketplace, hindering the growth of the industry. EPA's failure to approve the registration for corn ethanol facilities that have registered for producing cellulosic biofuel from corn kernel fiber (CKF).

As a result of the uncertainty of the RFS and the delays in new technologies coming to market, companies who have researched and developed technologies in the United States are looking to commercialize advanced and cellulosic biofuel technologies in countries like India and China which are investing heavily in biofuels to improve their air quality.

BIO appreciates USDA's continued support of the biofuels industry. To ensure success of the sustainable fuels industry, enable agriculture to reduce emissions and bring even greater job growth to rural America, we urge the Department to push EPA to end its unwarranted expansion of SREs and move forward on stalled pathways and facility registrations.

Further, we request the Department to encourage and support EPA to interpret the RFS broadly and accommodate all pathways and approve facility registrations that could fall within the existing statute. Specific areas that would have an impact immediately to accelerate the production of low carbon sustainable fuels are related to biological carbon capture and utilization (CCU), the interpretation and eligibility of "renewable biomass", the use of biointermediates, and life-cycle and tracking methodologies for sustainable fuels from waste agricultural residues such as CKF. This would have immediate benefits for the agricultural sector by create more demand for waste feedstocks and renewable biomass.

[80] https://www.epa.gov/fuels-registration-reporting-and-compliance-help/rfs-small-refinery-exemptions

Transition from a RFS to a Clean Fuel Standard

As the Department explores options to harness the power of agriculture to decarbonize our transportation sector, we urge it to support new policies and programs that are technology and feedstock neutral and are based off of performance and their ability to deliver carbon reductions. Toward that end it will be critical for the Department to work with Congress in developing a Clean Fuel Standard (CFS) that builds on the success of the RFS and ensures agriculture and biofuels are part of the solution in reducing emissions.

Given the success of the California model, other states[81] and regions[82] are beginning to consider establishing their own CFS programs to address emissions and air pollution. Not only does the establishment of these programs provide an additional value to biofuels, helping spur investment, production, and consumption of advanced biofuels, a national CFS would spur immediate, and additional carbon savings by allowing America's farmers to contribute by adopting practices that enhance soils natural ability to sequester carbon. When a CFS is coupled with a voluntary carbon crediting and verification program it would allow farmers to contribute quickly and effectively to fighting climate change.

Adoption of a CFS would not only incentive advanced biofuels like sustainable aviation fuel, but it would also incentivize fuels which have traditionally been left out of the RFS. Advanced technologies for the conversion of waste carbon oxides to sustainable aviation fuels and cellulosic diesels from woody residues that are poised for success today but have traditionally been left out of the RFS due to regulatory interpretations. A CFS that builds off the volumes and infrastructure put in place by the RFS is a simple, yet elegant way to steadily reduce emissions in transportation, allowing all forms of cleaner mobility to contribute, and bridge the divide between rural America and urban America.

III. Biobased Manufacturing

Support Farmers and Revitalize Manufacturing

The expansion of biobased manufacturing can revolutionize industry by creating a sustainable value chain that use biological processes to convert renewable, low cost, or waste feedstocks into everyday products. It creates new markets for agricultural crops, crop residues and waste streams, as well as opportunities for innovation in producing consumer goods.

These technologies represent novel, innovative ways to address plastic pollution and climate change. Already some 8 mmt of plastics enter our ocean on top of the estimated 150 mmt that currently circulate our marine environments.[83] Through the application of biotechnology, we can create renewable chemicals, which can be used to produce sustainable plastics that are recyclable or biodegradable. While these materials are molecularly like their petrochemical equivalent, they reduce greenhouse gas emissions since they are produced from renewable or waste resources instead of oil and gas.

[81] https://www.act-news.com/news/california-leads-with-low-carbon-fuel-standard-programs/
[82] http://blog.opisnet.com/rfs-lcfs
[83] https://oceanconservancy.org/trash-free-seas/plastics-in-the-ocean/#:~:text=Every%20year%2C%208%20million%20metric,currently%20circulate%20our%20marine%20environments.

According to the U.S. Energy Information Administration, U.S. chemical production uses 28 percent of the total energy used by all industrial sectors.[84] Without action, these emissions are expected to grow. In January, Louisiana regulators approved an air quality permit that will allow Sunshine Project, to pump 13.6 million tons of carbon dioxide into the atmosphere every year. That is equivalent to adding 2.6 million cars to the road annually. In 2018, only 13 coal plants emitted more.[85] A report in *Environmental Research Letters* identified 88 petrochemical projects along the Gulf Coast that are either in the planning stage or under construction. If all are completed, their combined emissions output could reach 150.8 mmt, the equivalent of 38 coal plants.[86,87]

However, biobased products can provide a solution to the increasing rise in emissions in petrochemical plastic production. The USDA found that the development of renewable chemicals and biobased products removed 12.7 mmt of CO_2 from the manufacturing sector in 2016 alone in its report, *An Economic Impact Analysis of the U.S. Biobased Products Industry*.[88] This is due to the displacement of petroleum and reduction of fossil fuels in the manufacturing and use of biobased products. The report goes on to note:

> The use of biobased products reduces the consumption of petroleum equivalents by two primary mechanisms. First, chemical feedstocks from biorefineries have replaced a significant portion of the chemical feedstocks that traditionally originate from crude oil refineries. Biorefineries currently produce an estimated 150 million gallons of raw materials per year that are used to manufacture biobased products. Second, biobased materials are increasingly being used as substitutes for petroleum-based materials, which have been used extensively for many years. An example of this petroleum displacement by a biobased material is the use of natural fibers in packing and insulating materials as an alternative to synthetic foams, such as Styrofoam. In this report we updated the oil displacement values from the 2016 report to reflect economic growth. In 2016 the estimated oil displacement is estimated to be as much as 9.4 million barrels of oil equivalents.

In addition to the environmental benefits, USDA found that the value added to the U.S. economy by biobased products was $459 billion in 2016. While employment in the industry increasing from 4.22 million jobs in 2014 to 4.65 million jobs in 2016.

Even greater reductions of greenhouse gas emissions are possible through the expansion of biotechnology in manufacturing. World Wildlife Fund found "if existing biotech solutions were used extensively in other traditional industries, such as detergent, textile, and pulp and paper manufacturing, another 52 mmt of greenhouse gas emissions reductions would be achieved annually."[89]

Biotechnology is enabling the production of biobased plastics providing a sustainable alternative to petroleum-based plastics. More than half of all plastic ever created was produced in the last 15 years, and right now, about 335 mmt of new, virgin plastic is created each year. Virtually all that new plastic will be made from oil and gas. Plastics now

[84] https://www.eia.gov/energyexplained/use-of-energy/industry.php
[85] https://www.eenews.net/climatewire/stories/1062133995
[86] Ibid.
[87] https://iopscience.iop.org/article/10.1088/1748-9326/ab5e6f/pdf
[88] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf
[89] http://assets.panda.org/downloads/wwf_biotech.pdf

account for 3.8 percent of global greenhouse gas emissions and at the current rate will account for 15 percent of global emissions by 2050.[90]

Because some bioplastics are derived at least in part from corn, sugarcane, or other plants, they have a smaller carbon footprint, with lower cradle-to-plant-gate greenhouse gas emissions than their fossil fuel-based counterparts.[91] Substituting the annual global demand for fossil-based polyethylene (PE) with biobased PE would save more than 42 mmt of CO_2. This equals the CO_2 emissions of 10 million flights aground the world per year.[92] Replacing conventional 1,4-Butanediol (BDO) with biobased BDO would save over seven million tons of greenhouse gas emission per year, or the equivalent of taking 1.5 million cars off the road.[93] In addition to reducing greenhouse gas emissions, biobased BDO can produce compostable plastic packaging, reducing plastic waste.

All biomanufacturing processes – whether enzymatic or microbial – share the unique characteristic of avoiding use of toxic feedstocks and process reagents, which in turn minimizes toxic waste and byproducts. Manufacturers must manage byproducts of bioprocesses to prevent pollution.[94] Just as enzymes improve biofuel production, manufacturers are using enzymes commercially to produce pharmaceuticals and other chemical compounds, food ingredients, detergents, personal care products, textiles, and paper products, avoiding use of toxic feedstocks and process reagents, which in turn minimize toxic waste and byproducts.[95] By utilizing enzymes, textile mills used less energy and reduced their CO_2 emissions by 12 mmt. This technology also has the added benefit of reducing the use of water in textile production by 8.1 billion cubic meters, equal to the annual consumption of 140 million households.[96]

Sugar from crops like corn and wheat can be fermented using yeast to create renewable bio-succinic acid, which is commonly used as an emollient or fragrance carrier in various skin creams and lotions. Succinic acid is effective in combating acne and reducing skin flakiness and wrinkles. By using biotechnology, many personal care products can be made using a range of renewable, sustainable resources, including agricultural feedstocks. Carbon captured from industrial processes can be recycled and fermented using microbes to create renewable non-toxic isopropanol, a common alcohol used to extract and purify oils found in skin care products, such as acne treatments. Using synthetic biology, carbon-rich gases can be used to develop esters, a class of chemical compounds used to create certain aromas and fragrances in perfumes and cosmetics. By capturing and recycling these gases to be converted to esters instead of going into the atmosphere, environmental impact is reduced. Replacing petroleum-based butylene glycol with butylene glycol produced from a sustainable and renewable sugar fermentation process reduces greenhouse gas emissions by 51 percent and allows consumers to avoid petroleum-based ingredients in their personal care products.[97]

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[90] https://www.nature.com/articles/s41558-019-0459-z?utm_source=commission_junction&utm_medium=affiliate
[91] https://ihsmarkit.com/research-analysis/bioplastics-offer-a-smaller-carbon-footprint.html
[92] https://www.european-bioplastics.org/bioplastics/environment/
[93] https://www.genomatica.com/wp-content/uploads/Genomatica-Sustainability-and-Social-Responsibility-2019.pdf
[94] http://www.bioprocessintl.com/manufacturing/facility-design-engineering/minimizing-the-environmental-footprint-of-bioprocesses-303905/
[95] https://www.thebalance.com/enzyme-biotechnology-in-everyday-life-375750
[96] https://www.novozymes.com/en/news/news-archive/2019/05/biological-solutions-on-the-catwalk-to-find-answers-for-sustainable-fashion
[97] https://www.genomatica.com/wp-content/uploads/SOFW-LCA-Article.pdf

Biotechnology can also improve the environmental footprint of textiles. Replacing petroleum based paraxylene with a bio-paraxylene produced from a mix of sugar cane and corn-based ethanol results in a 70 percent reduction in carbon emissions. Bio-paraxylene can be used to produce a 100 percent bio-polyester. This can lead to a 25 percent to 50 percent reduction in carbon emissions when compared to petroleum based polyester products. Further bio-polyester produced using bio-paraxylene can be recycled in the same recycling infrastructure as petroleum-based polyester.[98] Gas fermentation, which uses biology to convert waste industrial emissions to ethanol production, can produce textiles through conversion of this sustainable ethanol into fibers.[99]

Traditional carpets take up the second-largest amount of U.S. landfill space. Approximately 3.5 billion pounds of carpet are put in U.S. landfills every year. Carpets are made up of a complex array of chemicals, either made of nylon, polyester, or polypropylene. Biotechnology can manipulate the polyester to form every element of the carpet, from base to tufts. The flooring, when discarded, can be returned to the manufacturer, ground up, and repurposed as another carpet, reducing the need for petroleum to manufacture new carpet.[100] Biological gas fermentation combined with gasification, can convert mixed flooring wastes into the same chemicals used in carpet production.

Overcoming Regulatory Barriers

These novel, innovative approaches to address domestic and global climate challenges are desperately needed. Just as it did with air pollution from transportation, COVID-19 has brough to light the impact petrochemical production has on human health, particularly on communities of color. This is exemplified in what has been called "Cancer Alley" in Louisiana[101]. As Beverly Wright, the founder and executive director of the Deep South Center for Environmental Justice in New Orleans stated in the New York Times April 29, 2020 article, *'A Terrible Price': The Deadly Racial Disparities of Covid-19 in America*, "As soon as I heard about Covid, I started getting nervous about the relationship between PM 2.5 and this virus."

Regulatory proposals to address plastic waste and pollution should set a performance standard that recognizes reductions in emissions in the production of chemicals and plastics. Further government efforts to promote and incentivize recyclability and reduce plastic waste should also seek to promote the use of bioplastics. Finally, the government should give broad regulatory acceptance of, and where applicable, regulatory preference for, innovative and sustainable biobased products.

With these policies and principals we can achieve our goal of creating value added markets for commodities, rebuilding our national economy and workforce in a forward-looking, self-sufficient manner with the added benefit of addressing climate change and enhancing human health through improved air quality.

[98] https://www.virent.com/technology/sustainability/
[99] https://www.lanzatech.com/2019/10/07/world-first-products-made-from-recycled-pollution-reduce-emissions-and-keep-carbon-in-the-ground/
[100] https://www.fastcompany.com/3067849/the-first-100-recyclable-carpets-are-here
[101] https://www.businessinsider.com/louisiana-cancer-alley-photos-oil-refineries-chemicals-pollution-2019-11

Provide Robust Funding of Public and Private Sector Scientific Research

The federal government's long history of generously funding research is an important foundation for the nation's bioeconomy and the development of the revolutionary technologies highlighted throughout BIO's comments. The successful adoption and deployment of biotechnologies in agriculture, renewable energy, and the bioeconomy have been enabled by USDA, the U.S. Department of Energy (DOE), and the Department of Defense (DOD), among other federal agencies.

As America's foreign competitors are investing greater amounts in research to lure the development of new technology offshore, these programs to support and incentivize foundational research and development activities are ever more critical to maintaining America's global preeminence in food, agriculture, bioenergy, and biobased manufacturing production. This investment also translates into opportunities for large private sector investment in applied research and development.

I. Invest in Agricultural Research

Benefits of Research and Development

Research has been central to the improvements in agricultural productivity. As the National Coalition for Food and Agricultural Research (NC-FAR) highlights, recent analysis by the International Food Policy Research Institute of 292 studies of the impacts of agricultural research and extension published since 1953 found an average annual rate of return on public investments in agricultural research and extension of 48 percent – an extremely high rate of return by any benchmark.[102]

USDA Research, Education, and Economics (REE) programs have been critical to this success. USDA National Institute of Food and Agriculture (NIFA) and the Agriculture and Food Research Initiative (AFRI) have been essential for the foundational research and agricultural workforce development that complements and underpins large systems-level research, education, and extension activities. This core competitive grant program has been essential in establishing America the preeminent global leader in food, agricultural, and bioenergy production.

USDA's Agricultural Research Service (ARS) plays a critical role in partnering with the university community and industry to advance science-based solutions. Research and Extension Programs such as McIntire-Stennis, 1890 Extension, Evans Allen, Hatch Act, and Smith-Lever have been assisting farmers and ranchers in adopting best practices that increase productivity while improving soil, water, and air quality.

Provide Greater Investment in Research and Development

Public and private investments in U.S. agricultural research and practical application have paid huge dividends to the United States. However, this unparalleled success story in the nation's food and agricultural system is in large part the product of past investments. Federal funding for food and agricultural science has been essentially flat for over 20 years

[102] https://www.ncfar.org/need.asp

despite much greater demonstrated needs and has reportedly declined by about 25 percent in real terms since 2003.[103]

As researchers with ISU CARD pointed out in its report *Measuring Public Agricultural Research and Extension and Estimating their Impacts on Agricultural Productivity: New Insights from US Evidence*[104] with the world expected to reach 9.6 billion people – a 29 percent increase over 2013 – by 2050, society must increase agricultural productivity without causing immense environmental damage and hunger. To achieve this will require greater investment in agricultural research and extension.

The need to modernize our nation's aging food and agricultural science infrastructure, both at USDA labs and universities, is critical. Greater funding should be made to strengthen land-grant universities and HBCUs. Not only to bolster research for scientific agricultural advances, but to train the next generation of ag scientists and researchers and farmers and ranchers. Additional investments in research and education is also critical in assisting producers in increasing their use of precision agriculture, deployment of new crops, and sequestering more carbon in their soil.

Programs such as USDA's Biotechnology Risk Assessment Research Grants Program (BRAG) supporting the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the potential effects of introducing into the environment genetically engineered organisms, including plants, microorganisms – such as fungi, bacteria, and viruses – arthropods, fish, birds, mammals and other animals excluding humans. Continuation of programs like BRAG will be critical in supporting these technologies with advancing modern regulatory approaches need to advance innovation.

II. Sustainable Fuels

Benefits of Research and Development

Bolstering funding of DOE, USDA, and other government research programs is necessary for the growth of the advanced biofuels industry. DOE's Office of Energy Efficiency and Renewable Energy (EERE) invests in clean energy technologies that strengthen the economy, protect the environment, and reduce dependence on foreign oil.

According to DOE's *Aggregate Economic Return on Investment in the U.S. DOE Office of Energy Efficiency and Renewable Energy,*[105] research and development (R&D) investments provide significant economic benefits. A total taxpayer investment of $12 billion (inflation-adjusted 2015 dollars) in EERE's R&D portfolio has yielded more than $388 billion in net economic benefits to the United States.

The Bioenergy Technologies Office (BETO) within EERE funds vital research and development of technologies to convert our nation's biomass resources into clean, renewable fuels. BETO recognizes that biofuels are especially needed in the aviation industry, where liquid fuels are still the only viable fuel source for commercial airlines.

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[103] https://www.ncfar.org/NCFAR_Testimony_FY_20_House_040519.pdf
[104] https://lib.dr.iastate.edu/agpolicyreview/vol2016/iss1/3/
[105] Dowd, J. "Aggregate Economic Return on Investment in the U.S. DOE Office of Energy Efficiency and Renewable Energy." (Oct. 2017) Available at: https://www.energy.gov/sites/prod/files/2017/11/f39/Aggregate%20ROI%20impact%20for%20EERE%20RD%20-%2010-31-17.pdf

USDA regional perspective has also been critical. Research through NIFA has helped support the development and production of advanced biofuels compatible with agricultural systems. It has brought together researchers, landowners, communities, and private industry to grow bioenergy and develop new biomass crops and supply chains.

Federal Aviation Administration (FAA) programs are also critical to support the research and development, commercialization, and deployment of Sustainable Aviation Fuel. FAA's Office of Environment and Energy's R&D Program provides scientific understanding, development of new technologies, fuels and operations, and analyses to support achieving the Next Generation Air Transportation System (NextGen), and its goals of environmental protection that allow for sustained growth. The NextGen program is working with partners to develop solutions to reduce the impacts associated with aviation noise and exhaust emissions and increasing energy efficiency and availability. In alliance with research institutions and industry stakeholders, the program will accelerate the maturation of engine and airframe technologies to reduce aviation noise, fuel use, and emissions. FAA's Center of Excellence (COE) is charged with discovering, analyzing, and developing science-based solutions to the energy and environmental challenges facing the aviation industry. Through COE, FAA has been supportive of alternative jet fuel testing and analysis efforts through the ASCENT. This program is working collaboratively with its 16 main universities and five affiliate universities.

These programs have been vital to research and development and growth of the advanced and cellulosic biofuels sector.

Greater Investments in Research and Development

As the government seeks to reduce emissions throughout the economy its critical for the federal government to recognize that liquid fuels will remain the main source of energy for transportation and to continue to invest in research and development of technologies to convert biomass and waste feedstocks into clean renewable fuels.

Research and development in sustainable fuels should also remain feedstock neutral. To advance the next generation of biofuels, DOE should also support policy, research, and infrastructure directed to the use of using corn cobs, stover, and corn kernel fiber as a fuel to generate steam and electricity and as a source of cellulosic feedstock for ethanol.

III. Biobased Manufacturing

Benefits of Research and Development

Research supported by USDA ARS has been critical in finding new uses of agricultural commodities and by products. Research related to biobased products focuses on developing technologies leading to new and improved non-food products that expand markets for farm products, replace imports and petroleum-based products, and offer opportunity to meet environmental needs. Research also addresses the development of appropriate feedstocks for biobased products.

DOE EERE programs including BETO and the Advanced Manufacturing Office (AMO) have been essential in supporting, developing, and deploying new, novel technologies that help domestic manufacturing become more sustainable resilient, adaptable, and globally competitive.

Globally, there is a strong push to decarbonize fuels and materials from wastes and residues. Conversion technologies are being developed in Europe and Asia, where there is both supportive policies and significant investment in research, development, and demonstration projects. Technologies that have been developed in the U.S. are often initially commercialized elsewhere. We urge the Department to consider support for pilot and demonstration scale projects in the U.S., and, where appropriate, provide funding to support U.S. industry partnerships with international collaborators to speed the rate of deploying U.S. based technologies at home and abroad.

Greater Investments in Research and Development

As USDA highlighted in its 2018 report *An Economic Impact Analysis of the U.S. Biobased Products Industry* many countries world-wide are investing in these technologies, and the U.S. should do so as well. Research is critical to spurring innovation and increasing the variety and efficacy of biobased products and fully utilizing biobased feedstocks. Many of the biobased innovation available today began in university laboratories. Supporting the source of these important developments will be vital to enhancing the growth of the industry. The government should increase opportunities for private sector and university collaboration through ongoing National Science Foundation (NSF), USDA, and DOE funding grants[106].

Also critical to the development of the biobased economy is determining its value and identifying the segments which need investment and research and development. Key to this is updating the North American Industry Classification System (NAICS) codes. BIO supported language in the 2018 Farm Bill[107]. BIO applauds USDA's comments to the 2017 NAICS Updates for 2022 to establish a measurement for biobased products[108].

Funding of base biological and environmental research also has broad implication in environmental remediation, and reengineering of microorganisms and plants with direct relevance to energy, climate, and the environment and enhancing the sustainability of biobased products and renewable fuels.

Support of land-grants and HBCUs will also be critical for STEM education so that as the bioeconomy grows, we have a domestic workforce that can take advantage of the increasing number of high-paying scientific jobs.

IV. Investing in Platform Technologies

To achieve the goals set out in the AIA and meet the challenge of feeding a growing world and tackling climate change will require significant investments in platform technologies such as gene editing and synthetic biology.

Investments in next generation biotechnologies and genomics also have great potential to meet this challenge and achieve the Departments goals set forth in the AIA. Gene editing for multi-trait seed improvements can enable agriculture to increase production by up to 400 mmt, reduce emissions by up to 30 megatonnes of CO_2, reduce freshwater withdrawals

[106] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf
[107] https://republicans-agriculture.house.gov/uploadedfiles/greenwood_testimony.pdf
[108] https://www.regulations.gov/document?D=USBC-2020-0004-0046

by up to 180 billion cubic meters, reduce the number of micronutrient deficient by up to $100 million, while generating up to $100 billion in additional farmer income[109].

As highlighted earlier, advancements in animal biotechnology can further our nation's efforts to safeguard animal health, food safety, and the environment. Increasing genomic research in animal agriculture will also unleash enormous progress in terms of food production and security.

Just like animal biotech, research and development of plant protein and cellular agriculture can provide solutions for improving the productivity and environmental sustainability of food, feed, and animal production and addressing the increasing demand for protein in a growing world. These technologies have tremendous potential for expanding our nation's bioeconomy and diversifying our food supply to adapt and mitigate disease and environment. Supportive research by USDA AFRI can help advance the development and optimization of cell lines, cell culture media, scaffolding, and cultivators (bioreactors) for producing meat through cellular agriculture.

Increasing research in synthetic biology will unlock innovations in agriculture and food productions, energy, and manufacturing. Biotechnology companies have identified opportunities to incorporate synthetic biology[110] in groundbreaking advances in industrial biotechnology manufacturing processes. Companies have begun using science to optimize the processes for producing renewable chemicals, biobased products, and biofuels. With synthetic biology techniques, industrial biotechnology companies can save time by shortening the number of steps used in traditional processes, reducing costs while developing new products. They can also reduce the products' impact on the environment. With proper support synthetic biology can transform our economy.

Because of strong federal support, the United States is a leading nation in the development of synthetic biology. This success and high research productivity are not lost on foreign governments, including China, who are trying to kick-start their biomanufacturing sectors to catch up to, or even leapfrog, the U.S. Our continued growth will be fueled by robust scientific research, strong intellectual property rights, well-functioning technology transfer, dynamic capital investment, science- and risk-based regulation that minimizes obstacles, and public support that embraces the positive influence of biotechnology.

Supportive grants for research and development and startup will provide significant advances in foundational tool development and practical applications ranging from bioenergy, biomanufacturing, to biomedicine. The recommendations put forward by the National Academies of Sciences Engineering Medicine report, *Safeguarding the Bioeconomy*[111] can give further guidance in advancing the bioeconomy for the betterment of the U.S. and society.

BIO has also supported S. 3734, the Bioeconomy Research and Development Act[112] to strengthen and broaden engineering biology by establishing an initiative to advance research and development, advance biomanufacturing, and develop the future bioeconomy workforce. The legislation would also establish a committee to coordinate research in engineering biology across the federal agencies.

[109] https://www.ncfar.org/HSS_20200713_Presentation.pdf
[110] https://www.bio.org/blogs/synthetic-biology-innovation-industrial-biotechnology
[111] https://www.nap.edu/resource/25525/interactive/
[112] https://www.congress.gov/bill/116th-congress/senate-bill/3734

DOD's Synbio Manufacturing MII initiative also has great potential for collaborative, pro-innovation opportunities to expand American leadership in biotechnology.

Modernize Infrastructure

Growing a resilient bioeconomy of the future will also require important investments in infrastructure, such as increased, widespread access to broadband internet technology, pipelines, construction of bioreactors and biobased manufacturing facilities, and distribution capacity for carbon dioxide and sustainable fuels. It will also require the government working with financial institutions and investors to promote access to capital for startups in the biobased manufacturing sectors across food, material products, and energy.

COVID-19 showed the vulnerabilities in our supply chain. To mitigate the effect climate change will have on it in the future, it is critical we develop a cleaner, more resilient agricultural, energy, and manufacturing infrastructure.

I. Access to Broadband

COVID-19 has highlighted the importance of broadband to the modern economy and the digital divide rural communities are facing. The Federal Communications Commission[113] estimated in 2017 that it would cost $80 billion to bring high-speed internet to remaining parts of the country that do not have access, while a more recent U.S. Department of Agriculture[114] report estimated it would require between $130 and $150 billion over the next five to seven years, to adequately support rural coverage and 5G wireless densification.

Despite this cost, bringing high-speed internet infrastructure to rural areas is essential to building a bioeconomy. Farmers and ranchers who participate in carbon markets will need reliable internet access to transmit the data that emissions reductions from soil carbon sequestration are real and verifiable. Reliable access to the internet is also critical to the deployment of next generation precision agriculture technologies which will be essential to sustainably increasing production.

The internet is also critical to ensuring biobased manufacturers and biofuel producers can remain economically competitive

II. Grants and Loan Guarantees for biorefineries.

USDA has been a critical partner in supporting and providing financial support to the development of advanced biofuels and renewable chemicals.

The Biorefinery Assistance Program loan guarantee program provides manufacturers access to capital for large-scale projects in rural communities. Without the loan guarantee program, new innovative companies might never be able to pool sufficient capital to commence development of a project in rural communities with a small population. These biorefineries are proven drivers of job and economic growth for rural communities.

The 2018 Farm Bill expanded access to this program to renewable chemical and biobased product manufacturers; however, it only provided mandatory funding to the program

[113] https://transition.fcc.gov/Daily_Releases/Daily_Business/2017/db0119/DOC-343135A1.pdf
[114] https://www.usda.gov/sites/default/files/documents/case-for-rural-broadband.pdf

through Fiscal Year 2020. To spur growth of additional biorefineries in rural communities, USDA should provide loan guarantees to new projects from the funding already allocated to this program. Additional funding should be provided in future years to support the construction of additional biorefineries.

III. Investments in Biofuels Infrastructure

Pumps and Pipelines

USDA has been a great champion in promoting the development of infrastructure needed to expand the marketplace to supply more renewable fuel to America's drivers through the Biofuel Infrastructure Partnership (BIP) and the proposed Higher Blends Infrastructure Program (HBIIP).

In addition to funding the installation and conversion of pump infrastructure, the government should also make investments in pipelines and terminals to deliver greater volumes of sustainable fuels as well as distribute CO_2 developed from biofuels. Having greater distribution capacity can help avoid the supply disruption the food industry faced due to COVID-19 when the closure of ethanol facilities led to a CO_2 crunch.

Sustainable Aviation Fuels

The development of sustainable aviation fuels also represents a growing opportunity for the development of biofuels producers and biomass producers. To support that effort investments should be made in infrastructure to incentivize the creation and use of sustainable aviation fuels in commercial aviation to reduce fuel costs, pollution, and the overall environmental footprint of U.S. aviation.

USDA Collaboration

In 2016, the U.S. Navy Great Green Fleet demonstrated the potential of advanced biofuels in reducing emissions in maritime engines. Named to honor President Theodore Roosevelt's Great White Fleet, the year-long initiative in the John C. Stennis Strike Group (JCSSG) used alternative fuel sources, energy conservation measures, and operational procedures to reduce its fuel consumption. The fleet used biofuels made from 10 percent beef tallow provided from farmers in the Midwest and 90 percent marine diesel, and it was cost competitive with traditional fuels. It is used as a drop-in alternative, meaning no modifications to engines or operational procedures are required.[115]

The Great Green Fleet was the result of the DOD, USDA, and DOE, providing funding under the Defense Production Act toward the construction of biorefineries that produce cost-competitive, drop-in military biofuels.[116] As a result, these refineries are now coming online, capable of producing fuels for the military and aviation sector.

The military is the nation's largest single consumer of fuel, so the Navy's purchase of 450,000 gallons of biofuel for the exercise signaled a potentially huge defense market for

[115] https://www.navy.mil/submit/display.asp?story_id=95398
[116] http://www.biofuelsdigest.com/bdigest/2014/09/19/breaking-news-us-navy-doe-usda-award-210m-for-3-biorefineries-and-mil-spec-fuels/

liquid renewables. However, when the program essentially ended in 2017, along with the Navy's issuance of short-term contracts, it left investors wary of financing biofuel refineries.

Given the size of the military's fuel demand issuing a requirement for federal agencies to use a certain volume of biofuels could spur long-term investment[117] in the development of sustainable fuel facilities.

IV. Tax Incentives

The biobased economy and industrial biotechnology contribute greatly to the U.S. economy. Enacting sustained, supportive tax policy will lead to even greater growth domestically in this industry. Targeted tax policies will enable emerging technologies in advanced biofuels, renewable chemicals, and biobased products to overcome the challenging capital environment for first-of-a-kind biorefinery construction and allow them to bring their technologies to commercial deployment. This will unleash our members' scientific innovation potential and grow the bioeconomy.

Biofuels

Biofuel tax provisions supporting the development of advanced and cellulosic biofuels – particularly the Second Generation Biofuel Producer Tax Credit (PTC), the Special Depreciation Allowance for Second Generation Biofuel Plant Property, the Biodiesel and Renewable Diesel Fuels Credit, and the Alternative Fuel Vehicle Refueling Property Credit – are incredibly important to our companies that are making significant investments to create new agricultural supply chains, build infrastructure for liquid biofuels, and develop innovative new technologies. These credits have enabled our industry to create new jobs, contribute to rural prosperity, and diversify our nation's energy supply. For example, the biodiesel tax credit has supported the production of biofuels used in aviation.[118]

The expiration and continued on-again off-again nature of these incentives has created uncertainty for investors and the industry about the availability of these credits, jeopardizing the long-term investments necessary for the development of biofuels. While these tax incentives enjoy broad[119] bipartisan[120,121] support[122] for these tax incentives their short-term availability makes it difficult for companies to make long-term planning decisions. Ensuring the growth of advanced and cellulosic biofuels industry will require long-term tax incentives to avoid creating uncertainty for investors and companies trying to raise capital.

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[117] https://www.bloomberg.com/news/articles/2020-07-09/biofuel-revolution-was-doomed-by-policy-and-investment-failures

[118] https://www.nata.aero/assets/Site_18/files/GIA/121SMS/Aviation%20Industry%20Coalition%20Support%20for%20Biodiesel%20credit%20extension%20Neal%20Brady.pdf

[119] https://finkenauer.house.gov/sites/finkenauer.house.gov/files/documents/Second%20Gen%20Biofuels%20Extender%20Support.pdf

[120] https://www.biotech-now.org/wp-content/uploads/2019/11/Second-Gen-Biofuels-Letter-11-26-18.pdf?_ga=2.27182452.850446835.1573066958-1287514846.1535039721

[121] http://kce.informz.net/KCE/data/images/Final%20Signed%20Feb%202019%20Loebsack%20LaHood%20Biodiesel%20Letter.pdf

[122] https://finkenauer.house.gov/sites/finkenauer.house.gov/files/3435_001.pdf

The development of a long-term SAF specific blender's tax credit[123] could attract significant investment to the sector and address existing structural and policy disincentives that have prevented the aviation biofuels industry from taking off.

Renewable Chemicals

To realize the full potential of the domestic renewable chemicals industry, existing renewable energy, manufacturing, or environmental tax incentive regimes should be opened to renewable chemicals. Providing a federal income tax credit for domestically produced renewable chemicals, could create domestic jobs and other economic activity that can help secure America's leadership in the important arena of green chemistry. Like current law for renewable electricity production credits, the credits would be general business credits available for a limited period per facility.

Carbon Capture and Utilization

Maintaining and extending the 45Q tax credits for CCUS will help drive investment and development of innovative new technologies which can capture carbon. The credit monetizes carbon to produce valuable products. Capturing waste carbon from power plants and manufacturing facilities can be converted into valuable products such as advanced biofuels, animal feed, and chemicals. As a result, CCUS helps displace petroleum and other carbon feedstocks. Already, integrating CCUS with biofuels projects is producing negative emissions fuels.[124]

Opportunity Zones

The Opportunity Zone (OZ) tax incentive has spurred investment in undercapitalized communities. Any corporation or individual with capital gains can qualify. However, the OZ guidance is unclear to investors and developers if biobased technologies can qualify for OZ tax incentivizes. A relatively minor clarification to OZ Guidance could potentially unlock billions of development dollars for bioeconomy manufacturing facilities.

V. Bolstering the Supply Chain

Biobased manufacturing can be a solution to making sure those on the ground fighting the pandemic have the protection they need. Demand for personal protective equipment (PPE) is currently outpacing supply. To ensure that we can adequately fight the virus, it is critical that doctors, nurses, first responders, and scientists developing potential cures have access to PPE.

Increasing production of renewable chemicals made from innovative biotechnologies and synthetic biology will help us meet the growing demand of PPE. Development of PPE and other products from biobased materials can also help address the increase in waste from disposable masks and other PPE which is posing new problems for the Earth's oceans.[125] One study estimated if every person in the United Kingdom used a single-use face mask a day for a year it would create an additional 66,000 metric tons of contaminated waste and

[123] https://www.bio.org/letters-testimony-comments/sustainable-aviation-fuels-saf-tax-incentive-letter-congress
[124] https://www.gasworld.com/velocys-signs-ccus-agreement-with-oxy/2017915.article
[125] https://www.fastcompany.com/90520661/masks-gloves-and-other-coronavirus-waste-are-starting-to-fill-up-our-oceans?

57,000 metric tons of plastic packaging.[126] Since these products can be biodegradable or recyclable, they can significantly reduce the amount of waste. It will also increase the demand for biomass feedstocks as producers are faced with a downturn in commodity prices.
In addition to PPE, biobased products can help meet the growing need for testing products to track the virus and research cures. It can also help us meet the demand for sterilizing and cleaning products. In addition to ethanol producers, biotech companies are developing key ingredients that can help in the production of hand sanitizers. Green surface cleaners can meet the growing demand to sterilize surfaces in hospitals, public places, and homes. While enzyme developers are enhancing detergents that can increase cleaning efficacy even in low temperature washing, circumventing the need for hot water and reducing the environmental footprint of the sterilization process.

To meet this demand, the Department and the Administration need to make greater investments in research, development, and deployment of biobased products to tackle COVID-19. We would encourage USDA to use whatever authorities it has to bolster the biobased sector, including expedited distribution of loans under the Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program to build expedited capacity for biorefineries producing renewable chemicals, increasing promotion of the benefits biobased products can provide in addressing the COVID-19 under the BioPreferred Program and ensuring federal agencies are adhering to the program's procurement requirements.

Incentivize Farmers

I. Carbon Sequestration

To increase agricultural production while reducing the environmental impacts and emissions from production will require incentivizes throughout the entire value chain, especially at the farm level.

Promoting greater utilization of crops and practices that impart more carbon into the soil and out of the atmosphere through their roots will be critical to keeping warming below 2 degrees Celsius. This can be accomplished through simple, low-cost incentives to farmers for capturing carbon. The FAO noted that soils can sequester approximately 20 petagrams of carbon in 25 years, that's more than 10 percent of anthropogenic emissions.[127] The *United States Mid-Century Strategy for Deep Decarbonization* estimated that U.S. lands have been a net "carbon sink" for the last three decades and through enhancement they could offset up to 45 percent of economy wide emissions by 2050.

What is needed from government is the establishment of infrastructure to measure and verify those carbon sequestrations at the local farm level. Furthermore, farmers need assistance in understanding and accessing the current voluntary and compliance markets for these credits. Common sense policy will make sure that America agriculture continues to lead on this new frontier of climate change mitigation and restoration.

[126] https://www.greenbiz.com/article/how-face-masks-gloves-and-other-coronavirus-waste-are-polluting-ocean
[127] http://www.fao.org/fileadmin/user_upload/soils-2015/docs/Fact_sheets/En_IYS_ClCng_Print.pdf

Toward this end, BIO is supportive[128] of the Growing Climate Solutions Act[129] (GCSA) (S.3894/H.R. 7393) introduced by Senators Mike Braun (R-IN) and Debbie Stabenow (D-MI) and Representatives Abigail Spanberger (D-VA) and Don Bacon (R-NE) This bill will support America's farmers, ranchers, and foresters who want to adopt innovative practices that combat climate change, while continuing to provide the world with food, feed, and fiber.

II. Incentivizing New Technologies

GCSA or other carbon markets can foster acceptance for new technologies that can further reduce the environmental impact of agriculture, including tools like precision plant breeding, biostimulants, and microbial inoculants and enhancing animal feed with enzymes and other additives to reduce emissions in livestock. These improved agricultural practices increase crop yields and provide several environmental benefits including capturing nitrogen directly from the atmosphere and increasing root growth that binds carbon to the soil.

Combined with modern agricultural techniques and sustainable farming practices such as planting cover crops and no-till, these innovative technologies that enhance productivity can play a key role in sequestering carbon dioxide in the soil, improving soil health, and protecting America's waterways.

To further encourage the use of these technologies additional incentivizes could be created. The Section 45Q provides a performance-based tax credit to power plants and industrial facilities that capture, store, and/or utilize carbon oxides that would otherwise be emitted into the atmosphere as CO_2. Expanding the credit to new technologies that are being developed to amplify soil carbon sequestration through forestry and crops would incentivize producers to utilize this technology reducing atmospheric carbon.

Build Public Support and Increase Market Access for Innovative Technologies

I. Build Public Support and Market Access

Growing Trust in Innovation

Innovation flourishes when science and consumer values are aligned and complement one another. The U.S. government's regulatory approach toward innovative products should be supported by credible transparency measures. A proactive approach to transparency stands to build trust with the broader agri-food ecosystem.

During the public comment period on the SECURE Rule,[130] BIO advocated[131] for a process to improve public access to information about new agricultural biotechnology products. While the final rule does not contain a mechanism for mandatory notification, BIO encourages increased openness about products entering the marketplace and best practices developers use in advancing beneficial products to the commercial marketplace.

[128] https://www.bio.org/press-release/bio-supports-growing-climate-solutions-act
[129] https://www.congress.gov/bill/116th-congress/senate-bill/3894
[130] https://www.bio.org/letters-testimony-comments/bio-comments-usdas-proposed-part-340-revisions
[131] https://www.bio.org/letters-testimony-comments/bio-submits-letter-office-management-and-budget-part-340

BIO is advocating that the U.S. government play a role in driving an inclusive and impactful approach to transparency. We encourage agencies to ensure that regulatory policies are durable and legally defensible. Further, we encourage agencies to articulate to the public the rationale for their approach, including safety assessments.

The U.S. government should establish a biotechnology clearinghouse that is geared toward consumers and builds off the Food and Drug Administration's Agricultural Biotechnology Education and Outreach Initiative[132]. This clearinghouse should provide information about common uses of biotechnology, like gene editing, and the safety of innovations commonly used in the food and agricultural system.

We look forward to working with agency experts to evaluate mechanisms to affirm and communicate the safety and benefits of biotechnology.

To learn more please visit BIO's Growing Trust in Innovation webpage: https://www.bio.org/growing-trust-innovation

BioPreferred

Managed by USDA, the goal of the BioPreferred program is to increase the purchase and use of bio-based products from agricultural feedstocks. The BioPreferred Program was created by the 2002 Farm Bill and reauthorized and expanded in the 2018 Farm Bill. The program's purpose is to spur economic development, create new jobs and provide new markets for farm commodities. The increased development, purchase, and use of biobased products reduces our nation's reliance on petroleum, increases the use of renewable agricultural resources, and mitigates adverse environmental and health impacts.[133] Prior to the 2018 Farm Bill, due to limitations in verification methodology, the BioPreferred program only incentivized procurement of plant-based products. The 2018 Farm Bill requests USDA to develop verification methods for products made from biological CCU. This will expand opportunities for biobased products made from waste resources.

The BioPreferred Program is transforming the marketplace for biobased products through two initiatives: purchasing requirements for Federal agencies and their contractors; and voluntary product certification and labeling. As highlighted above, the label is helping drive consumer recognition of biobased products that are displacing about 300 million gallons of petroleum per year – the equivalent to taking 200,000 cars off the road.[134] However, while federal law, the Federal Acquisition Regulation, and Presidential Executive Orders direct all federal agencies and their contractors to purchase biobased products in categories identified by USDA through the BioPreferred Program,[135] oftentimes federal agencies fail to give preference to bio-based products. To ensure the BioPreferred Program drives growth of the bioeconomy, the Administration should ensure federal agencies follow through with the requirements to give preference to bio-based products and identify noncompliance.

[132] https://www.fda.gov/food/agricultural-biotechnology/agricultural-biotechnology-education-and-outreach-initiative
[133] https://www.biopreferred.gov/BioPreferred/faces/pages/AboutBioPreferred.xhtml
[134] https://www.usda.gov/media/press-releases/2016/10/03/usda-report-shows-growing-biobased-products-industry-contributes
[135] https://www.gsa.gov/governmentwide-initiatives/sustainability/buy-green-products-services-and-vehicles/buy-green-products/biobased-and-biopreferred-products

The following recommendations put forward in *An Economic Impact Analysis of the U.S. Biobased Products Industry*[136] can make this achievable:

- Improve the ability of the Federal Government, including the General Services Administration and other acquisition departments of federal agencies, to track the purchase of biobased products in acquisition systems. Currently, there is not a singular way of doing so, and it is difficult to accurately determine the increases in the use of biobased products by the Federal Government.

- Expand marketing and consumer education of the BioPreferred Program's USDA Certified Biobased Product label. Currently, many consumers are confused or are unaware of what a biobased product is, and they do not recognize or understand the label. While there are certainly benefits to having products labelled as USDA Certified Biobased, increased market recognition would help the biobased products industry grow and encourage more companies to pursue certification.

- Leverage the similar goals between the USDA and the DOE to cooperate on increasing the purchase of biobased products. Both agencies have similar objectives in terms of growth and less reliance on nonrenewable resources, and research supported by both agencies can provide greater power and increased success.

Demonstrate Sustainability

Developing carbon markets are not only beneficial to incentivizing producers to sequester carbon in the soil, but can bring greater value to sustainable fuels, biobased products, and food and feed applications. These markets allow the manufacturers of biobased chemicals, plastics, food, animal feed, and everyday materials to reliably demonstrate their true environmental benefit, from farm to consumer.

Additional mechanisms should be developed to better enable producers to showcase the benefits of these technologies.

Trade

An effective U.S. government trade policy is critically necessary to address tariff and non-tariff barriers that affect the trade of, and innovation in, biotech products globally. In particular, the U.S. bioeconomy needs a proactive trade agenda focused on enhancing IP protection abroad, a harmonized and science-based regulatory environment, fair and equitable technology transfer policies, and access and enforcement policies that appropriately value American innovation and are governed by the rule of law. We applaud that the United States is actively negotiating agreements with key trading partners such as China to address systemic trade practices such as forced technology transfer and IP theft that threatens biotechnology ecosystem across sectors.

With respect to agricultural biotechnology, U.S. leadership is essential to ensure that U.S. agriculture can benefit from advances in science that reduce its environmental footprint while improving crop production. Many U.S. trading partners, including China and Europe, maintain unjustified, non-science barriers that delay the approval of new plant biotech products. To reduce the potential for trade disruption, biotech companies will often delay

[136] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2018.pdf

commercialization of new products in the United States until China and Europe have approved the same products. Such delays impact U.S. competitiveness and cost our economy dearly. A recent study estimates Chinese delays between 2011 and 2016 reduced farm income by $5 billion and U.S. GDP by $7 billion.[137]

For new innovations like gene editing, the global regulatory landscape is unclear, and there is a risk that genome-edited products will be brought under outdated, discriminatory, and highly burdensome regulatory frameworks previously adopted for transgenic ag-biotech products, even though many of the newer products being developed using gene editing do not contain DNA from outside the plants gene pool. This creates the potential for enormous barriers to entry for this emerging industry, potentially limiting the use of this game-changing technology to only a handful of companies and in only large-scale crops. The United States currently is working with like-minded governments to chart a more reasonable path forward for new innovations in biotechnology like gene editing. The U.S. government also has joined many governments from across the Americas, Africa, and Asia to support agricultural applications of precision biotechnology.[138] This international effort is a clear signal to the world that innovations in precision biotechnology, like genome editing, should not face arbitrary and unjustified treatment by regulatory authorities. We applaud these efforts and encourage renewed urgency in their implementation.

Conclusion

BIO applauds USDA for taking a proactive approach and seeking information about facilitating the transformative breakthroughs for agriculture to meet the challenges of the 21st Century and increase agricultural production by 40 percent while cutting the environmental footprint by 50 percent.

Achieving this goal and addressing the challenges of climate change and inequality in society, will require the rapid development and deployment of biology-based technologies throughout the agricultural supply chain. It will require USDA and the federal government to establish supportive policies and regulations, provide robust funding for research and development, modernize infrastructure, support all farmers and ranchers, and build public support of new technologies.

We urge the Administration to seize the opportunity to expand on this American leadership, by acting and supporting the pro-innovation technologies and policies we outlined in our comments. We look forward to our continued partnership in this critical endeavor.

[137] https://www.bio.org/press-release/new-report-shows-substantial-economic-costs-chinese-delays-ag-biotech-approvals
[138] https://www.usda.gov/media/press-releases/2018/11/02/wto-members-support-policy-approaches-enable-innovation-agriculture