Biocom California

January 20, 2023

Ms. Arati Prabhakar
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: Biocom California's Response to the White House Office of Science and Technology Policy's Request for Information Regarding the National Biotechnology and Biomanufacturing Initiative

Submitted electronically

Dear Director Prabhakar:

Biocom California appreciates the opportunity to offer comments on the Office of Science and Technology Policy's (OSTP) Request for Information; National Biotechnology and Biomanufacturing Initiative[1].

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,700 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products.

California's life sciences industry generates over $375 billion in annual economic activity, supports 435,000 jobs, and increases labor income by $115 billion per year[2]. In 2021, California exported almost $20 billion in life science products, of which 85% came from food and agricultural biotechnology[3]. Additionally, California prioritizes these industries in our educational systems, including hosting the largest number of community college biotechnology programs in the nation and being home to institutions recognized nationally for their ground-breaking biomanufacturing programs, such as the University of California and California State systems[4].

Biocom California is encouraged that the Administration is recognizing the promise of the biotechnology and biomanufacturing industries for innovative solutions in food, agriculture, health, and supply chain resilience, and appreciates the opportunity to respond to OSTP's Request for Information (RFI) explaining how biotechnology and biomanufacturing can further societal goals. Biocom California offers responses to the following questions:

[1] Federal Register, 87 FR 77901, pp. 77901-77903, December 20, 2022.
[2] Biocom California 2022 Economic Impact Report Databook. https://www.biocom.org/eir/
[3] Ibid.,20.
[4] Ibid.,12.

Harnessing Biotechnology and Biomanufacturing R&D To Further Societal Goals

1. *a. What specific bold goals can be achieved through advances in biotechnology and biomanufacturing in the short-term (5 years) and long-term (20 years)?*

Prevention, earlier diagnosis, and personalized disease treatments

Genetic screening and diagnostic testing are currently used to provide information to patients and their providers to facilitate disease prevention or earlier diagnosis. With this information and a timelier diagnosis, new treatment techniques are being developed, such as immunotherapy, cell and gene therapies, and precision medicine, and have revolutionized modern medicine by enabling the development of more precise, preventative, and individualized treatments. **As the cost of healthcare continues to increase, we look to genetic information and engineering as one way to improve care delivery performance, target previously untreatable diseases, develop more effective treatments, improve patient quality of life, avoid costly unsuccessful diagnostics and therapies, and prevent adverse patient outcomes.** These efficiencies can reduce healthcare expenditures almost immediately for our nation. Over the next 5 years, as academia and industry continue to refine genetic engineering techniques and establish scalable manufacturing processes, there will be 1) an increase in the commercialization of these therapies, especially those currently in late-stage clinical trials, and 2) a reduction in the cost of biomanufacturing. The economic impact of this cost reduction may be seen in the next 20 years as human disease and mortality rates decrease.

Pharmaceutical biomanufacturing

A short-term goal is to have active pharmaceutical ingredients with stereocenters produced via biomanufacturing. **In the long term, this goal could expand to include new, novel drugs and generics manufactured through bio-based supply chains and production routes.** Companies could aim to use biomanufacturing techniques such as cell-free biocatalysis to remove up to 30% of petrochemicals from drug manufacturing in the next 5 years and 80% over the next 20 years. Investments in biomanufacturing techniques can reduce both the short- and long-term use of petrochemicals in pharmaceutical manufacturing and increase the overall sustainability of the industry.

Alternative food sources

Investments in cellular agricultural and alternative protein biotechnology, including the development of recombinant animal proteins in plants and fermentation systems, over the past decades, have paved the way for alternative food sources that can diversify the food supply and help feed more populations throughout the world, while lessening the human impact on the environment. Within the next 20 years, alternative protein consumption is predicted to reach up to 22% of the market share[5]. By 2050, investment in cellular agriculture alone has the potential to 1) yield $5.5 trillion in climate mitigation benefits such as reduced greenhouse gas and carbon emissions, 2) generate an anticipated 10 million jobs, and 3) add $1 trillion in gross value across the globe[6]. Alternative protein and cellular agriculture-related jobs could include positions in the conventional farming sector to farm genetically engineered crops and supply raw ingredients, manufacturing jobs to produce food-lab equipment such as bioreactors, and engineering and science roles to utilize ingredients and develop new products. **Some of the world's most successful cell-cultured food companies are in the U.S. and long-term investment in cellular agriculture by the Government can help the U.S. bioeconomy further grow this emerging industry[7]. Advanced genetic engineering techniques used in agriculture can also increase the nutritional quality of crops while conferring pest resistance, drought mitigation, the diversification of protein sources, and other environmental benefits.**

Plant-based products manufacturing

Through advances in biomanufacturing that utilize plant-based feedstock for fuel instead of petroleum, one goal is to use sustainably grown feedstock to power domestic biomanufacturing facilities. This advancement would strengthen the resiliency of the U.S. supply chain and allow the industry more traceability in the production process across multiple sectors. Plant-based feedstock provides the ability to manufacture materials with up to a 90% carbon reduction rather than petroleum and fossil fuels used in current technologies. This advancement in biomanufacturing will allow the industry to work towards its goal of reducing carbon emissions over the next 20 years. If plant-based organic compounds and fatty alcohols were to replace their petroleum-derived counterparts, carbon dioxide emissions could be reduced drastically each year. **In addition to reducing climate impacts, plant-based feedstock for biomanufacturing can de-risk supply chains and incentivize manufacturing to return to the U.S.**

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[5] Boston Consulting Group, "Food for Thought: The Protein Transformation" (2021). https://web-assets.bcg.com/a0/28/4295860343c6a2a5b9f4e3436114/bcg-food-for-thought-the-protein-transformation-mar-2021.pdf.

[6] Vivid Economics, "Global Innovation Needs Assessment: Protein diversity" (2021). https://www.climateworks.org/wp-content/uploads/2021/11/GINAs-Protein-Diversity.pdf.

[7] Ibid.

1. *b. What research and development (R&D) is needed to achieve the bold goals outlined in (a), with a focus on cross-cutting or innovative advances? How would the Government support this R&D, including through existing Federal programs, creation of new areas of R&D, and/or development of new mechanisms?*

As an increasing number of cell and gene therapies populate the clinical pipeline, safety and commercial-scale manufacturability are of critical focus. Closed, scalable, high throughput instrumentation platforms designed to simplify the complex manufacturing process can help overcome many of the current challenges associated with processes lacking robustness and reproducibility. Most importantly, the development of innovative tools and solutions that enable process automation and digital integration will support process standardization, which can increase manufacturing success rates and significantly reduce the cost of goods. These efforts will culminate in making life-saving cell and gene therapies accessible to the patients who need them at an affordable price.

To support this R&D, a collaborative relationship between technology developers and regulators is necessary. We support efforts from the Food and Drug Administration (FDA) to establish early engagement programs focused on collaborating with developers and streamlining their questions. An increased collaborative relationship can be achieved by assigning dedicated personnel to these efforts, participating in increased face-to-face meetings, engaging in more pilot-type programs, and ensuring that FDA personnel communicate the most current information possible to the industry. **We are appreciative of several programs that have been designed to provide early engagement with the agency to solicit product development feedback, such as the Center for Biologics Evaluation and Research Advanced Technologies Team (CATT) Program but cannot stress enough the importance of adequate funding and staffing to ensure the success of these efforts**. To facilitate lower-cost discovery R&D, we also suggest that federal agencies explore computational prototyping capabilities for genetic engineering and provide funding for this intersection of computational modeling and biology to promote academic and industrial product discovery. Using advanced virtual prototyping or software to build and test products before physical development will help develop gene therapy biologics more efficiently.

To achieve the aforementioned pharmaceutical biomanufacturing goals, federal agencies should invest in R&D to understand a greater breadth of biocatalytic reactions including carbon to carbon bond forming reactions and complexity-generating transformations. **Additionally, R&D should also focus on novel bio-based chemical entities that can create more optimal products compared to their current petroleum-based counterparts and products that can be produced more cleanly through biocatalytic pathways.** Cleaner alternatives can exist due to the potential of biocatalysis and this advancement in biotechnology should be explored further in R&D supported by the U.S. Government.

1. *c. How else can the Government engage with and incentivize the private sector and other organizations to achieve the goals outlined in (a)?*

Biocom California has been encouraged by the Executive Order's emphasis on the need for federal investment in biotechnology and biomanufacturing innovation[8]. **We ask that federal agencies review funding applications in a timely manner while prioritizing technologies that are at the forefront of providing innovative health, food, climate, and energy benefits.**

In addition to funding, it is essential for the Federal Government to develop an industry-friendly framework of financial, regulatory, and reimbursement incentives that support the research of new products and processes, especially in areas of unmet needs, and the establishment of domestic biomanufacturing facilities, including preserving existing tax credits (R&D and orphan drug), creating tax incentives for the production of and investment in renewable energy, ensuring the clarity and continuity of review and approval pathways, maintaining the ability of companies to recoup their investments, and issuing coverage determinations that enable the development of and access to new therapies and technologies, such as genetic and diagnostic tests. These decisions and incentives have a direct impact on incentivizing the private sector to explore and develop novel, innovative solutions.

While Asia and the European Union (EU) have exhibited competitive landscapes for biomanufacturing investments, recent action by Congress and the Administration has encouraged companies to return production to the U.S.; especially considering current energy and security risks in the EU and global supply chain disruptions. Department Of Energy programs such as the "Industrial Decarbonization and Emissions Reduction Demonstration-to-Deployment" funding

[8] Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/

opportunity and Title 17 Innovative Energy Loan Guarantee Program are important for the industry to begin domestic capital infrastructure projects[9,10].

For the cellular agriculture and alternative protein industries, including companies producing recombinant animal proteins in plants or in fermentation systems, the Federal Government could establish a loan program to provide access to companies that are seeking to scale up production efforts in the U.S. For example, a program like the U.S. Department of Agriculture's (USDA) Food Supply Chain Guaranteed Loan Program could serve companies within the cell-cultured food and broader alternative protein industry by removing geographic restrictions, expanding eligibility requirements, and increasing loan amounts[11]. Additionally, the Government could support cellular agriculture and alternative protein companies with securing loans for equipment that will facilitate R&D and production. Lastly, since cellular agriculture and the alternative protein sector are emerging industries, the Federal Government can establish projects like the USDA's Local Food Promotion Program to support nationwide education and promotion of these products[12].

With respect to pharmaceuticals, federal policy can be a key driver to incentivize the industry to adopt more bio-based methods for drug discovery and manufacturing. The Federal Government could establish a center, similar to the National Science Foundation's Center for Selective C–H Functionalization, which brings together industry and academia to discover and publish biocatalytic reactions and complexity-generating transformations. Current organizations exploring this work are structured to require increased intellectual property (IP) sharing and this can prevent smaller companies from collaborating with these groups. Additionally, the Government could partner with industry and academic groups developing novel chemical entities to assist them in finding novel, safe uses for these compounds**. Federal regulatory and funding agencies should ensure that regulations, definitions, and labeling of bio-based products support the more widespread adoption of biomanufacturing methods.**

Lastly, the U.S. government should continue to support a strong patent system through a well-funded and innovation-driven U.S. Patent and Trademark Office and reject any regulatory or legislative proposals which weaken patents, impose greater requirements on innovators, restrict legitimate patent holders' ability to assert their IP rights, and increase litigation risks. Adoption of such practices would undermine the very goals the Federal Government is trying to achieve by dissuading investments in R&D due to uncertain or frivolously contested IP.

2. *Public engagement and acceptance are of critical importance for successful implementation of biotechnology solutions for societal challenges. How might social, behavioral, and economic sciences contribute to understanding possible paths to success and any hurdles? What public engagement and participatory models have shown promise for increasing trust and understanding of biotechnology?*

Federal outreach that engages the public through effective communication and education may increase trust and understanding of biotechnology. For example, the introduction of the COVID-19 mRNA vaccines demonstrates both successes and pitfalls that biologics, genetic, and cellular medicines may continue to face. **Biocom California suggests educating the public in layman's terms about these novel products, their risks/benefits, and their function to assist with the public's acceptance of these biotechnologies. Voluntary programs that engage the public in national goals, such as the *All of Us Research Program* also provide opportunities for the public to not only enhance public health but also be active participants in overcoming societal challenges. We also suggest developing a science-based curriculum for schools to foster future understanding of these technologies.**

Data for the Bioeconomy

3. *What data types and sources, to include genomic and multiomic information, are most critical to drive advances in health, climate, energy, food, agriculture, and biomanufacturing, as well as other bioeconomy-related R&D? What data gaps currently exist?*

Currently, genomic, transcriptomic, and epigenetic data sources drive biotechnological advancements and bio-based processes, and chemical compounds are important to advancing biomanufacturing. However, there is an unmet need for more advanced proteomic sequencing technologies that operate rapidly and without bias. Furthermore, in terms of scientific knowledge, there are data gaps in understanding and measuring the glycome and its role in health.

[9] DE-FOA-0002935, Industrial Decarbonization and Emissions Reduction Demonstration-to-Deployment Funding Opportunity Announcement. https://oced-exchange.energy.gov/Default.aspx#FoaId17338316-4d87-4ff7-87e6-619175602ce3.
[10] https://www.energy.gov/lpo/title-xvii
[11] https://www.rd.usda.gov/food-supply-chain-guaranteed-loans
[12] https://www.ams.usda.gov/services/grants/lfpp

With respect to biomanufacturing, there is a need for databases that list 1) commercialized bio-based processes and their locations, 2) chemical compounds occurring in nature, and 3) commercialized compounds. These databases would assist manufacturers in product development and in identifying intellectual and commercial partners. Lastly, from an administrative perspective, data gaps currently exist with the Environmental Protection Agency's database which does not facilitate registering multiple new biocompounds.

4. *How can the Federal Government, in partnership with private, academic, and non-profit sectors, support a data ecosystem to drive breakthroughs for the U.S. bioeconomy? This may include technologies, software, and policies needed for data to remain high-quality, interoperable, accessible, secure, and understandable across multiple stakeholder groups.*

Biocom California appreciates the Government's current resources, such as the National Institutes of Health National Center for Biotechnology Information databases, which allow researchers to acquire data files from federally-funded research projects. However, the databases' queries and data structures can be challenging for researchers to navigate, and the Government should consider improving the user design to better meet stakeholder needs. **The Federal Government can also draft policies and provide incentives for secure data-sharing partnerships between academic, private, and non-profit organizations to foster collaboration.** This could be accomplished by establishing a government-sponsored voluntary, pro bono data-sharing platform that hosts studies and datasets on cloud-based data storage and management systems. **Additionally, the Government could work with the private sector to establish standards for data quality, interoperability, security, and accessibility that will ensure that data remain usable and trustworthy across different sectors.** Lastly, while there are many useful software tools intended for research, it is unclear how the biotechnology industry can leverage them for commercial purposes. Therefore, there is a need for open-access tools that can be used for structure prediction, protein design, and machine learning related to all aspects of biology.

Building a Vibrant Domestic Biomanufacturing Ecosystem

5. *What is the current state of U.S. and global biomanufacturing capacity for health and industrial sectors and what are the limits of current practice?*

Currently, the global industry lacks the capacity to support the growing demand for biotechnology R&D and biomanufacturing services, and, domestically, the capacity to meet this demand has grown at a slower pace compared to Asia and the EU. On average, it takes about 5 years to build and operationalize a biopharma manufacturing facility in the U.S. and this timeline is a current limitation in the domestic ability to accommodate this industry. Another limitation of domestic biomanufacturing is that most raw materials and ingredients are almost exclusively made abroad, and this has led to significant supply chain disruptions in recent years. **In order to avoid these disruptions and support domestic manufacturing, we ask that the Government implement the supply chain provisions included in the Consolidated Appropriations Act, 2023 in a timely manner**[13].

6. *What can the Federal Government do to expand and scale domestic biomanufacturing capacity and infrastructure? What level of investment would be meaningful and what incentive structures could be employed?*

The Federal Government could expand and scale domestic biomanufacturing capacity by utilizing contract research and manufacturing organizations. Global contract service providers bridge the current domestic capacity gap by allowing U.S. companies to develop and manufacture treatments in a timely and cost-effective manner. The U.S. government should streamline regulations and incentives for international contract service organizations with a large U.S. customer base. These organizations can sustain the current biomanufacturing demand while the government simultaneously expands and scales the domestic biomanufacturing capacity. Therefore, these organizations can help sustain American competitiveness, strengthen domestic supply chains, and stimulate job creation while also ensuring existing high standards for patient safety.

Furthermore, in order to expand biomanufacturing, the government should invest in companies commercializing novel biomanufacturing methods and bioproducts. With respect to food and agriculture, the government should codify cellular agriculture and alternative proteins as a research priority and provide additional funding through existing grant programs. These industries can become USDA strategic priorities for the Agriculture and Food Research Initiative Programs and incentives such as R&D tax credits and loan guarantees should be created to lower costs and risks for these companies. By providing subsidies to biomanufacturing companies, the federal government can create an ecosystem geared towards the discovery and commercialization of bio-based products.

[13] Public Law 117-328. https://www.congress.gov/bill/117th-congress/house-bill/2617/text.

In addition, manufacturing scalability continues to be one of the key challenges in therapeutics delivery today, along with the need for process standardization, to ensure that safe and quality therapies are produced. This multi-step, labor-intensive process is prone to human error and contamination, which contributes to a high degree of lot-to-lot variability and a relatively high failure rate in a zero-failure tolerance setting. Automating the manufacturing process removes limiting factors such as the manual processing of cells, which may be susceptible to human error while increasing the robustness and reproducibility of manufacturing. **Through automation, manufacturing organizations can increase efficiency, scale up, reduce cost, and bring these therapies to patients cheaper, faster, and safer.**

7. *What are barriers that must be addressed in order to better enable domestic supply chains for biomanufacturing (e.g., feedstocks, reagents, consumables)?*

Biomanufacturing supply chains should be strengthened moving forward and there is a need for better amino acid manufacturing routes and other foundational compounds necessary to produce essential bi-products such as feedstock and reagents that are used in many areas of bio-based research and manufacturing. Furthermore, to reduce food-related supply chain threats, **the U.S. should diversify its food sourcing by investing in the domestic production of cell-cultured foods and alternative proteins.** A strong domestic cellular agriculture and alternative protein supply chain can reduce the country's reliance on foreign food products, increase product traceability, and provide new sources of alternative protein. Due to recent supply chain disruptions, these companies have had difficulty sourcing materials and equipment such as culture media and bioreactors, to sustain their R&D and production activities; therefore, delaying bringing products to market.

Biobased Products Procurement

9. *What are new, environmentally sustainable biobased products that the Federal Government could purchase through its BioPreferred Program? How can the Federal Government incentivize development of new categories of sustainable biobased products?*

The Government could purchase amino acids, additional pharmaceutical precursors, and expand its antimicrobial drug stockpile to include biomanufactured antimicrobials. Additionally, the Government could also procure products that are biomanufactured using plant-based materials such as nylon. The BioPreferred Program should focus on connecting producers of biobased chemicals, plastics, textiles, and other goods made from biobased materials and processes with procurement officers across multiple federal agencies. This may incentivize the development of new types of sustainable biobased products as it signals to producers that there is a viable market, with the Federal Government being a key consumer. We believe it is important for the industry to understand that there is a demand for these products before companies invest in the R&D necessary for breakthrough innovations.

Biotechnology and Biomanufacturing Workforce

10. *How can the U.S. strengthen and expand the biotechnology and biomanufacturing workforce to meet the needs of industry today and in the future? What role can government play at the local, state, and/or Federal level?*

The industry's technological advances have outpaced the development of the country's biotechnology workforce with the skills necessary to support this progress. Through our Biocom California Institute and Generation STEAM program, Biocom California is committed to ensuring a pipeline of life science talent for generations to come. We partner with the biotechnology industry and research institutions to support programming that educates students on careers in science, technology, engineering, arts, and math (STEAM) to inspire, prepare, and diversify the life science workforce.

We believe the U.S. can strengthen and expand the workforce by improving STEAM education in all communities, especially those outside of biotechnology hubs, to enhance technical knowledge and encourage participation in these careers in the future. Additionally, the Biocom California Institute hosts professional development courses and fosters partnerships that allow mission-driven individuals to develop the skills needed to meet the industry's current advancements, such as our Life Science Young Leaders program and our Veterans Initiative. The Government could increase its support for similar programs, as well as incentivize organizations to incorporate workforce development into their hiring and retention policies to cultivate a workforce of high and evolving aptitudes. **Additionally, the Government can partner with industry to create apprenticeship and training programs that provide work experience and help prepare workers for careers in biotechnology and biomanufacturing.** Lastly, supporting immigration policies that allow companies to recruit foreign talent to complement the U.S. workforce and fill temporary gaps would help increase the overall talent pool and sustain a strong workforce.

Measuring the Bioeconomy

15. *How should the North American Industry Classification System and the North American Product Classification System be revised to enable characterization of the economic value of the U.S. bioeconomy? Specifically, which codes or categories do not distinguish between functionally identical bio-based and fossil fuel-based commodities?*

The North American industry and product classification systems should be amended to assign codes to bio-based products in order to recognize their significant contributions to the bioeconomy. U.S. biobased products contributed a total of $470B in value added to the U.S. economy and supported 4.6 million American jobs[14]. Biobased products also have the potential to reduce greenhouse gas emissions by an estimated 12.7 tons per year and replace 9.4 million barrels of petroleum annually[15]. **The government should develop codes for renewable chemical manufacturers and producers of biobased products so that federal agencies can accurately classify, collect data, and report on the growing bioeconomy**. Furthermore, without assigned codes, companies are not eligible to appear in the BioPreferred product catalog nor apply for federal contracts through the small business offices at federal agencies.

International Engagement

16. *What are opportunities for the U.S. Government to advance research and development, a skilled workforce, regulatory cooperation, and data sharing for the bioeconomy through international cooperation? Which partnerships and fora are likely key to advance these priority areas?*

Throughout Biocom California's history, we have fostered global collaboration through strategic partnerships with international biotechnology organizations. International collaboration remains key to advancing biotechnological R&D and there are many opportunities for greater collaboration between the U.S. government and foreign entities. **First, the U.S. Government can work with international partners to ensure a robust and secure supply chain for the entire pipeline of products and services required to develop and manufacture biotechnology.** Supply chain resiliency is needed for the materials and products used to produce biotechnological solutions in addition to the supplies needed to construct and operationalize biomanufacturing facilities. **Additionally, we encourage the Government to implement policies that more readily facilitate R&D and manufacturing collaboration between U.S. and international companies.** This could include increased efforts to streamline the application process and document review that allows foreign companies to work in the U.S. or partner with a U.S.-based company.

17. *What risks are associated with international biotechnology development and use, and how can the U.S. Government work with allies and partners to mitigate these risks?*

Risks such as geopolitical instability and global supply chain disruptions threaten the international biotechnology community as they limit the ability of companies to receive the materials needed for development and use. The U.S. Government can mitigate these risks by working with allies and partners to diversify supply chains and identify additional resources for materials often used in biotechnology and biomanufacturing. These international efforts can minimize the effects of geopolitical instability and supply chain disruptions on these industries. **Lastly, it is extremely important for the federal government to uphold innovators' intellectual property rights. Free-trade agreements and other trade deals must uphold U.S. IP protections in order to level the playing field with foreign countries by bringing them closer to our IP standards and limiting foreign "free-riding" on American innovation.** Waiving IP protections, IP theft and other IP violations are damaging U.S. leadership in biomedical innovation.

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Associate Manager of Regulatory Policy, Zoe Bilis, at zbilis@biocom.org for additional information or questions. We look forward to continuing to work with you on this matter.

Sincerely,

Joe Panetta
President and CEO, Biocom California

[14] USDA Rural Development, "An Economic Impact Analysis of the U.S. Biobased Products Industry," July 2021, available at https://www.rd.usda.gov/sites/default/files/usda_rd_economic_impact_analysis_us_biobased_products_industry.pdf.
[15] Ibid, 9, 74.