

Federal Activities Report on the Bioeconomy: ALGAE (This page intentionally left blank)

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OVERVIEW OF THE BR&D BOARD AND BIOECONOMY INITIATIVE

The Biomass Research and Development (BR&D) Board coordinates research and development activities concerning biobased fuels, products, and power across federal agencies and aims to maximize the benefits of federal programs and bring coherence to federal strategic planning. The BR&D Board includes members from the U.S. Departments of Energy, Agriculture, Interior, Transportation, and Defense; the U.S. Environmental Protection Agency; the National Science Foundation; and the Office of Science and Technology Policy.

The BR&D Board oversees the interagency Bioeconomy Initiative, a coordinated federal effort to expand the sustainable use of the nation's abundant biomass resources for biofuels, bioproducts, and biopower. The vision of the Bioeconomy Initiative is a vibrant U.S. bioeconomy that enhances economic growth, energy security, and environmental quality by maximizing sustainable use of the nation's domestic biomass resources for affordable biofuels, bioproducts, and biopower.

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Acronyms and Abbreviations

AAFCO	Association of Animal Feed Control Officials
AAS	Advanced Algal Systems
ABCDE	Algae Bioproducts and CO, Direct-Air-Capture Efficiency
ABLC	Advanced Bioeconomy Leadership Conference
ABY	Algae Biomass Yield
ABY2	Advancements in Algal Biomass Yield, Phase 2
ACOE	
ADO	U.S. Army Corps of Engineers
AFRI	Advanced Development and Optimization
	Agriculture and Food Research Initiative
APHIS	Animal and Plant Health Inspection Service
AQUA	Aquaculture Research Competitive Grants Program
ARRA	American Recovery and Reinvestment Act
ARPA-E	Advanced Research Projects Agency – Energy
ARS	Agricultural Research Service
ASAP	Advancements in Sustainable Algal Production
AWG	Algae Interagency Working Group
BER	Biological and Environmental Research
BES	Basic Energy Sciences
BETO	Bioenergy Technologies Office
BIO	Biological Sciences (NSF)
BR&D	Biomass Research and Development
BRDI	Biomass Research and Development Initiative
BRS	Biotechnology Regulatory Services
BSSD	Biological Systems Science Division
CAPP	Coastal Aquaculture Planning Portal
CBET	Chemical, Bioengineering, Environmental, and Transport Systems
CCUS	carbon capture, utilization, and storage
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CIPA	Cultivation Intensification Processes for Algae Area of Interest
CO ₂	carbon dioxide
CVM	Center for Veterinary Medicine
СХ	Categorical Exclusion
DAF	Division of Animal Feeds
DOC	U.S. Department of Commerce
DOE	U.S. Department of Energy

ECUAS	Efficient Carbon Utilization in Algal Systems
EERE	Office of Energy Efficiency & Renewable Energy
EHSS	Office of Environment, Health, Safety, and Security
EISA	Energy Investment and Security Act
ENG	Engineering (NSF)
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act
FDA	U.S. Food and Drug Administration
FE	Office of Fossil Energy
FFDCA	Federal Food, Drug, and Cosmetic Act
FOA	funding opportunity announcement
FSIS	Food Safety and Inspection Service
FY	fiscal year
GEO	Geosciences (NSF)
GREET	Greenhouse gases, Regulated Emissions, and Energy use in Transportation
HABHRCA	Harmful Algal Bloom and Hypoxia Research and Control Act
HHS	U.S. Department of Health and Human Services
IBR	integrated biorefinery
IWG-A	Interagency Working Group on Aquaculture
IWG-HABHRCA	Interagency Working Group on the Harmful Algal Bloom and Hypoxia Research and Control Act
IWG-OA	Interagency Working Group on Ocean Acidification
JGI	DOE Joint Genome Institute, an Office of Science user facility operated by BER
MARINER	Macroalgae Research Inspiring Novel Energy Resources
MCAN	Microbial Commercial Activity Notice
MOU	Memorandum of Understanding
MSA	Magnuson-Stevens Fishery Conservation and Management Act
NCCOS	National Centers for Coastal Ocean Science
NEPA	National Environmental Policy Act
NIFA	National Institute of Food and Agriculture
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NSF	National Science Foundation
OCSPP	Office of Chemical Safety and Pollution Prevention
OFAS	Office of Food Additive Safety
OPPT	Office of Pollution Prevention and Toxics
PAPPG	Proposal and Award Policies and Procedures Guide

PD2B3	Project Development for Pilot and Demonstration Scale Manufacturing of Biofuels,
r <i>D2</i> D3	Bioproducts and Biopower
PEAK	Productivity Enhanced Algae and Tool-Kits
PPQ	Plant Protection and Quarantine
R&D	research and development
RD	Rural Development
RFI	Request for Information
RHA	U.S. Rivers and Harbors Act
SBIR	Small Business Innovation Research
SC	Office of Science
SCA	Subcommittee on Aquaculture
SCUBA	Scale Up of Bench Applications
SEA	Science Emphasis Area
SOPO	Statement of Project Objectives
STTR	Small Business Technology Transfer
SWIM	Synergistic Wastewater Integration with Microalgae
TABB	Targeted Algal Biofuels and Bioproducts
TERA	TSCA Experimental Release Application
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture
VS-CVB	Veterinary Services Center for Veterinary Biologics

Executive Summary

The Algae Interagency Working Group (AWG) under the Biomass Research and Development (BR&D) Board meets to discuss U.S. federal funding and regulatory activities to increase awareness and coordination among algae-relevant government programs. The *Federal Activities Report on the Bioeconomy: Algae* is a follow on report to the BR&D Board's *Federal Activities Report on the Bioeconomy* that summarizes Bioeconomy Initiative activities for the algae stakeholder community. The primary goal of this document is to share information on the breadth and scope of federal resources available to researchers and companies seeking to understand and use algae for the benefit of the bioeconomy. Ideally, readers of this report will discover a new source of available funding or receive clarity on regulatory oversight on product development. This report also includes information on external engagement opportunities (e.g., workshops, notice and comment on the proposed rulemaking, and requests for information) to show how stakeholders can get involved in AWG activities and provide information and feedback to members of the Bioeconomy Initiative.

This report is divided into two areas of focus: (1) federal investment in algae research and development (R&D) and (2) federal regulatory oversight of algae. The activities of AWG member offices in each of these areas are summarized in reference tables within each section. The federal government funds a range of R&D activities to better understand and improve upon how algae biology, cultivation, harvesting, preprocessing, and conversion can result in a profitable and sustainable industry that supports the bioeconomy. The AWG works to coordinate these R&D activities and communicate scientific results to stakeholders. This report categorizes federally funded R&D activities into basic, applied, process performance, and analysis and then further categorizes the summaries by research topic areas. The range of investments spans from fundamental R&D of microbiomes and intracellular processes to applied research that informs the siting and standards for large-scale algal biomass production.

AWG members also represent offices that provide regulatory oversight of the production, use, and application of algal biomass and bioproducts. Regulatory oversight is summarized in this report in two sections: (1) oversight for uses and application of algae and (2) oversight for the production of algae. This report also outlines five broad regulatory categories for the use and/or application of algal biomass: food and health, chemicals and materials, energy, services, and indirect uses.

In addition to the activity summary tables in this report, the appendices provide greater detail on the roles and authorities of AWG member offices. Appendix A includes a summary of regulatory oversight authorities. Appendix B lists federal offices that could have a role related to the beneficial use of algae for the bioeconomy that are not included in the body of this report, as well as federal offices with purview over harmful algal blooms. Appendix C contains detailed information from member offices related to regulatory oversight authority, and Appendix D includes those related to R&D activities.



Algae production ponds at Global Algae Innovations in Lihue, Hawaii. Photo by Global Algae Innovations, Inc.

1 Introduction

1.1 The Bioeconomy Initiative and the Algae Interagency Working Group

The Bioeconomy Initiative is a coordinated federal effort to expand the sustainable use of the nation's abundant biomass resources for biofuels, bioproducts, and biopower. The Biomass Research and Development (BR&D) Board leverages interagency working groups to enhance information sharing and program coordination among U.S. federal agencies to achieve the Bioeconomy Initiative's mission. Made up of technical experts from the BR&D Board member agencies, these working groups meet regularly to implement annual work plans aligned with the goals of the initiative. The Algae Interagency Working Group (AWG) advises, communicates, and coordinates federal research and development (R&D) activities relating to the production and use of algal biomass sustainably within an appropriate regulatory framework.¹

The AWG includes representatives from the U.S. Department of Agriculture (USDA), U.S. Department of Commerce (DOC), U.S. Department of Energy (DOE), U.S. Department of Health and Human Services (HHS) – Food and Drug Administration (FDA), U.S. Environmental Protection Agency (EPA), and the National Science Foundation (NSF).

1.2 Purpose of the Federal Activities Report on the Bioeconomy: Algae

This report summarizes the current scope of AWG member office activities on R&D and regulatory oversight authority related to the beneficial production, use, and application of algal biomass and bioproducts for the bioeconomy. Additional sections cover external engagement and coordination with other Interagency Working Groups. This document is current as of January 2020. There are four appendices at the end of the document. Appendix A provides an office summary of regulatory oversight authority. Appendix B is a listing of other federal offices that may have a role related to the beneficial use of algae for the bioeconomy that are not included in this report, as well as identified offices that have R&D and regulatory authority pertaining to harmful algal blooms and hypoxia. Appendix C comprises the full responses from member offices related to regulatory oversight authority. Appendix D contains the full responses from member offices related to R&D activities.



InShore Harvesting of Kelp at the University of New Hampshire. Photo by Zach Mosciki, Trophic LLC.

¹ Biomass Research and Development Board, "Interagency Working Groups," last modified July 11, 2019, <u>https://www.biomassboard.</u> gov/board/working_groups.html.

1.3 Status of the Algae Industry

Algae encompass a broad category of organisms that can be classified into two main categories: microalgae (microscopic photosynthetic eukaryotic organisms and cyanobacteria) and macroalgae (seaweed). Algal biomass is composed primarily of lipids (i.e., polyunsaturated fatty acids), proteins, carbohydrates, nucleic acids, and natural pigments that can be used to develop products such as nutraceuticals, pigments, human foods, animal feeds, fertilizers, bioplastics, and biofuels. The sale of algal biomass for specialty products such as dietary supplements and food additives is well established. Algal biomass intended for beneficial or commercial purposes is grown in open raceway ponds, closed systems like photobioreactors and fermenters, harvested from seaweed farms, or obtained from natural standing stocks and potentially, with careful controls, harmful algal blooms. In 2018, the global market for algal products was estimated at \$3.98 billion and is projected to reach \$5.17 billion by 2023 based on trends in the food and beverage, dietary supplements, and personal care industries.² Federal agencies have a role in regulating the production and/or sale of these products, ensuring their safety.

Commodity-scale sale of algae for products such as biofuels and bioplastics has yet to be achieved due to the high cost of algal cultivation, harvesting, and logistics. Recoverable bioproducts are highly dependent on the composition of the algal biomass, which is dynamic and dependent on the algal strain, nutrient inputs, and the cultivation environment.³ Federal agencies such as the DOE, USDA, NOAA, and NSF are funding strategic R&D in



1.1 acre ponds growing Nannochloropsis at the Columbus, New Mexico algae farm run by Green Stream Farms for Qualitas Health. Photo by Rebecca White, Qualitas Health, Inc.

complementary areas to increase algal biomass productivity and product yield in economically and environmentally sustainable systems. A 2017 DOE national laboratory analysis estimates that the United States has the land and resources to sustainably and economically produce 104 to 235 million metric tons of algal biomass and 10 to 27 billion gasoline gallon equivalents of algal biofuels per year, assuming productivity and fuel yield targets are reached.⁴

- ² MarketsandMarkets, Algae Products Market by Type, Application, Source, Form and Region Global Forecast to 2023 (ReportLinker, April 2018), <u>https://www.reportlinker.com/p05385681/Algae-Products-Market-by-Type-Application-Source-Form-And-Region-Global-Forecast-to.</u> <u>httml</u>.
- ³ Lieve Laurens, Jennifer Markham, David Templeton, Earl Christensen, Stefanie Van Wychen, Eric Vadelius, Melodie Chen-Glasser et al., "Development of Algae Biorefinery Concepts for Biofuels and Bioproducts; A Perspective on Process-Compatible Products and their Impact on Cost-Reduction," *Energy & Environmental Science* 8, (2017): 1716–1738, <u>http://www.doi.org/10.1039/c7ee01306j</u>.
- ⁴ Ryan E. Davis, Jennifer N. Markham, Christopher M. Kinchin, Christina Canter, Jeongwoo Han, Qianfeng Li, Andre Coleman, Sue Jones, Mark Wigmosta, and Yunhua Zhu, 2017 Algae Harmonization Study: Evaluating the Potential for Future Algal Biofuel Costs, Sustainability, and Resource Assessment from Harmonized Modeling, Golden, CO: National Renewable Energy Laboratory, NREL/TP-5100-70715 https://www.nrel.gov/docs/fy18osti/70715.pdf.

2 Federal Summary Respondents

The R&D and/or regulatory oversight information for the *Federal Activities Report on the Bioeconomy: Algae* was provided by the AWG member offices listed in Table 1. This summary and Table 1 do not represent all the federal offices and activities relevant to algae. Appendix B contains a list of additional offices that may have scopes of work relevant to algae.

Table 1. Description of AWG Offices that Contributed to the Summary of Federal Algae Activities

U.S. DEPARTMENT OF AGRICULTURE Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS), Regulatory Oversight Plant Protection and Quarantine (PPQ), Veterinary Services Center for Veterinary Biologics (VS-CVB) BRS regulates the introduction (importation, interstate movement, or environmental release) of certain genetically engineered organisms. PPQ regulates the introduction (particularly importation) of plant material into the United States. VS-CVB requires licenses for any facilities manufacturing veterinary biologics. National Institute of Food and Agriculture (NIFA) R&D Administers federal funding to address the agricultural issues impacting people's daily lives and the nation's future. NIFA programs propel cutting-edge discoveries from research laboratories to farms, classrooms, communities, and back again. <u>Rural Development</u> (RD), Rural Business – Cooperative Service Energy Programs Rural Business - Cooperative Service's Biofuels, Renewables Chemicals and Biobased Products Program; R&D Rural Energy for America Program; BioPreferred Program; Value Added Producer Program; and Business and Industry Program promote economic development by helping to finance development of renewable energy systems and energy efficiency improvements for rural small businesses and agricultural producers and to mitigate the risk of new, innovative, first-of-a-kind technology projects. U.S. DEPARTMENT OF COMMERCE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION (NOAA) National Marine Fisheries Service (Fisheries), Office of Aquaculture 7&D Support and research, as well as design federal policymaking and regulation to grow sustainable aquaculture, including macroalgae, in the United States and reap its social, economic, and environmental benefits while supporting commercial and recreational fisheries. **Fisheries Science Centers** R&D Several of the six regional NOAA Fisheries Science Centers have research and facilities in support of the growth of marine aquaculture, including both macroalgae and microalgae. National Centers for Coastal Ocean Science (NCCOS) R&D Delivers ecosystem science solutions for stewardship of the nation's ocean and coastal resources to sustain thriving coastal communities and economies.

<u>Sea Grant</u> (SG) Invests in the development of sustainable marine and Great Lakes aquaculture to help coastal communities maintain a safe and sustainable local seafood supply thorough grants and an extension service. Sea Grant's investment in aquaculture focuses on research and technology transfer, often through one-on-one interactions with extension agents, to support and expand America's aquaculture industry.	R&D
U.S. DEPARTMENT OF ENERGY	
<u>Advanced Research Projects Agency – Energy</u> (ARPA-E) Advances high-potential, high-impact energy technologies that are too early for private-sector investment. Through funding, technical assistance, and market readiness, ARPA-E empowers America's energy researchers.	R&D
Office of Science (SC), <u>Basic Energy Sciences</u> (BES) Supports basic scientific research and scientific user facilities to understand, predict, and ultimately control matter and energy at the electronic, atomic, and molecular levels to provide the foundations for new energy technologies and advance DOE missions in energy, environment, and national security. BES research emphasizes discovery, design, and understanding of materials and new chemical, biochemical, and geological processes.	R&D
SC, <u>Biological and Environmental Research</u> (BER) Supports scientific research and facilities to achieve a predictive understanding of complex biological, earth, and environmental systems with the aim of advancing the nation's energy and infrastructure security.	R&D
<u>DOE Joint Genome Institute</u> (JGI) JGI is a DOE Office of Science National Genomics User Facility, operated by BER, supporting biological research, including algal research, by providing advanced capabilities in the areas of genomics, gene synthesis, metabolomics, and bioinformatics.	R&D
Office of Energy Efficiency & Renewable Energy (EERE), <u>Bioenergy Technologies Office</u> (BETO), Advanced Algal Systems (AAS) subprogram Supports early-stage applied research and development to lower the costs of producing algal biofuels and bioproducts.	R&D
<i>EERE, <u>BETO</u>, Advanced Development and Optimization (ADO) subprogram</i> Supports mid- to late-stage applied research and development to develop and test algae production technologies.	R&D
<i>EERE, Office of Environment, Health, Safety, and Security (EHSS)</i> Does not specifically regulate algal biomass and bioproducts, but all projects that receive funding from DOE do fall under the National Environmental Policy Act (NEPA) and undergo evaluation. The majority of EERE NEPA reviews relative to algae research and development tend to receive categorical exemptions from further review, as the research represents the lowest level of potential impacts.	Regulatory Oversight

Office of Fossil Energy (FE), Office of Clean Coal and Carbon Management FE is responsible for federal research, development, and demonstration efforts on advanced power generation; power plant efficiency; water management; and carbon capture, utilization, and storage (CCUS) technologies. The Office of Clean Coal and Carbon Management advances safe and cost effective capture, permanent geologic storage, and/or use of carbon dioxide (CO ₂).	R&D
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION	
Center for Veterinary Medicine (CVM), <u>Division of Animal Feeds</u> (DAF) Monitors and establishes standards for feed contaminants, approves safe food additives, and manages medicated feed and pet food programs.	Regulatory Oversight
<u>Center for Food Safety and Applied Nutrition</u> (CFSAN), Office of Food Additive Safety (OFAS) Approves and issues regulations for food and color additives, evaluates the safety of food ingredients, food packaging, and food processing equipment as well as foods derived from bioengineered plants. CFSAN OFAS has premarket review authority over the safe use of algal biomass and bioproducts as food ingredients, color additives, and food packaging materials.	Regulatory Oversight
U.S. ENVIRONMENTAL PROTECTION AGENCY	
Office of Pollution Prevention and Toxics (OPPT) Has the delegated authority to regulate chemical substances, including new microorganisms, to ensure that they do not present an unreasonable risk to human health or the environment under the intended conditions of use.	Regulatory Oversight
NATIONAL SCIENCE FOUNDATION	
The NSF is the only federal agency whose mission includes support for all fields of fundamental science and engineering. NSF does not hire researchers or directly operate laboratories or similar facilities. Instead, NSF supports scientists, engineers, and educators directly through their own home institutions. Relevant directorates include <u>Biological Sciences</u> (BIO), <u>Engineering</u> (ENG), and <u>Geosciences</u> (GEO).	R&D

3 Federal Investment in Algae R&D

R&D investment in algae contributes to a greater understanding of algae physiology and ecology in nature, leading to sustainable and affordable production and the use of algae to make bioproducts and biofuels. In addition, federal R&D funds also support the delivery of services performed by algae-like water remediation and carbon dioxide utilization. The AWG relies on an understanding of how different members are investing in algae R&D to coordinate distinct and complementary research programs, and to contribute to realizing the mission of the Bioeconomy Initiative. A general overview of federal R&D investment also helps companies, universities, and research institutions more effectively identify which federal offices are best suited to support them.



Through the funding of ARPA-E's MARINER research portfolio, a drone tug being launched at Woods Hole Oceanographic Institution in the summer of 2018. Photo by Clifford A. Goudey, C.A. Goudey & Associates.

3.1 Spectrum of R&D Investment

Federally funded R&D activities were categorized into basic, applied, process performance, and analysis R&D and further broken down by algae-relevant topic areas. The range of investments spans from fundamental R&D of microbiomes and intracellular processes to applied research that informs the siting and standards for algae biomass production (i.e., the cultivation, harvesting, and preprocessing of algal biomass before conversion to bioproducts).

Fundamental biology research was binned into extracellular and intracellular categories. Extracellular fundamental biology describes basic science that investigates ecological phenomena outside the cell, such as the study of the algae microbiome (sometimes described as the phycosphere or cultivation microbiome). Intracellular fundamental biology includes research on processes within the cell-like the structure of light harvesting complexes in photosynthesis. Applied R&D categories include crop development, cultivation system development, and product



A Los Alamos National Laboratory researcher prepares an algae growth experiment. Photo by the U.S. Department of Energy.

development. Crop development aims to improve the productivity, robustness, and biochemical quality/value of algae, while cultivation system development improves how efficiently the algae are grown. Downstream processing and product development optimize the harvesting and storage of biomass, the conversion of biomass to products, and the validation of algae-production technology through verified proof of performance in engineering-scale systems and relevant environments. Process performance R&D emphasizes integrated system research in relevant testing environments to reduce technology uncertainty and enable subsequent industry-led scale-up activities. The scale of R&D is dependent on the maturity of the technology and ranges from partially integrated equipment to pilot-scale facilities and first-of-a-kind commercial plants.

Analysis R&D evaluates potential locations for biomass cultivation and environmental resources like solar insolation and irrigation required to enable algae farming, which is economically, environmentally, and socially sustainable.

While many of the potential bioeconomy benefits of microalgae and macroalgae are the same, the differences between the cultivation, harvesting, and processing of macroalgae versus microalgae are significant. For example, microalgae are typically cultivated in constructed open-pond or photobioreactor facilities on land, whereas macroalgae production is typically marine-based. Some federal agencies choose to have distinct programs to address the differences in microalgae and macroalgae R&D strategies.

Multiple algal R&D efforts across the supply chain are needed to understand how algal biology, cultivation, harvesting, preprocessing, and conversion can result in a profitable and sustainable industry that supports the bioeconomy. The AWG works to coordinate this R&D and communicate results to stakeholders. Table 2A summarizes the R&D areas of work within the scope of AWG member offices, and Table 2B delineates these efforts between microalgae and macroalgae.



Table 2A. Spectrum of Federal R&D Investment in Algae by Type of R&D Support

Key: Binary qualitative depiction of algae R&D emphasis by agency.



means greater area of R&D support

means smaller area of R&D support



Table 2B. Spectrum of Federal R&D Support in Algae by Type of Algae

Key: Microalgae

Macroalgae



Algae grown on a runway at the Bio Century Research farm in Des Moines, Iowa. Photo by Dennis Schroeder, NREL.



Checking the longline of 6 month old sugar kelp. Photo by Charles Yarish, University of Connecticut.

3.2 Funding Opportunities

AWG member offices support algae R&D through a variety of funding mechanisms. For the purposes of this summary, the AWG categorized support as either intramural or extramural funding opportunities, which are explained in more detail in the following sections.

Intramural:

Intramural research programs support scientists internal to their respective agencies or who have collaborative agreements with those agencies. In general, agencies have intramural research programs to develop and maintain core R&D competencies for the nation. While intramural programs are designed for internal scientists, collaboration with industry and universities is encouraged.

NOAA Fisheries and multiple offices from the DOE reported having intramural research programs. Fisheries provides funding to investigators at <u>Fisheries Science Centers</u> through a yearly Internal Call for Funding (ICAF). DOE offices support intramural and contractual research at <u>National Laboratories</u>. One vehicle for scientists to work with DOE National Laboratory scientists is to apply for <u>Technology Commercialization Funds</u>, which match private partners with intramural funds to promote promising energy technologies for commercial purposes. National Lab scientists and engineers are also encouraged to participate in the <u>Energy I-Corps</u> program, where they are empowered with the tools, resources, and relationships necessary to discover potential market pathways for their innovations.

Extramural:

Extramural programs support R&D activities at companies, institutions, and universities regardless of affiliation to the funding office. The frequency of announcing an extramural funding opportunity, applicant requirements, and the specifics of the request for funding vary by AWG office. BETO, SC BER, SC BES, NIFA, RD, Fisheries, Sea Grant, and NSF typically offer extramural funding opportunities on an annual basis. Other offices, such as ARPA-E, provide funding opportunities that are not on a set timetable. JGI does not offer funding, but does provide



A hole being punched in the meristematic region of the sugar kelp (hole is 10 cm from the junction of the stipe). Photo by Charles Yarish, University of Connecticut.

free user access to large-scale DNA sequencing, synthesis, and complimentary omics capabilities annually or semiannually through the <u>Community Science Program</u>. The federal government encourages and enables U.S. companies to engage in R&D through <u>Small</u> <u>Business Innovation Research</u> (SBIR) and <u>Small Business</u> <u>Technology Transfer</u> (STTR) programs. Table 3 details the AWG offices that participate in SBIR and STTR programs.



NREL researchers examine a bio-based non-isocyanate polyurethane (NIPU) resin in the Biofuel Research Lab at NREL. Photo by Dennis Schroeder, NREL.



Biodegradation of algae-based polyurethane foams in soil (top) and home compost (bottom) over 12 weeks. These foams can make biodegradable shoes and flip flops. Photo by Natasha Gunawan, University of California San Diego.



Test tubes that hold a selection of lipids extracted from several algal strains. Photo by Dennis Schroeder, NREL.

Table 3. AWG-Reported Participation in SBIR/STTR Programs

FEDERAL AGENCY	OFFICE	SBIR/STTR	ALGAE ELIGIBLE
	ARPA-E	\checkmark	\checkmark
	BETO	\checkmark	\checkmark
DOE	FE	\checkmark	\checkmark
DUE	JGI	×	N/A
	SC BER	\checkmark	×
	SC BES		×
ΝΟΑΑ	Fisheries		\checkmark
NUAA	Sea Grant		\checkmark
NSF	ENG		\checkmark
	NIFA		\checkmark
USDA	RD	×	N/A

Key: 🗸 Yes

No N/A Not applicable

4 Federal Regulatory Oversight of Algae

The AWG shares information among its members on regulatory oversight of the production, use, and application of algal biomass and bioproducts. By understanding federal oversight, the AWG can better direct R&D funding and support recommendations on how to facilitate the development of the algae industry. A comprehensive view of the oversight authority of member offices allows federal agencies to consult more effectively on expertise. This overview also helps stakeholders understand which offices to contact for certain activities and the basis of their regulatory authority.

Regulatory oversight is summarized in two sections: (1) oversight for uses and application of algae and (2) oversight for the production of algae. In many cases, AWG members indicated that the use and application of the biomass principally determines whether an office has federal oversight authority. This means that, in general, if an office has oversight over the use and/or application of the biomass, then it most likely has oversight over the production of the biomass. There are also Regulatory Offices, like APHIS BRS and PPQ, which do not regulate on the intended use. Instead, these offices regulate based on whether the movement of the algae will directly or indirectly lead to the dissemination of plant pests or noxious weeds.

4.1 Oversight for Uses and Applications of Algae

The AWG outlined five broad categories for the use and/or application of algal biomass: food and health, chemicals and materials, energy, services, and indirect uses. Specific uses and applications of biomass are defined within each category. The AWG regulatory oversight areas as listed in Tables 4-8 below encompass both the use and application of whole algal biomass or a component of algal biomass and attempt to cover all scenarios in which the specific use and application may be relevant. For example, HHS would have purview over "plastics, polymers, resins and lubricants" if they are used



Nannochloropsis paste from a harvest at the Columbus, New Mexico algae farm run by Green Stream Farms for Qualitas Health. Photo by Rebecca White, Qualitas Health, Inc.



An NREL scientist homogenizing biomass in the Compositional Analysis Lab in the Field Test Laboratory Building at NREL. Photo by Dennis Schroeder, NREL.

in an animal food, in or on (e.g., as a component of food packaging) foods intended for consumption by humans, or in a medical product. However, EPA would have purview over the production of plastics, polymers, resins,

and lubricants for industrial or consumer uses. "Human medical applications" describes use for anticoagulants, sterilizing agents, iodine, and laxatives. "Veterinary medical drugs" includes the use for growth promotants, production claims, alternatives to antimicrobial agents, immune modulation, and environmental abatement claims. Animal food for aquaculture feed pertains to finfish and crustaceans. Color additives includes the use for human or animal food, drugs, and human cosmetics. For further details on each category of application and use as well as regulatory authority citations, see Appendix C.

USES AND APPLICATIONS OF ALGAL BIOMASS FOR FOOD AND HEALTH	EPA OPPT	HHS FDA CVM	HHS FDA CFSAN	USDA APHIS
Whole algal biomass for human food	×	×	 ✓ 	×
Component of algal biomass as human food ingredient or additive	×	×	 ✓ 	×
Human dietary supplements	×	×	b	×
Human medical application	×	×	×	×
Veterinary medical drug	×		×	¢
Veterinary medical device	×		×	×
Animal food for livestock and poultry	×		×	×
Animal food for pet food	×		×	×
Animal food for aquaculture feed	×		×	×
Color additives	×	a		×

Table 4. Regulatory Oversight for the Use and Application of Algal Biomass for Food and Health

Key: 🗸 Yes 🗴 No

^a The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for evaluating and approving color additives for all FDA-regulated products. When a color additive is intended for use in an animal food or new animal drug, CFSAN will consult with Center for Veterinary Medicine (CVM).

^b Dietary supplements and dietary ingredients used in dietary supplements are under the purview of CFSAN's Office of Dietary Supplement Programs. CFSAN-OFAS does not have oversight for dietary supplements or dietary ingredients used in dietary supplements.

^c APHIS VS-CVB ensures that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective. See Appendix A Section USDA VS CVB and https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics.



Demonstration testing of direct flue gas injection into a filamentous algae open system operated by the Orlando Utilities Commission at the Stanton Energy Center and MicroBio Engineering Inc. Photo by MicroBio Engineering Inc.

Table 5. Regulatory Overs	sight for the Use and Application	n of Algal Biomass for Ch	emicals and Materials

USES AND APPLICATIONS OF ALGAL BIOMASS FOR CHEMICALS AND MATERIALS	EPA OPPT	HHS FDA CVM	HHS FDA CFSAN	USDA APHIS
Plastics, polymers, resins, and lubricants		a	d	×
Cosmetics and personal well-being products	×	a,b	e	×
Industrial colorants, dyes, and inks		a,c	d	×
Building or construction material		×	×	×
Biomedical polymers	×	a,f	×	×
Other chemicals		a,f	d	×
Biomedical polymers	Image: Control of the second	a,f	× ×	

^a Only if the material will be added directly to an animal food, or if any algae byproduct derived from its manufacture is diverted for use as an animal food or food ingredient.

🗸 Yes 🗴 No

^b Cosmetic-like and similar products for animals are called grooming aids.

- ^c CFSAN is responsible for evaluating and approving all color additives. When a color additive is intended for use in an animal food or new animal drug, CFSAN will consult with CVM.
- ^d Only if the material will be used in or on (e.g., as a component of food packaging) foods intended for consumption by humans.

Key:

^e Cosmetics and ingredients used in cosmetics are under the purview of CFSAN's Office of Cosmetics and Colors. CFSAN OFAS oversees the review process for color additives used in cosmetics; however, CFSAN OFAS does not have oversight for other ingredients used in cosmetics.

^f If intended to be used as a veterinary medical device or as a new animal drug.

USES AND APPLICATIONS OF ALGAL BIOMASS FOR ENERGY	EPA OPPT	HHS FDA CVM DAF	HHS FDA CFSAN	USDA APHIS	
Biofuel	\checkmark	a	×	×	
Biopower	 ✓ 	a	×	×	
Refining of biocrude into biofuel	\checkmark	a	×	×	
Blending of biofuels with fossil feedstocks		×	×	×	
Key: 🗸 Yes 🛞 No					

Table 6. Regulatory Oversight for the Use and Application of Algal Biomass for Energy

^a Only if the algae biomass itself or any fermentation substrate used therein will be added directly to an animal food.

Table 7. Regulatory Oversight for the Use and Application of Algal Biomass for Services

USES AND APPLICATIONS OF ALGAL BIOMASS FOR SERVICES	EPA OPPT	HHS FDA CVM DAF	HHS FDA CFSAN OFAS	USDA APHIS
Wastewater treatment		a	×	×
Impaired water remediation		a	×	v b
Utilization of gaseous industrial emissions	\checkmark	e	×	×
Utilization of gaseous power plant emissions		e	×	×
Soil amendment (biofertilizer) and reclamation		v a	×	×
Deacidification		×	×	×
Restoration of ecosystem services		a	×	C
Restoration of ecosystem services		a	×	¢

Key: 🗸 Yes 🗴 No

^a Only if the spent algae biomass or remediated substrate will be used in animal food, including grazing land application.

^b Only if the water remediation resulted from noncompliance of a permit condition for a regulated organism.

^c Only if the restoration resulted from noncompliance of a permit condition for a regulated organism.

INDIRECT USES AND APPLICATIONS OF ALGAL BIOMASS	EPA OPPT	HHS FDA CVM DAF	HHS FDA CFSAN OFAS	USDA APHIS	
Transport/sale of biomass	-	a	a	b	
Transport/sale of bioproducts		×	√ ^a	b	
Key: 🗸 Yes 🔅 No					

Table 8. Regulatory Oversight for the Indirect Use and Application of Algal Biomass

^a Only if the material being transported will be used in or on (e.g. as a component of food packaging) foods intended for consumption by humans.

 $^{\rm b}\,$ Only if the biomass contains live organisms regulated by APHIS.

4.2 Oversight of the Production of Algae

Oversight for algae production is guided by how the algae is grown, transported, and disposed of. Installation of cultivation systems includes the installation of open raceway ponds, photobioreactors, and marine cultivation systems. The cultivation resources and nutrients described in "Delivery and application of cultivation resources and nutrients" in Table 9 are water, CO_2 , nitrogen, phosphorous, and trace metals. "Environmental release of cultivation resources, nutrients and/or biomass or bioproducts" includes intentional and/or unintentional release. Table 9 details the AWG offices with regulatory oversight over the cultivation microalgal (eukaryotic microalgae and cyanobacteria) and macroalgal biomass. However, EPA has not evaluated whether its delegated authority under TSCA extends to macroalgae.



Attendees of the Future of Algae for Food and Feed Global Initiative's Summit enjoy a lunch where all the dishes, from salad vinaigrettes to pasta sauces and salsas, include algae as an ingredient. Photo by Josh Lake for Alexandria.

Table 9. Regulatory Oversight for the Production of Algal Biomass

PROCESSES FOR THE CULTIVATION OF ALGAL BIOMASS	DOC NOAA FISHERIES	EPA OPPT	HHS FDA CVM DAF	HHS FDA CFSAN	USDA APHIS
Site selection of cultivation area	Consults with U.S. Army Corps of Engineers (ACOE)	×	×	×	ď
Installation of cultivation systems	Consults with ACOE	×	×	×	×
Delivery and application of cultivation resources and nutrients	Consults with ACOE	×	⊘ ^a	√ ^b	×
Growth of algal biomass	Consults with ACOE		a	√ ^b	e
Harvesting of algal biomass	Consults with ACOE		a	√ ^b	f
Transport/sale of biomass	x		e	v b	e
Recycling of cultivation resources and nutrients	×	×	a	×	×
Environmental release of cultivation resources, nutrients, and/or biomass or bioproducts	Consults with ACOE	Ø	a,c	¢°	✓ ^h
Disposal of cultivation resources, nutrients, and/ or biomass or bioproducts	×		e	×	h
Key: 🗸 Yes 🔅 No					

^a Only if the material will be added directly or indirectly to an animal food, including access by grazing animals.

^b Only if the material will be used in or on (e.g., as a component of food packaging) foods intended for consumption by humans.

^c FDA assesses the environmental impact of its regulatory actions (i.e., approval of a food additive, color additive, or allowing a food contact substance notification to become effective).

^d Oregon Endangered Species Act considerations. The site cannot be a critical habitat if the organism is regulated by APHIS.

^e If the organism is regulated by APHIS under the Plant Protection Act, there may be permit conditions for the growth of the algal biomass.

^f If the organism is regulated by APHIS under the Plant Protection Act, there may be permit conditions that specify how the algal biomass is harvested.

^g If the biomass contains live organism and is regulated under the Plant Protection Act.

^h If the organism is regulated under the Plant Protection Act, must be confined, and there is a possibility the organism would be release by the activity.

5 External Engagement

The *Bioeconomy Initiative: Implementation Framework* recognizes that realizing a successful bioeconomy relies on collaboration and communication among a strong network of informed public and private partners. To facilitate information sharing, the AWG has documented general opportunities for the public to engage with member offices.

AWG members engage with external stakeholders using a variety of approaches. Broad public engagement opportunities include conferences, workshops, meetings, notice and comment on the proposed rulemaking, and requests for information. These opportunities are often advertised on AWG member offices' websites. The Biotechnology Regulatory Service of APHIS hosts an annual stakeholder meeting and publishes a monthly stakeholder notice.⁵ Fisheries,⁶ BETO,⁷ JGI,⁸ and NIFA have newsletters that also broadcast this information. <u>NIFA Listens</u> began in 2017 and NIFA anticipates holding similar input sessions on a regular basis in the future. Offices will also engage with stakeholders via site visits or direct communication to submitters when it is necessary to obtain specific—sometimes commercially private—information.



Attendees of the Future of Algae for Food and Feed Global Initiative's Summit networking. Photo by Josh Lake for Alexandria.

- ⁵ APHIS Biotechnology Regulatory Service Meetings: <u>https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/meetings/ct_meetings_archive</u>.
- ⁶ Link to register NOAA Fisheries email updates: <u>https://public.govdelivery.com/accounts/USNOAAFISHERIES/subscriber/new?topic_id=USNOAAFISHERIES_2</u>.
- ⁷ Link to register for BETO email updates: <u>https://public.govdelivery.com/accounts/USEERE/subscriber/new?topic_id=USEERE_145</u>.
- ⁸ Link to register for JGI updates: <u>https://jgi.doe.gov/contact-us/</u>.

5.1 Conferences

AWG members participate in conferences and workshops to learn about and advance the algae industry. Stakeholders are encouraged to network with AWG members at these events. Even when federal officials are not present, attendees can learn about member offices by connecting with researchers who are presenting on federally funded projects.

Recent conferences that AWG member offices have participated in or that typically have many researchers funded by AWG member offices are:

- Advanced Bioeconomy Leadership Conference
- Algae Biomass Summit
- Algae for Food and Feed
- Annual Meeting of the Phycological Society of America
- Aquaculture America
- BIO World Congress
- European Phycological Congress
- Gordon Research Conferences
- International Conference on Algal Biomass, Biofuels, and Bioproducts

- International Genetically Engineered Machine Competition
- International Seaweed Symposium
- JGI Annual User Meeting
- Society for Industrial Microbiology and Biotechnology
- Seagriculture
- Symposium on Biotechnology for Fuels and Chemicals
- Western Photosynthesis Conference
- World Aquaculture

5.2 Workshops

Most AWG member offices will organize workshops to seek guidance from the public on a narrow topic. For example, in 2017 BETO hosted a workshop titled <u>Algae Cultivation for Carbon Capture and Utilization</u>. OPPT held two workshops in 2015 and 2016. These workshops were titled: <u>EPA Workshop for Public Input on Considerations for Risk Assessment of Genetically Engineered Algae</u> and <u>Public Meeting and Opportunity for Public Comment on</u> <u>EPA's Draft Algae Guidance for the Preparation of TSCA Biotechnology Submissions</u>. In general, ARPA-E Funding Opportunity Announcement (FOA) programs are preceded by a stakeholder workshop; for example, ARPA-E had a <u>macroalgae workshop</u> before releasing the Macroalgae Research Inspiring Novel Energy Resources (MARINER) program FOA. In DOE's Office of Science, BER and BES hold workshops focused on fundamental science with relevance to their missions.⁹ JGI organized roundtables with algae researchers in 2018 and 2019. Future algal workshops may be held in conjunction with JGI User Meetings. NOAA's National Sea Grant Seaweed Hub hosted a National Sea Grant Seaweed Symposium March 2–4, 2020 in Providence, Rhode Island. The seaweed hub is a multi-state collaboration to share information, better understand challenges and learn about opportunities within the domestic seaweed industry.

⁹ BER and BES workshop reports are available online at: <u>https://science.osti.gov/ber/Community-Resources</u> and <u>https://science.osti.gov/bes/Community-Resources</u>, respectively.



The Interagency Working Group on Algae presents on the Biomass R&D Board's Bioeconomy Initiative and the group's activities at the 2019 Algae Biomass Summit. Photo by the Bioenergy Technologies Office.

5.3 Program Reviews

AWG member offices host public reviews of their research programs. Attending a program review can be an excellent opportunity for someone to obtain a detailed and comprehensive overview of a federal program, as well as provide expert input on federally supported projects and programs. The frequency of the review is dependent on the office and the size of the program. Generally, offices will publish reports on program reviews.

The NOAA Fisheries¹⁰ program rotates review of their science programs, with one formal science review of projects in a program about every five years. The next formal review relevant to algae is to be scheduled after 2021. BETO holds a <u>peer review</u> of all projects every two years, with the most recent one held in March 2019. FE holds an annual <u>CCUS program review</u> meeting, which is usually held in August in Pittsburgh, Pennsylvania. ARPA-E programs may have annual meetings. ARPA-E organizes <u>annual meetings</u> for the MARINER program to share and review progress made in the various projects with awardees and the public. The most recent MARINER meeting was in January 2020. BES and BER conduct peer review of all research projects. Each research division in BES organizes Principal Investigator meetings to present and discuss recent research, evaluate opportunities for inter-project collaboration, exchange scientific ideas among the researchers, and provide program management the opportunity to assess overall balance across the portfolio and evaluate future research. BER also holds an annual Principal Investigators meeting to discuss research successes and challenges in an environment that encourages research collaborations among attendees.

¹⁰ NOAA Fisheries, "NOAA Fisheries Science Program Review," Last modified October 22, 2018, <u>https://www.fisheries.noaa.gov/national/about-us/noaa-fisheries-science-program-review.</u>

6 Conclusion

The Bioeconomy Initiative's vision is a vibrant U.S. bioeconomy that enhances economic growth, energy security, and environmental quality by maximizing the sustainable use of the nation's domestic biomass resources for affordable biofuels, bioproducts, and biopower. As one of the Biomass R&D Board's interagency working group contributing to the Bioeconomy Initiative, the Algae Interagency Working Group communicates and coordinates federal research, development, and demonstration activities relating to algae, as well as algae production for biobased fuels and products, all in a sustainable manner and within an appropriate regulatory framework. Successfully achieving the Bioeconomy Initiative's vision will rely in part on a strong network of informed public and private partners. The *Federal Activities Report on the Bioeconomy: Algae* is one step by the AWG to build this strong network.



Sunset over a 1.1 acre pond at the Columbus, New Mexico algae farm run by Green Stream Farms for Qualitas Health. Photo by Rebecca White, Qualitas Health, Inc.

Appendix A: Office Summary of Regulatory Oversight Authority

A.1 Member Offices Involved in Federal Oversight

Below is a summary of the regulatory oversight functions of the Algae Interagency Working Group (AWG) member offices and the basis of regulatory authority.

EPA, Office of Pollution Prevention and Toxics (OPPT):

Under the Toxic Substances Control Act (TSCA) and the regulations supporting its implementation,¹¹ the U.S. Environmental Protection Agency (EPA) currently requires reporting of "new" microorganisms¹² that are manufactured, processed, or distributed in commerce. Examples of TSCA applications include biomass conversion, chemical production, bioremediation, biofertilizers, and other applications not specifically excluded from TSCA oversight. Excluded uses include food, food additives, cosmetics, drugs, pesticides (but not pesticide intermediates), medical devices, tobacco, nuclear materials, and firearms. OPPT's oversight authority under these rules is contingent on the use being for commercial purposes, which includes research and development (R&D) with the intent to commercialize for a use subject to TSCA oversight.

FDA, CVM:

The Center for Veterinary Medicine (CVM) has oversight under the Food Drug and Cosmetic Act, Food Safety Modernization Act, and 21 Code of Federal Regulations (CFR) if those products, in whole or part, are (1) intended for use in animal food (all animal species), (2) used to create color additives for food,¹³ or (3) used as a component to cure, treat, or prevent an animal disease, or used as a component of a veterinary medical device.

Any application or use of algae (in whole or part) in an animal food, veterinary medical device, or drug product, regardless of its source or intended use, falls under their jurisdiction. This covers veterinary medical drugs and use of whole algae biomass or its components in animal food for livestock, poultry, pet food, and aquaculture feed, color additives in animal food, and veterinary medical devices.¹³ There is also oversight for any industrial chemicals or biofuel production that have products or byproducts that are used in animal food or drugs.

FDA, CFSAN, OFAS:

The Center for Food Safety and Applied Nutrition (CFSAN)/Office of Food Additive Safety (OFAS) administers various regulatory programs (food additive and color additive petition, "generally recognized as safe" notification, and food contact substance notification) to assess the safety of human food ingredients and food contact substances.¹⁴ CFSAN/OFAS has oversight under the Federal Food, Drug, and Cosmetic Act (FFDCA) to evaluate

 $^{^{\}rm 11}$ 40 CFR Parts 700, 720, 721, 723, and 725.

¹² A "new" microorganism is an "intergeneric microorganism," which is a microorganism formed by the deliberate combination of genetic material originally isolated from organisms of different taxonomic genera, and one that is not on the TSCA Chemical Substance Inventory.

¹³ The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for evaluating and approving all color additives. When a color additive is intended for use in an animal food or new animal drug, CFSAN will consult with CVM.

¹⁴ The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for evaluating and approving all color additives. When a color additive is intended for use in an animal food or new animal drug, CFSAN will consult with CVM.

safety and regulate substances added to food. The FFDCA defines a food additive as "any substance the intended use of which results or may reasonably be expected to result—directly or indirectly—in its becoming a component or otherwise affecting the characteristics of any food." This definition includes any substance used in the production, processing, treatment, packaging, transportation, or storage of food. The legal definition for a "food additive" imposes a premarket approval requirement. This definition excludes ingredients with uses that are generally recognized as safe, those ingredients approved for use by the Food and Drug Administration (FDA) or the U.S. Department of Agriculture (USDA) prior to the food additives provisions of law, and color additives and pesticides where other legal premarket approval requirements apply.

USDA, APHIS, BRS:

The Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) authority is derived from the Plant Protection Act. Authority is for the interstate movement, importation, and environmental release of genetically engineered organisms that meet the definition of a plant pest. Most genetically engineered algae would not meet the definition of a plant pest and would not be regulated by USDA APHIS.

USDA, APHIS, PPQ:

APHIS Plant Protection and Quarantine (PPQ) authority is also derived from the Plant Protection Act. They require permits for the importation of algae into the Unites States and phytosanitary certificates that attest that the sample is free of pests. If the algae are on a federal invasive weed list, a risk assessment will be completed prior to issuing the permit and conditions will be imposed on the use of that algae in the Unites States should a permit be granted.

USDA, APHIS, VS-CVB:

APHIS Veterinary Services Center for Veterinary Biologics (VS-CVB) authority is derived from the Virus-Serum-Toxin Act. CVB licenses all facilities that produce Veterinary Biologics to ensure that such materials are safe for use in animals.

DOC, NOAA, Fisheries:

NOAA Fisheries and the Regional Fishery Management Councils have direct regulatory authority, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (MSA), to manage the harvest of wild macroalgae, or more specifically "all other forms of marine animal and plant life." This authority could be extended to the farming of algae if a Council found the need to do so using its management authority. Additionally, NOAA Fisheries or the Fishery Management Councils may consult on seaweed cultivation projects if it affects either Essential Fish Habitat under the MSA or could affect protected marine species pursuant to the Endangered Species Act or Marine Mammal Protection Act. In the case of macroalgae systems anchored in the ocean, NOAA Fisheries typically consults with the U.S. Army Corps of Engineers, who issues the permit under their authority provided by the Rivers and Harbors Act.

Appendix B: Other Federal Offices That Could Have a Federal Role as It Relates to Algae

B.1 Other Federal Offices That Could Have a Federal Role as It Relates to the Intentional Beneficial Use of Algae

The federal offices listed in Table B.1 and B.2. may perform research or regulate algae in a beneficial capacity.

Table B.1. Other Federal Offices that could have a federal role as it relates to algae

U.S. DEPARTMENT OF COMMERCE				
<u>The National Institute of Standards and Technology, Technology Partnerships Office</u> Fosters preeminent science and technological innovation through federal investments in research and development, partnerships, or licensing opportunities at the National Oceanic and Atmospheric Administration.	R&D			
U.S. DEPARTMENT OF ENERGY				
Office of Energy Efficiency and Renewable Energy, <u>Hydrogen and Fuel Cell Technologies Office</u> Focuses on applied research, development, and innovation to advance hydrogen and fuel cells for transportation and diverse applications enabling energy security, resiliency, and a strong domestic economy in emerging technologies.	R&D			
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION				
<u>Center for Veterinary Medicine, Office of Surveillance and Compliance</u> Has oversight over pre- and post-market animal feed.	Regulatory Oversight			
<u>Center for Veterinary Medicine, Office of New Animal Drug Evaluation</u> Evaluates all materials intended to treat, mitigate, or prevent disease or enhance animal productivity.	Regulatory Oversight			
Association of Animal Feed Control Officials A body of state and federal regulators that work with the U.S. Food and Drug Administration in the evaluation of new ingredient definitions that are acceptable for use in animal foods (within the limitations set forth by the Association of Animal Feed Control Officials).	Regulatory Oversight			

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Water, Office of Wastewater Management (OWM)

To support the Clean Water Act, the OWM promotes effective and responsible water use, wastewater treatment, disposal and management as well as encourages the protection and restoration of watersheds. OWM provides regulatory standards, voluntary management approaches, and financial and technical assistance to states, tribes, communities, and regulated entities to protect human health and aquatic ecosystems, reduce flooding, and protect the nation's infrastructure investment.

U.S. UNITED STATES DEPARTMENT OF AGRICULTURE

Agricultural Research Service (ARS)

Develops and transfers solutions to agricultural problems of high national priority and provides information access and dissemination to sustain a competitive agricultural economy.

B.2 Other Interagency Working Groups That Coordinate with the Algae Interagency Working Group

Table B.2. Other Interagency Working Groups with Missions Relevant to Algae

SUBCOMMITTEE ON AQUACULTURE (SCA)

Interagency Working Group on Aquaculture (now SCA)

The SCA serves as the federal interagency coordinating group to increase the overall effectiveness and productivity of federal aquaculture research, regulation, technology transfer, and assistance programs. Among other things, the SCA has interest in macro- and microalgae as both aquaculture feed ingredients and algae as a product in its own right. Some members of the AWG also participate in the SCA.

Regulatory Oversight & R&D

R&D

INTERAGENCY WORKING GROUP ON HARMFUL ALGAL BLOOM AND HYPOXIA RESEARCH AND CONTROL ACT

Harmful algal blooms and hypoxic events (severe oxygen depletion) are some of the most scientifically complex and economically damaging coastal issues challenging our ability to safeguard the health of our nation's coastal ecosystems. Almost every state in the U.S. now experiences some kind of harmful algal bloom event and the number of hypoxic water bodies in the U.S. has increased 30-fold since the 1960s, with over 300 coastal systems now impacted.

In 1998, Congress recognized the severity of these threats and authorized the Harmful Algal Bloom and Hypoxia Research and Control Act (<u>HABHRCA 1998; embedded in Public Law 105-383</u>), which was reauthorized in 2004, 2014, and 2017 (<u>HABHRCA 2004, Public Law 108–456</u>; <u>HABHRCA 2014, Public Law 113–124</u>; <u>HABHRCA 2017, Public Law 115-423</u>). HABHRCA mandates that NOAA (coastal and Great Lakes) and EPA (inland freshwater and Great Lakes) advance the scientific understanding and ability to detect, monitor, assess, and predict harmful algal bloom and hypoxia events and develop methods of prevention, control, and mitigation.

HABHRCA also required a Task Force, now known as the Interagency Working Group on the Harmful Algal Bloom and Hypoxia Research and Control Act (<u>IWG-HABHRCA</u>), which is tasked with coordinating and convening federal agencies and their stakeholders to discuss harmful algal bloom and hypoxia events in the United States and to develop action plans and assessments of these situations. The IWG-HABHRCA is co-chaired by representatives from NOAA (Department of Commerce), the U.S. EPA, and the Office of Science and Technology Policy. Additionally, it is composed of the follow member agencies and departments:

- Centers for Disease Control and Prevention, Food and Drug Administration (FDA), and the National Institute of Environmental Health Services of the Department of Health and Human Services
- United States Army Corps of Engineers and the Department of the Navy, of the Department of Defense
- United States Geological Survey, the National Park Service, and the Fish and Wildlife Service of the Department of the Interior
- National Aeronautics and Space Administration
- National Institute of Food and Agriculture (NIFA), Natural Resources Conservation Service, and the Agricultural Research Service (ARS) of the United States Department of Agriculture (USDA)
- State Department
- National Science Foundation (NSF)

The IWG-HABHRCA is concerned with preventing and mitigating the deleterious impacts of algae, whereas the AWG is tasked with promoting their beneficial uses. Communication between the working groups would be helpful because of overlap in member agencies and common interests such as the ability of algae to remove nutrients or harvesting algae, either to obtain beneficial compounds or remove harmful ones.

WORKING GROUPS OF THE BIOMASS R&D BOARD

In 2008 the Biomass Research and Development (BR&D) Board charged several <u>interagency working groups</u> to enhance information sharing and program coordination for specific components of the biofuel supply chain to fulfill its mission. These groups implement annual work plans, as part of the Bioeconomy Initiative, to expand the sustainable use of the nation's abundant biomass resources for biofuels, bioproducts, and biopower. The vision of the Bioeconomy Initiative is a vibrant U.S. bioeconomy that enhances economic growth, energy security, and environmental quality by maximizing sustainable use of the nation's domestic biomass resources for affordable biofuels, bioproducts, and biopower.

The nine interagency working groups and their focuses are as follows: Advanced Aviation Fuels; Algae; Feedstock Genetic Improvement; Feedstock Logistics; Feedstock Production and Management; Conversion; Transportation, Distribution, and End Use; Analysis; and Sustainable Bioeconomy.

Appendix C: Detailed AWG Member Office Information on Regulatory Oversight Authority

C.1 Summary

This appendix details the regulatory authority over algal biomass and bioproducts. There are two tables that elaborate the regulatory oversight of the use, application, and production of algal biomass. Federal agency offices that are members of the Biomass Research and Development Board Algae Working Group in the regulatory authority appendix are:

- U.S. Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics (OPPT)
- U.S. Department of Health and Human Services (HHS), Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), Division of Animal Feeds
- HHS FDA, Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety (OFAS)
- U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Biotechnology Regulatory Services
- U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy (EERE), Office of Environment, Health, Safety, and Security (EHSS)

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C.2 EPA, Office of Pollution Prevention and Toxics (OPPT)

Description of regulatory authority over algal biomass and bioproducts:

OPPT, within EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), has the authority to regulate certain algal biomass and bioproducts. The Toxic Substances Control Act (TSCA),¹⁵ amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, provides EPA the authority to require reporting, recording keeping, and testing requirements and restrictions relating to chemical substances and/or mixtures (excluding, among other substances, food, drugs, cosmetics, and pesticides). EPA determined that the broad definition of "chemical substance" gives EPA authority to review microorganisms under TSCA for TSCA-covered uses.¹⁶

Under TSCA and the regulations supporting its implementation,¹⁷ EPA currently requires reporting of "new" microorganisms that are not manufactured, processed, or distributed in commerce for an excluded use. Microorganisms formed by the deliberate combination of genetic material originally from organisms classified in different taxonomic genera, including microorganisms constructed with synthetic genetic material that is not identical to DNA that would be derived from the same genus as the recipient microorganism, are considered "intergeneric" microorganisms. A new microorganism is one that is intergeneric and not listed on the TSCA Chemical Substance Inventory. Naturally occurring microorganisms are considered existing chemicals and are implicitly listed on the TSCA Chemical Substance Inventory. As such, they are subject to the same regulatory authority as other existing chemicals under TSCA. Intergeneric microorganisms that are not on the TSCA Chemical Substance Inventory and are used in TSCA applications are subject to pre-manufacture notice requirements under Section 5 of TSCA. Examples of TSCA applications include biomass conversion, chemical production, bioremediation, biofertilizers, and other applications not specifically excluded from TSCA oversight. Excluded uses include food, food additives, cosmetics, drugs, pesticides (but not pesticide intermediates), medical devices, tobacco, nuclear materials, and firearms. For new chemical substances, EPA has regulatory oversight over the manufacture, processing, distribution in commerce, use, or disposal of chemical substances (including microorganisms), or any combination of such activities, in order to evaluate whether the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations.¹⁸ This evaluation covers the proposed conditions of use described in the submissions received by EPA as well as other known and reasonably foreseen conditions of use. A Microbial Commercial Activity Notice (MCAN) is required when there is intent to commercialize an intergeneric microorganism. A TSCA Experimental Release Application (TERA) is required when there is intent for commercial research and development of an intergeneric microorganism in the environment (e.g., open ponds).¹⁹

¹⁵ U.S. EPA, "Summary of the Toxic Substances Control Act," accessed August 3, 2018, <u>https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act</u>.

¹⁶ "Applicability of the Toxic Substances Control Act (TSCA) to Microbial Products," Federal Register, June 26, 1986, 51 (123): 23324.

¹⁷ 40 CFR Parts 700, 720, 721, 723, and 725.

¹⁸ U.S. EPA, "Full Text of the Frank R. Lautenberg Chemical Safety for the 21st Century Act," June 22, 2016, <u>https://www.epa.gov/</u> assessing-and-managing-chemicals-under-tsca/full-text-frank-r-lautenberg-chemical-safety-21st.

¹⁹ U.S. EPA, "Filing a Biotechnology Submission under TSCA," <u>https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-biotechnology-submission-under-tsca-and-fifra/filing-tsca-and-fifra/filing-biotechnology-submission-unde</u>

Office's authority and/or rule contingent on the use for R&D and/or commercial purposes:

OPPT's oversight authority under this rule is contingent on the use being for commercial purposes, which includes R&D with the intent to commercialize for a use subject to TSCA oversight. For new microorganisms, the stage of development and commercial intent determine the appropriate type of notification, such as an MCAN or a TERA. Additionally, the regulations exempt certain R&D activities without requiring notification to EPA. MCANs are expected to only be submitted for intergeneric microorganisms intended for general commercial use. There are several types of R&D exemptions for microorganisms that exempt activities subject to the oversight of other federal programs or agencies (i.e., projects funded by another agency and conducted following relevant National Institutes of Health guidelines), activities conducted inside a structure, and activities conducted with certain microorganisms under certain conditions outside a structure. For microbes that are not eligible for the exemption for activities conducted outside a structure, EPA may allow release (e.g., growth of an intergeneric algae in an open pond) after review of a TERA, which can be submitted for any type of new microorganism. There are also non-R&D exemptions, including the Test Marketing Exemption and the general exemptions (Tier I and Tier II). Only certain microorganisms are eligible for the general exemptions, which do not include any algae.

Reporting requirements and information used to review TSCA biotechnology submissions are outlined in 40 C.F.R. 725 and in specific guidance documents, including the 1997 "*Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms*" (hereafter referred to as the *Biotech PtC*).²⁰ EPA is in the process of developing an "Algae Supplement" to the *PtC* which specifically addresses the information recommended to be included for algal submission.

Office's authority and/or use contingent on where the production of algal biomass and bioproducts occurs: EPA/OPPT's authority under the amended TSCA is not limited to places within the United States and its territories where the production of algal biomass and bioproducts occurs. Chemical substances, including algal biomass and bioproducts, that are imported into the United States are subject to the TSCA definition of "manufacture" and to TSCA oversight.

Office's rule or authority contingent on how the production of algal biomass and bioproducts occurs: EPA/OPPT's authority under the amended TSCA is not contingent on how the production of algal biomass and bioproducts occurs.

Office's rule or authority on the production of algal biomass and bioproducts contingent on the use of algal biomass and bioproducts:

EPA/OPPT's authority under TSCA is contingent on the use of algal biomass and bioproducts, as certain substances are specifically excluded from TSCA oversight, including substances manufactured, processed, or distributed in commerce for use as food and food additives, drugs, cosmetics, medical devices, pesticides (but not pesticide intermediates), tobacco, nuclear material, and firearms.²¹ Examples of uses within TSCA jurisdiction include biomass conversion, chemical production, microbial fuel cells, mining and resource extraction, building materials,

²⁰ U.S. EPA, "Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms," 1997.

²¹ U.S. EPA, "Summary of the Toxic Substances Control Act," accessed August 3, 2018, <u>https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act</u>.

waste remediation and pollution control, non-pesticidal agriculture applications such as bio-fertilizers, weather and climate modification, various consumer products, and all other applications of intergeneric microbial biotechnology products not otherwise excluded under TSCA. If a new intergeneric microorganism produces a new chemical (a chemical that is not listed on the TSCA Chemical Substance Inventory), the company may also need to submit a Pre-Manufacture Notice (PMN) for the chemical in addition to an MCAN for the intergeneric microorganism.

Office's rule or authority contingent on the organism being naturally occurring or genetically modified: Under TSCA, EPA/OPPT has authority over both naturally occurring and genetically modified microorganisms, so long as their use is not specifically excluded from TSCA. EPA/OPPT's reporting requirements are contingent on the organism being an intergeneric microorganism, without regard for the process used to create the organism. The necessity for agency review under Section 5 of TSCA is based on whether a microorganism is "new" or is subject to a significant new use rule (SNUR). Under the regulations in 40 CFR Part 725, a microorganism is considered to be "new" if it is not on the TSCA Chemical Substance Inventory, it is "intergeneric" (as described above), and used for TSCA purposes. Naturally occurring microorganisms are considered to be implicitly listed on the TSCA Chemical Substance Inventory, and therefore are not considered to be "new."

Description of interagency frameworks or Memoranda of Understanding (MOUs) relevant to the Office that pertain to regulatory oversight of algae:

There is no MOU in place that directly pertains to the regulatory oversight of algae. However, as outlined in *Modernizing the Regulatory System for Biotechnology Products: An Update to the Coordinated Framework for the Regulation of Biotechnology*, published in 2017,²² agencies with regulatory oversight do collaborate on products with overlapping jurisdictions. Current interagency working groups ensure continuous communication and collaboration between regulating agencies.

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Food and Health		
Whole algal biomass for human food	No	N/A
Component of algal biomass as human food ingredient or additive	No	N/A

Table C.1. Regulatory Oversight for the Use and Application of Algal Biomass for EPA OPPT

²² The White House, "Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology," accessed August 3, 2018, <u>https://obamawhitehouse.archives.gov/sites/default/files/</u> microsites/ostp/2017_coordinated_framework_update.pdf.

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Human dietary supplements	No	N/A
Human medical applications: anticoagulants, sterilizing agents, iodine, laxatives	No	N/A
Veterinary medical drugs (growth promotants, production claims, alternatives to antimicrobial agents, immune modulation, environmental abatement claims)	No	N/A
Use of whole algae biomass or its components in animal food for livestock and poultry	No	N/A
Use of whole algae biomass or its components in animal food for pet food	No	N/A
Use of whole algae biomass or its components in animal food for aquaculture feed (finfish and crustaceans)	No	N/A
Color additives (human or animal food, drugs, and human cosmetics)	No	N/A
Chemicals and	d Materials	
Plastics, polymers, resins, and lubricants	Yes	TSCA
Cosmetics and personal well-being products	No	N/A
Industrial colorants, dyes, and inks	Yes	TSCA
Building or construction material	Yes	TSCA
Biomedical polymers	No	N/A

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Other chemicals. Please describe in the Authority Description column.	Yes	TSCA gives the authority for EPA/ OPPT to regulate intergeneric microorganisms used for the production of other chemicals including enzymes, specialty chemicals, and commodity chemicals if they are TSCA applications. See footnote 23 in Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for Regulation of Biotechnology.
Energ	gy	
Biofuel	Yes	TSCA
Biopower	Yes	TSCA
Refining of biocrude into biofuel	Yes	TSCA
Blending of biofuels with fossil feedstocks	Yes	TSCA
Servio	es	
Wastewater treatment	Yes	TSCA
Impaired water remediation	Yes	TSCA
Utilization of gaseous industrial emissions	Yes	TSCA
Utilization of gaseous power-plant emissions	Yes	TSCA
Soil amendment (biofertilizer) and reclamation	Yes	TSCA
Deacidification	Yes	TSCA
Restoration of ecosystem services	Yes	TSCA

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION	
Oversight of Indirect Uses and Applications			
Transport/sale of bioproducts	Yes	TSCA	
Other oversight of indirect uses and applications. Please describe in the Authority Description column.	N/A	In risk assessments, OPPT must identify and evaluate known, intended, and reasonably foreseen conditions of use.	

Description of standards and/or certifications relevant to algal biomass and bioproducts: $\ensuremath{\mathrm{N/A}}.$

Other Offices in the Agency that have oversight on the use of algal biomass and bioproducts:

Office of Pesticide Programs, under the Federal Insecticide, Fungicide, and Rodenticide Act and Federal Food, Drug, and Cosmetic Act (FFDCA).

Table C.2. Regulatory Oversight for the Production of Algal Biomass for EPA

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Regulatory Oversight for the Cultivation of Algal Biomass		
Site selection of cultivation area	No	Although EPA does not dictate the site, EPA does consider it in our risk assessments for TSCA.
Installation of cultivation systems (open raceway ponds, photobioreactors, marine cultivation systems)	No	Although EPA does not dictate the installation of cultivation systems, EPA does consider the structures, sizes, integrity of materials, etc., in our risk assessments for TSCA. In some cases, OPPT may place restrictions on their cultivation systems.

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Delivery and application of cultivation resources and nutrients (water, CO_2 , nitrogen source, phosphorous source, trace metals)	No	N/A
Growth of algal biomass	Yes	TSCA
Harvesting of algal biomass	Yes	TSCA
Transport/sale of biomass	Yes	TSCA
Recycling of cultivation resources and nutrients	Yes	TSCA
Environmental release of cultivation resources, nutrients, and/or biomass or bioproducts (intentional and/or unintentional)	Yes	TSCA
Disposal of cultivation resources, nutrients, and/or biomass or bioproducts	Yes	TSCA

C.3 HHS, FDA, Office of Foods and Veterinary Medicine, CVM, Division of Animal Feeds

Description of regulatory authority over algal biomass and bioproducts:

The Center for Veterinary Medicine has authority if those products, in whole or part, are (1) intended for use in animal food (all species); (2) used to create color additives for food; (3) used as a component to cure, treat, or prevent an animal disease; or (4) as a veterinary medical device.²³

Office's authority and/or rule contingent on the use being for R&D and/or commercial purposes: Any application or use of algae (in whole or part) in an animal food or drug product, regardless of its source, falls under CVM's jurisdiction.

Office's authority and/or use contingent on where the production of algal biomass and bioproducts occurs: Any application or use of algae (in whole or part) in an animal food or drug product, regardless of its source, falls under our jurisdiction.

²³ There is no premarket approval required for veterinary medical devices or grooming aids. Note that what some think are veterinary medical devices are actually new animal drugs.

Office's rule or authority contingent on how the production of algal biomass and bioproducts occurs: Any application or use of algae (in whole or part) in an animal food or drug product, regardless of its source, falls under our jurisdiction.

Office's rule or authority on the production of algal biomass and bioproducts contingent on the use of algal biomass and bioproducts:

FDA CVM regulates based upon intended use. If it is present in an animal food or drug or a color additive, we have jurisdiction.

Office's rule or authority contingent on the organism being naturally occurring or genetically modified: FDA CVM regulates both wild-type and engineered organisms.

Description of interagency frameworks or Memoranda of Understanding (MOUs) relevant to the Office that pertain to regulatory oversight of algae:

FDA CVM has an MOU with the Association of American Feed Control Officials (AAFCO), where CVM serves as the scientific advisor for AAFCO regarding materials used as, or in, animal food/feed. This includes, but is not limited to, algae and algal products.

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Food and	Health	
Whole algal biomass for human food	No	N/A
Component of algal biomass as human food ingredient or additive	No	N/A
Human dietary supplements	No	N/A
Human medical applications: anticoagulants, sterilizing agents, iodine, laxatives	No	N/A
Veterinary medical drugs (growth promotants, production claims, alternatives to antimicrobial agents, immune modulation, environmental abatement claims)	Yes	Food Drug and Cosmetic Act, 21 CFR Part 500s.

Table C.3. Regulatory Oversight for the Use and Application of Algal Biomass for FDA CVM

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Use of whole algae biomass or its components in animal food for livestock and poultry	Yes	Food Drug and Cosmetic Act, Food Safety Modernization Act, 21 CFR Parts 501, 570–589, AAFCO-OP
Use of whole algae biomass or its components in animal food for pet food	Yes	Food Drug and Cosmetic Act, Food Safety Modernization Act, 21 CFR Parts 501, 570–589, AAFCO-OP
Use of whole algae biomass or its components in animal food for aquaculture feed (finfish and crustaceans)	Yes	Food Drug and Cosmetic Act, Food Safety Modernization Act, 21 CFR Parts 501, 570–589, AAFCO-OP
Color additives (animal food and animal drugs)	Yes	Food Drug and Cosmetic Act, Food Safety Modernization Act, 21 CFR Parts 70s, 573.ª
Other food and health. Please describe in the Authority Description column.	Yes	Veterinary medical devices are regulated by CVM.
Chemicals and Materials		
	u materiais	
Plastics, polymers, resins, and lubricants	Yes	If used in an animal food or medical product.
Plastics, polymers, resins, and lubricants	Yes	For animals, they are called "grooming aids" if used to cleanse and beautify the animal, and FDA does not regulate. If, however, the product purporting to be a grooming aid is intended to cure, mitigate, treat, or prevent disease of an animal, or affect structure or function of body (as determined by formulation, labeling, and claims), it is a new animal drug and under

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Biomedical polymers	Yes	Regulated as new animal drug or veterinary medical device.
Energ	gy	
Biofuel	Yes	Only if byproducts are used in animal food/feed or drugs.
Biopower	Yes	Only if byproducts are used in animal food/feed or drugs.
Refining of biocrude into biofuel	Yes	Only if byproducts are used in animal food/feed or drugs.
Blending of biofuels with fossil feedstocks	No	N/A
Services		
Wastewater treatment	Yes	Only if byproducts are used in animal food/feed or drugs.
Impaired water remediation	Yes	Only if byproducts are used in animal food/feed or drugs.
Utilization of gaseous industrial emissions	Yes	Only if byproducts are used in animal food/feed or drugs.
Utilization of gaseous power-plant emissions	Yes	Only if byproducts are used in animal food/feed or drugs.
Soil amendment (biofertilizer) and reclamation	Yes	Only if byproducts are used in animal food/feed or drugs.
Deacidification	No	N/A
Restoration of ecosystem services	No	N/A

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION		
Oversight of Indirect Uses and Applications				
Transport/sale of bioproducts No N/A				

^a CFSAN is responsible for evaluating and approving all color additives. When a color additive is intended for use in an animal food or new animal drug, CFSAN will consult with CVM.

Description of standards and/or certifications relevant to algal biomass and bioproducts:

Firms will at times request a "certificate of free sale," but this is generally to permit export of a material unapproved for use in the United States.

Other Offices in the above Agency that likely have oversight on the use of algal biomass and bioproducts: The FDA CVM Office of Surveillance and Compliance regulates pre- and post-market animal feed and post-market animal drugs. The CVM Office of New Animal Drug Evaluation evaluates all materials intended to treat, mitigate, or prevent disease or enhance animal productivity. The FDA Center for Food Safety and Applied Nutrition (CFSAN) oversees materials used in human food, dietary supplements, color additives for human food, and cosmetics. The FDA Center for Drug Evaluation and Research evaluates human drug products.

Table C.4. Regulatory Oversight for the Production of Algal Biomass for FDA CVM	

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.	
Regulatory Oversight for the Cultivation of Algal Biomass			
Site selection of cultivation area	No	N/A	
Installation of cultivation systems (open raceway ponds, photobioreactors, marine cultivation systems)	No	N/A	
Delivery and application of cultivation resources and nutrients (water, CO ₂ , nitrogen source, phosphorous source, trace metals)	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.	

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Growth of algal biomass	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.
Harvesting of algal biomass	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.
Transport/sale of biomass	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.
Recycling of cultivation resources and nutrients	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.
Environmental release of cultivation resources, nutrients, and/or biomass or bioproducts (intentional and/or unintentional)	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.
Disposal of cultivation resources, nutrients, and/or biomass or bioproducts	Yes	Only if whole-cell algae or its by- products are used in animal food/ feed or drugs.

Description of how the Office partners with state agencies in relation to the production of algal biomass and bioproducts:

FDA CVM Division of Animal Feeds partners with AAFCO (a body of state and federal regulators) in the evaluation of new ingredient definitions that are acceptable for use in animal foods (within the limitations set forth by AAFCO). FDA CVM also partners with states for inspection of facilities.

Other Offices in the Agency that likely have oversight on the production of algae biomass and bioproducts: If the algae or algae product are used in a human or animal product, FDA would then have jurisdiction over cultivation.

C.4 HHS, FDA, Office of Foods and Veterinary Medicine, CFSAN, Office of Food Additive Safety (OFAS)

Description of regulatory authority over algal biomass and bioproducts:

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FDA's implementing regulations in Title 21 of the Code of Federal Regulations (CFR), CFSAN/OFAS has authority over the premarket safety review of algal biomass

and bioproducts if the material is intended for use: (1) in foods consumed by humans, (2) or is reasonably expected to become a component of food under its conditions of use (e.g., as a component of food packaging), or (3) as a color additive in any FDA-regulated product. FDA has regulatory authority when the product enters interstate commerce.

Office's authority and/or rule contingent on the use being for R&D and/or commercial purposes: Under the FFDCA and FDA's implementing regulations in Title 21 of the CFR, CFSAN/OFAS has authority if the material is intended for use: (1) in foods consumed by humans, (2) on foods intended for consumption by humans (e.g., as a component of food packaging), or (3) as a color additive in any FDA-regulated product. FDA has regulatory authority when the product enters interstate commerce.

Office's authority and/or use contingent on where the production of algal biomass and bioproducts occurs: Under the FFDCA and FDA's implementing regulations in Title 21 of the CFR, CFSAN/OFAS has authority if the material is intended for use: (1) in foods consumed by humans, (2) on foods intended for consumption by humans (e.g., as a component of food packaging), or (3) as a color additive in any FDA-regulated product. Regardless of where production occurs, FDA has regulatory authority when the product enters interstate commerce.

Office's rule or authority contingent on how the production of algal biomass and bioproducts occurs: Under the FFDCA and FDA's implementing regulations in Title 21 of the CFR, CFSAN/OFAS has authority if the material is intended for use: (1) in foods consumed by humans, (2) on foods intended for consumption by humans (e.g., as a component of food packaging), or (3) as a color additive in any FDA-regulated product. CFSAN/OFAS' regulatory authorizations for algal biomass and bioproducts used as food ingredients, color additives, and food packaging substances may include limitations and specifications for how the substance is produced to ensure its safe use. Regardless of how production occurs, FDA has regulatory authority when the product enters interstate commerce.

Office's rule or authority on the production of algal biomass and bioproducts contingent on the use of algal biomass and bioproducts:

Under the FFDCA and FDA's implementing regulations in Title 21 of the CFR, CFSAN/OFAS has authority if the material is intended for use: (1) in foods consumed by humans, (2) on foods intended for consumption by humans (e.g., as a component of food packaging), or (3) as a color additive in any FDA-regulated product. CFSAN/OFAS' regulatory authorizations for algal biomass and bioproducts used as food ingredients, color additives, and food packaging substances may include limitations and specifications for how the substance is produced to ensure its safe use. Regardless of how production occurs, FDA has regulatory authority when the product enters interstate commerce.

Office's rule or authority contingent on the organism being naturally occurring or genetically modified:

Under the FFDCA and FDA's implementing regulations in Title 21 of the CFR, CFSAN/OFAS has authority if the material is intended for use: (1) in foods consumed by humans, (2) on foods intended for consumption by humans (e.g., as a component of food packaging), or (3) as a color additive in any FDA-regulated product, regardless of whether the organism occurs naturally²⁴ or is genetically modified. FDA has regulatory authority when the product enters interstate commerce.

²⁴ FDA does not have a statutory/regulatory definition for the term "natural."

Description of interagency frameworks or MOUs relevant to the Office that pertain to regulatory oversight of algae:

Memorandum of Understanding (MOU) 225-00-2000 Amendment 1 establishes the working relationship to be followed by the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) and FDA/CFSAN for the use of food additives, including sources of radiation and food contact substances, generally recognized as safe substances, prior-sanctioned substances, and color additives subject to FDA regulation and intended for use in the production of FSIS-regulated meat, poultry, and egg products. Food ingredients used during the production of meat, poultry, and egg products are subject to regulation by FDA under the FFDCA. However, USDA/FSIS also has jurisdiction to regulate the use of those food ingredients used in the production of meat, poultry, and egg products Inspection Act, and Egg Products Inspection Act. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products in accordance with applicable FSIS laws, regulations, and policies.

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Food and	Health	
Whole algal biomass for human food	Yes	FFDCA, Section 409
Component of algal biomass as human food ingredient or additive	Yes	FFDCA, Section 409
Human dietary supplements	Noª	N/A
Human medical applications: anticoagulants, sterilizing agents, iodine, laxatives	No	N/A
Veterinary medical drugs (growth promotants, production claims, alternatives to antimicrobial agents, immune modulation, environmental abatement claims)	No	N/A
Use of whole algae biomass or its components in animal food for livestock and poultry	No	N/A

Table C.5. Regulatory Oversight for the Use and Application of Algal Biomass for CFSAN

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION	
Use of whole algae biomass or its components in animal food for pet food	No	N/A	
Use of whole algae biomass or its components in animal food for aquaculture feed (finfish and crustaceans)	No	N/A	
Color additives (human or animal food, drugs, and human cosmetics)	Yes	FFDCA, Section 409	
Other food and health. Please describe in the Authority Description column.	Yes ^b	FFDCA, Section 409	
Chemicals and	d Materials		
Plastics, polymers, resins, and lubricants	Yes⁵	FFDCA, Section 409	
Cosmetics and personal well-being products	No ^c	N/A	
Industrial colorants, dyes, and inks	Yes⁵	FFDCA, Section 409	
Building or construction material	No	N/A	
Biomedical polymers	No	N/A	
Other chemicals. Please describe in the Authority Description column.	Yes ^b	FFDCA, Section 409	
Energy			
Biofuel	No	N/A	
Biopower	No	N/A	
Refining of biocrude into biofuel	No	N/A	
Blending of biofuels with fossil feedstocks	No	N/A	

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Servic	ces	
Wastewater treatment	No	N/A
Impaired water remediation	No	N/A
Utilization of gaseous industrial emissions	No	N/A
Utilization of gaseous power plant emissions	No	N/A
Soil amendment (biofertilizer) and reclamation	No	N/A
Deacidification	No	N/A
Restoration of ecosystem services	No	N/A
Other services. Please describe in the Authority Description column.	No	N/A
Oversight of Indirect Uses and Applications		
Transport/sale of bioproducts	Yes⁵	FFDCA, Section 409
Other oversight of indirect uses and applications. Please describe in the Authority Description column.	Yes⁵	FFDCA, Section 409

^a Dietary supplements and dietary supplement ingredients used in dietary supplements are under the purview of CFSAN's Office of Dietary Supplement Programs. CFSAN OFAS does not have oversight for dietary supplements or dietary ingredients used in dietary supplements.

^b Only if the material will be used in or on (i.e., as a component of food packaging) foods intended for consumption by humans.

^c Cosmetics and cosmetic ingredients used in cosmetics are under the purview of FDA CFSAN's Office of Cosmetics and Colors. CFSAN OFAS oversees the review process for color additives used in cosmetics; however, CFSAN OFAS does not have oversight for other ingredients used in cosmetics.

Description of standards and/or certifications relevant to algal biomass and bioproducts:

As with other substances used in or on (e.g., as a component of food packaging) foods intended for consumption by humans, algal biomass and bioproducts used in or on foods must be used in accordance with good manufacturing practice. Title 21, Subpart A, Paragraph 172.5 of the Code of Federal Regulations (CFR) defines good manufacturing practice to include the following restrictions:

- (1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.
- (2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.
- (a) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to relieve the use of the substance from compliance with any other provision of the Act.
- (b) The existence of any regulation prescribing safe conditions of use for a nutrient substance does not constitute a finding that the substance is useful or required as a supplement to the diet of humans.
- 21 CFR 172.5 can be viewed at <u>www.ecfr.gov</u> and under Title 21 in the drop down menu.

Other Offices in the above Agency that likely have oversight on the use of algal biomass and bioproducts:

- FDA/CFSAN's Office of Dietary Supplement Products has regulatory authority for dietary supplements and dietary ingredients used in dietary supplements
- FDA/CFSAN's Office of Cosmetic and Colors has regulatory authority for cosmetics and ingredients used in cosmetics
- FDA's Center for Drug Evaluation and Research has regulatory authority for human drugs
- FDA's Center for Biologics Evaluation and Research has regulatory authority for biologics
- FDA's Center for Devices and Radiological Health has regulatory authority for devices and products that emit radiation.

Table C.6. Regulatory Oversight for the Production of Algal Biomass for CFSAN

ALGAL BIOMASS USES	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Regulatory Oversight for the Cultivation of Algal Biomass		
Site selection of cultivation area	No	N/A
Installation of cultivation systems (open raceway ponds, photobioreactors, marine cultivation systems)	No	N/A
Delivery and application of cultivation resources and nutrients (water, CO_2 , nitrogen source, phosphorous source, trace metals)	Yesª	FFDCA, Section 409

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Growth of algal biomass	Yesª	FFDCA, Section 409
Harvesting of algal biomass	Yesª	FFDCA, Section 409
Transport/sale of biomass	Yesª	FFDCA, Section 409
Recycling of cultivation resources and nutrients	No	FFDCA, Section 409
Environmental release of cultivation resources, nutrients, and/or biomass or bioproducts (intentional and/or unintentional)	Yes⁵	Information is available.°
Disposal of cultivation resources, nutrients, and/or biomass or bioproducts	No	N/A
Other. Please describe in the Authority Description column.	Yesª	N/A

^a Only if the material will be used in or on (i.e., as a component of food packaging) foods intended for consumption by humans.

^b FDA assesses the environmental impact of its regulatory actions (i.e., approval of a food or color additive or food contact substance).

^C https://www.fda.gov/food/food-ingredients-packaging/environmental-decisions

Description of how the Office partners with state agencies in relation to the production of algal biomass and bioproducts:

N/A

Other Offices in the Agency that likely have oversight on the production of algae biomass and bioproducts:

- FDA CFSAN's Office of Dietary Supplement Products has regulatory authority for dietary supplements and dietary ingredients used in dietary supplements
- FDA CFSAN's Office of Cosmetic and Colors has regulatory authority for cosmetics and ingredients used in cosmetics
- FDA's Center for Drug Evaluation and Research has regulatory authority for human drugs
- FDA's Center for Biologics Evaluation and Research has regulatory authority for biologics
- FDA's Center for Devices and Radiological Health has regulatory authority for devices and products that emit radiation.

C.5 USDA, APHIS, Biotechnology Regulatory Services

Office's authority and/or rule contingent on the use being for R&D and/or commercial purposes: APHIS BRS and PPQ authority is independent of commercial intent. APHIS VS-CVB authority is for the manufacture of veterinary biologics.

Office's authority and/or use contingent on where the production of algal biomass and bioproducts occurs:

APHIS PPQ requires a permit and phytosanitary certificate for the import of eukaryotic algae into the United States. If the algae are not on an invasive weed list, a 587 permit is used and generally use of the algae will not be restricted in the United States. If the algae are on an invasive weed list, a 526 permit is required, which imposes restrictive conditions on the use of the algae in the United States.

If the algae are genetically engineered, the algae may require a permit issued by BRS for importation, interstate movement, or outdoor release.

Any facility that uses algae in the production and testing of veterinary biologics will require a license from APHIS VS-CVB.

Office's rule or authority contingent on how the production of algal biomass and bioproducts occurs: The Office's authority under the Plant Protection Act (BRS and PPQ) is not contingent on the production method. The Office's authority under the Virus, Serum, and Toxin Act is contingent on the production method.

Office's rule or authority on the production of algal biomass and bioproducts contingent on the use of algal biomass and bioproducts:

The Office's authority under the Plant Protection Act (BRS and PPQ) is not contingent on the production method. The Office's authority under the Virus, Serum, and Toxin Act is contingent on the production method.

Office's rule or authority contingent on the organism being naturally occurring or genetically modified: Biotechnology Regulatory Services authority is only for algae that meet the definition of a plant pest. APHIS-Office of Plant Protection and Quarantine has authority over algae imported into the United States and for invasive algae.

Table C.7. Regulatory Oversight for the Use and	Application of Algal Biomass for APHIS

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Food and Health		
Whole algal biomass for human food	No	N/A

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION	
Component of algal biomass as human food ingredient or additive	No	N/A	
Human dietary supplements	No	N/A	
Human medical applications: anticoagulants, sterilizing agents, iodine, laxatives	No	N/A	
Veterinary medical drugs (growth promotants, production claims, alternatives to antimicrobial agents, immune modulation, environmental abatement claims)	Yes	Virus Serum Toxin Act 21 USC 151–159 et seq.	
Use of whole algae biomass or its components in animal food for livestock and poultry	No	N/A	
Use of whole algae biomass or its components in animal food for pet food	No	N/A	
Use of whole algae biomass or its components in animal food for aquaculture feed (finfish and crustaceans)	No	N/A	
Color additives (human or animal food, drugs, and human cosmetics)	No	N/A	
Chemicals and Materials			
Plastics, polymers, resins, and lubricants	No	N/A	
Cosmetics and personal well-being products	No	N/A	
Industrial colorants, dyes, and inks	No	N/A	
Building or construction material	No	N/A	
Biomedical polymers	No	N/A	

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION	
Energ	Energy		
Biofuel	No	N/A	
Biopower	No	N/A	
Refining of biocrude into biofuel	No	N/A	
Blending of biofuels with fossil feedstocks	No	N/A	
Servio	es		
Wastewater treatment	No	N/A	
Impaired water remediation	Yes	Only if the remediation resulted from noncompliance of a permit condition for a regulated organism.	
Utilization of gaseous industrial emissions	No	N/A	
Utilization of gaseous power-plant emissions	No	N/A	
Soil amendment (biofertilizer) and reclamation	No	N/A	
Deacidification	No	N/A	
Restoration of ecosystem services	Yes	Only if the restoration resulted from noncompliance of a permit condition for a regulated organism.	
Oversight of Indirect Uses and Applications			
Transport/sale of bioproducts	Yes	If the biomass contains live organisms and is regulated under the Plant Protection Act, permits are needed for importation and interstate movement. Sale is not regulated. Phytosanitary certificates can be issued for import as needed.	

Office's oversight regarding standards and/or certifications relevant to algal biomass and bioproducts: Phytosanitary certificates are required for the import of eukaryotic algae into the United States. They attest that the sample does not contain any plant pests. For BRS, under current regulations, a *regulated article* is "Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." See https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_export/sa_faqs/faqs.

Offices in the above Agency that likely have oversight on the use of algal biomass and bioproducts: APHIS VS-CVB licenses any facility that uses algae in the manufacture and testing of veterinary biologics.

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Regulatory Oversight for the C	cultivation o	f Algal Biomass
Site selection of cultivation area	Yes	Endangered Species Act (ESA) considerations – Section 7(a) (2) of the ESA requires that each federal agency, in consultation with the services and with the assistance of the relevant secretary, ensure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of a listed threatened and endangered species, or result in the destruction or adverse modification of designated critical habitat. (Also see implementing regulations in 50 CFR Part 402, Interagency Cooperation Regulations. APHIS ensures that any site subject to agency action is not designated critical habitat.)

Table C.8. Regulatory Oversight for the Production of Algal Biomass for APHIS

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Installation of cultivation systems (open raceway ponds, photobioreactors, marine cultivation systems)	No	N/A
Delivery and application of cultivation resources and nutrients (water, CO ₂ , nitrogen source, phosphorous source, trace metals)	No	N/A
Growth of algal biomass	Yes	If algae are subject to regulations 7 CFR 340 or 7 CFR 319 under the Plant Protection Act, there may be permit conditions for the growth of the algal biomass.
Harvesting of algal biomass	Yes	If algae need to be confined, harvesting method needs to be appropriate for confinement.
Transport/sale of biomass	Yes	Permits are needed for importation and interstate movement of regulated organisms. Sale is not regulated. Phytosanitary certificates are required for import but not for interstate movement.
Recycling of cultivation resources and nutrients	No	N/A
Environmental release of cultivation resources, nutrients, and/or biomass or bioproducts (intentional and/or unintentional)	Yes	Permits are required for environmental release of regulated organisms.
Disposal of cultivation resources, nutrients, and/or biomass or bioproducts	Yes	Yes, only if viable.

Description of Office's partnerships with state agencies in relation to the production of algal biomass and bioproducts:

APHIS works closely with state plant health directors. Permits are reviewed by state governments before issue by APHIS. Inspections are often coordinated with and conducted by state government employees. If remediation action is necessary, the action would be closely coordinated with state governments. In the past, the Office has consulted with the State of Hawaii when a company wanted to install a facility for the production of a genetically engineered algae. The Office helped them establish biocontainment conditions.

Description of Offices in your Agency that likely have oversight on the production of algae biomass and bioproducts:

If a developer sought to use an invasive alga for biomass and bioproducts, that would require permitting by APHIS PPQ under 7 CFR 319 for importation, interstate movement, and use. If a developer engineered an alga that is a plant pest or used plant pest sequences, a permit would be required from APHIS BRS under 7 CFR 340 for importation, interstate movement, and environmental release. If a developer sought to use algae to manufacture a veterinary biologic, that facility used would require licensing from APHIS VS-CVB.

C.6 DOE, EERE, Office of Environment, Health, Safety, and Security (EHSS)

Description of regulatory authority over algal biomass and bioproducts:

The National Environmental Policy Act (NEPA) Division within EHSS plays a key role in DOE by managing the NEPA review process in support of EERE's technology and program offices (including the Bioenergy Technologies Office). While NEPA does not specifically regulate algal biomass and bioproducts, this office is responsible for reviewing all projects proposed for federal funding by EERE's technology and program offices in compliance with the national environmental policy stated in NEPA. Compliance with a number of additional environmental laws is also managed through the NEPA Process. A few of the common environmental laws DOE is required to comply with under the NEPA "umbrella" include: the Endangered Species Act, the National Historic Preservation Act, the Marine Mammal Protection Act, and the Migratory Bird Treaty Act. Often, projects that involve work outdoors such as construction, installation of equipment, or data collection will trigger consultation requirements under these regulations. NEPA specialists are responsible for managing the NEPA review process, conducting training, and providing input into all phases of active project management, including funding opportunity announcement (FOA) documents development, merit reviews, award negotiation packages, project kickoff meetings, Statement of Project Objectives (SOPO) development, and contract terms and conditions development. Another area that the EERE NEPA Division assists with is conducting site visits. NEPA specialists provide guidance on what types of environmental conditions, information, or red flags to look for when planning a site visit and/or can accompany DOE program/project officers on site visits.

Office's authority and/or rule contingent on the use being for R&D and/or commercial purposes:

All projects proposed for federal funding by DOE (and any subsequent SOPO changes/award modifications) are subject to NEPA review regardless of the scope of the proposed project. However, there are three levels of NEPA review:

- Categorical Exclusion (CX)
- Environmental Assessment
- Environmental Impact Statement.

Each level of review has different requirements for analysis, documentation, and public participation. It is up to a NEPA Compliance Officer to determine the appropriate level of review for a project. This determination is based on a recommendation from a NEPA specialist after they have reviewed the project documentation, including the SOPO, and conducted an appropriate level of investigation into the proposed project location.

The majority of EERE NEPA reviews are CX reviews, which are considered the lowest level of NEPA review; however, this does not necessarily mean a lower level of effort. A CX is not a variance or exemption from NEPA. Even if a project qualifies for a CX, a certain level of NEPA review does still occur and is required to be documented. In addition, even if a project qualifies for a CX, DOE still needs to determine if the project will trigger any other regulatory requirements, such as consultation under the National Historic Preservation Act or the Endangered Species Act.

Some of the commonly applied CXs for Bioenergy Technologies Office-funded R&D and commercial-scale projects under certain conditions include (from 10 CFR 1021: DOE National Environmental Policy Act Implementing Procedures):

- B3.6 Small-scale R&D, laboratory operations, and pilot projects
- B5.15 Small-scale renewable energy R&D and pilot projects
- B5.20 Biomass power plants.

Office's authority and/or use contingent on where the production of algal biomass and bioproducts occurs: The Office's authority is not contingent on where the production occurs.

Office's rule or authority contingent on how the production of algal biomass and bioproducts occurs: The Office's authority is not contingent on how the production occurs.

Office's rule or authority on the production of algal biomass and bioproducts contingent on the use of algal biomass and bioproducts:

The Office's authority is not contingent on the use of algal biomass.

Office's rule or authority contingent on the organism being naturally occurring or genetically modified: The Office's authority is not contingent on the organism. However, the Office recognizes the potential for distinct environmental impacts resulting from the use of genetically modified organisms versus naturally occurring organisms, and as such requires the following information from award recipients:

"Would the proposed project involve the use or development of recombinant DNA or genetically engineered microorganisms, plants, animals, or similar technologies?"

This information is taken into account when assessing the potential environmental impacts of a proposed project and determining the appropriate level of NEPA review.

C.7 DOC, National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service, Aquaculture Office

Description of regulatory authority over algal biomass and bioproducts:

NOAA trust resources are living marine resources. They include commercial and recreational fishery resources (fish, shellfish, and their habitats), migratory fish species (like salmon and eels), endangered and threatened marine species (like whales, sea turtles, and their habitats), and other critical habitats (like marshes, mangroves, seagrass beds, and coral reefs) and resources associated with National Marine Sanctuaries and National Estuarine Research Reserves. The Regional Fishery Management Councils have authority, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (MSA), to manage the harvest of wild macroalgae, or more specifically "all other forms of marine animal and plant life" thorough the use of Fishery Management Plans. NOAA Fisheries implements and enforces these plans through regulation. Additionally, NOAA Fisheries or the Fishery Management Councils may consult on seaweed cultivation projects if it affects either Essential Fish Habitat under the MSA or could affect protected marine species pursuant to the Endangered Species Act or Marine Mammal Protection Act. This includes possible consultation on permits issued by the U.S. Army Corps of Engineers for seaweed production pursuant to the Rivers and Harbors Act. The Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2004 (HABHRCA 2004, Public Law 108-456) and 2014 (HABHRCA 2014, Public Law 113-124) reaffirmed and expanded the mandate for NOAA to advance the scientific understanding and ability to detect, monitor, assess, and predict harmful algal blooms and hypoxia events. The Coral Reef Conservation Act allows NOAA to remove invasive algae that may threaten the survival of coral reefs. NOAA has authority to protect and restore algae that may be designated as critical habitat for protected species, or for kelp that has been designated as essential fish habitat by either the Regional Fishery Management Councils or NOAA Fisheries. Additionally, as the primary federal natural resource trustee for coastal resources, NOAA has responsibility for ensuring the restoration of coastal resources injured by oil and hazardous substances, as well as national marine sanctuary resources injured by physical impacts.

Office's authority and/or rule contingent on the use being for R&D and/or commercial purposes: No.

Office's authority and/or use contingent on where the production of algal biomass and bioproducts occurs: Office consults on projects that seek a permit in waters of the United States (this could be U.S. Rivers and Harbors Act (RHA)) permits in estuarine waters as well). **Office's rule or authority contingent on how the production of algal biomass and bioproducts occurs:** No, authority is for all projects that may impact NOAA's trust resources.

Office's rule or authority on the production of algal biomass and bioproducts contingent on the use of algal biomass and bioproducts:

No, authority extends to activities that could impact wild stock resources (algae and animals), protected species, and critical habitats.

Office's rule or authority contingent on the organism being naturally occurring or genetically modified: No, authority is based on the potential for impact, not the type of organism.

Description of interagency frameworks or MOUs relevant to the Office that pertain to regulatory oversight of algae:

Table C.9. Regulatory	• Oversight for the Use and	Application of Alga	I Biomass for NOAA Fisheries
<u></u>			

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Food and	Health	
Whole algal biomass for human food	No	N/A
Component of algal biomass as human food ingredient or additive	No	N/A
Human dietary supplements	No	N/A
Human medical applications: anticoagulants, sterilizing agents, iodine, laxatives	No	N/A
Veterinary medical drugs (growth promotants, production claims, alternatives to antimicrobial agents, immune modulation, environmental abatement claims)	No	N/A
Use of whole algae biomass or its components in animal food for livestock and poultry	No	N/A

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Use of whole algae biomass or its components in animal food for pet food	No	N/A
Use of whole algae biomass or its components in animal food for aquaculture feed (finfish and crustaceans)	No	N/A
Color additives (human or animal food, drugs, and human cosmetics)	No	N/A
Chemicals and	d Materials	
Plastics, polymers, resins, and lubricants	No	N/A
Cosmetics and personal well-being products	No	N/A
Industrial colorants, dyes, and inks	No	N/A
Building or construction material	No	N/A
Biomedical polymers	No	N/A
Energy		
Biofuel	No	N/A
Biopower	No	N/A
Refining of biocrude into biofuel	No	N/A
Blending of biofuels with fossil feedstocks	No	N/A
Servio	es	
Wastewater treatment	No	N/A

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION		
Impaired water remediation	No	N/A		
Utilization of gaseous industrial emissions	No	N/A		
Utilization of gaseous power-plant emissions	No	N/A		
Soil amendment (biofertilizer) and reclamation	No	N/A		
Deacidification	Yes	NOAA Ocean Acidification Program supports research that focuses on economically and ecologically important marine species, including algae production that may help to improve ocean chemistry.		
Restoration of ecosystem services	Yes	Coral Reef Conservation Act allows NOAA to remove invasive algae that may threaten the survival of coral reefs. NOAA has authority to protect and restore algae that may be designated as critical habitat for protected species, or for kelp that has been designated as essential fish habitat by either the Regional Fishery Management Councils or NOAA Fisheries.		
Oversight of Indirect Uses and Applications				
Transport/sale of bioproducts	No	N/A		

Description of standards and/or certifications relevant to algal biomass and bioproducts: None

Other Offices in the above Agency that likely have oversight on the use of algal biomass and bioproducts: National Marine Fisheries Service (NMFS) Seafood Inspection Program (SIP) works to ensure confidence in U.S. seafood by protecting and strengthening the seafood market through global trade, establishing partnerships with industry and consumer groups, providing seafood inspection services, and analyzing seafood safety risks. The NMFS National Seafood Inspection Lab provides analyses, data management, regulatory compliance, and technology transfer expertise to meet seafood safety responsibilities on behalf of the U.S. Government.

ALGAL BIOMASS USE	IN SCOPE (Yes/No)	AUTHORITY DESCRIPTION What authority and/or rule is used for oversight? When possible, provide publicly available links to the authority and/or rule.
Regulatory Oversight for the O	ultivation o	f Algal Biomass
Site selection of cultivation area	Yes	NOAA Fisheries typically consults on issues related to the project's impact on habitat or protected resources with the permitting agency (usually the ACOE) that issues the permit. Authority is from the Endangered Species Act, the Marine Mammal Protection Act, and the Fisheries Conservation Act.
Installation of cultivation systems (open raceway ponds, photobioreactors, marine cultivation systems)	Yes	Same as above
Delivery and application of cultivation resources and nutrients (water, CO ₂ , nitrogen source, phosphorous source, trace metals)	Yes	Same as above
Growth of algal biomass	Yes	Same as above
Harvesting of algal biomass	Yes	Same as above
Transport/sale of biomass	Yes	Same as above
Recycling of cultivation resources and nutrients	No	N/A

ALGAL BIOMASS USE	IN SCOPE	AUTHORITY DESCRIPTION
Environmental release of cultivation resources, nutrients, and/or biomass or bioproducts (intentional and/or unintentional)	Yes	NOAA Fisheries typically consults on issues related to the project's impact on habitat or protected resources with the permitting agency (usually the ACOE) that issues the permit. Authority is from the Endangered Species Act, the Marine Mammal Protection Act, and the Fisheries Conservation Act.
Disposal of cultivation resources, nutrients, and/or biomass or bioproducts	No	N/A

Description of how the Office partners with state agencies in relation to the production of algal biomass and bioproducts:

N/A

Other Offices in the Agency that likely have oversight on the production of algae biomass and bioproducts: National Ocean Service (NOS) has oversight for harmful algal blooms, habitat for essential fish habitat, and protected resources for critical habitat; Regional Fishery Management Councils have authority for wild and farmed seaweed; NOAA Ocean Acidification Program plays a role in research; Office of Response and Restoration oversees coastal environments harmed by oil spills, etc., and for habitat restoration in National Marine Sanctuaries and National Estuarine Research Reserves.

Appendix D: Detailed AWG Member Office Information on R&D Activities

D.1 Summary

This appendix details the algae research and development (R&D) activities relevant to federal agency offices who are members of the Biomass R&D Board Algae Interagency Working Group. These offices include:

- U.S. Department of Commerce (DOC)
- U.S. Department of Energy (DOE)
- U.S. Department of Agriculture (USDA)
- National Science Foundation (NSF)

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D.2 DOC, NOAA, National Marine Fisheries Service, Aquaculture Office

Areas of R&D relevant to algae:

Table D.1. Areas of Algae Relevant R&D	Investment by National Marine	Fisheries Service. Aquaculture Office

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	Yes	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	Yes	Siting and resources	Yes
Algae crop development	Yes	Regulations and standards	Yes
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of miscellaneous scope:

The majority of the Office's work focused on algae is for macroalgae grown mostly in the ocean (seaweed farming). The Office has a minor effort with microalgae, which focuses on its use for shellfish and finfish hatcheries. Algae of all types have also been evaluated as components of fish feed.

Description of historical R&D emphasis area:

Seaweed farming is a relative newcomer to marine aquaculture but is expanding. NOAA fisheries has supported R&D and permitting for commercial-scale seaweed farms in the Northeast, Northwest, and Alaska. NOAA Fisheries is also responsible for reporting national statistics on products of marine aquaculture. Seaweeds are reported for the first time in 2018 fisheries statistics.

Description of historical macroalgae and microalgae eligibility:

Macroalgae has long been a part of NOAA's aquaculture research and development portfolio, albeit at a small effort relative to shellfish and finfish aquaculture. Microalgae has long been used in shellfish and finfish hatcheries. Some of the founding work on marine microalgae goes back to the early 1900s at <u>NOAA Milford Research Laboratory</u>. Macroalgae work at NOAA's <u>Manchester Research Laboratory</u> dates from the late 1990s. Currently, NOAA is adding macroalgae culture work to its <u>Alaska Fisheries Science Center</u> to expand capacity and service to this growing sector.

Description of extramural funding opportunities that support the development of an algae industry: NOAA supports the development of the algae industry through Sea Grant, Saltonstall-Kennedy, and Small Business Innovation & Research (SBIR) grant awards. The Agency also provides three Marine Fisheries Commissions (Atlantic States, Gulf States, and Pacific States) with funds for an annual grant competition that can support funding for algae work.

Description of intramural funding opportunities that support the development of an algae industry: NOAA's Office of Aquaculture provides funding to investigators at NOAA Fisheries Science Centers (primarily in New England and the Pacific Northwest) and algae research is an eligible topic area.

Description of other Offices in the above agency that support research areas relevant to algae:

The National Sea Grant Office (within the Office of Oceanic & Atmospheric Research), the Technology Partnerships Office, and the National Centers for Coastal Ocean Science (within the National Ocean Service) all support work related to algae culture and/or harmful algal blooms. The Ocean Acidification Program may support algae research.

Description of other interagency working groups that cover research areas relevant to algae: The Subcommittee on Aquaculture (SCA) considers research on algae as a part of its portfolio (<u>https://www.ars.</u> <u>usda.gov/IWGA/index.html</u>). The Interagency Working Group on Ocean Acidification (IWG-OA) likely includes research on algae and its effect on ocean chemistry (<u>https://oceanacidification.noaa.gov/_iwgoa/Home.aspx</u>).

D.3 DOC, NOAA, Sea Grant

Areas of R&D relevant to algae:

Table D.2. Areas of Algae Relevant R&D Investment by NOAA Sea Grant

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	No	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	No	Siting and resources	Yes
Algae crop development	Yes	Regulations and standards	No
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of miscellaneous scope:

The majority of the Office's work focused on algae is for macroalgae grown mostly in the ocean (i.e., seaweed farming). There is some work underway to study the economics and marketing of algae as a food product/additive. Algae of all types have also been evaluated as components of fish feed.

Description of historical R&D emphasis area:

While funding has been awarded for algae research in the past, it has primarily focused on microalgae as food for cultivated shellfish and for "sea vegetables." Only over the past few years have more significant investments been made in macroalgae work.

Description of historical macroalgae and microalgae eligibility:

Sea Grant has never had an algae-specific research call, but it has always been eligible for funding as part of their periodic and generic aquaculture funding opportunities.

Description of extramural funding opportunities that support the development of an algae industry:

The Office funded a Seaweed Hub, which is a multi-state collaboration to share information, better understand challenges, and learn about opportunities within the domestic seaweed industry.

Description of intramural funding opportunities that support the development of an algae industry: The Office provides funding to investigators through their 34 state programs and affiliate institutions and algae research is an eligible topic area.²⁵

Description of other Offices in the above agency that support research areas relevant to algae:

The Office of Aquaculture (within the National Marine Fisheries Service), the Technology Partnerships Office, and the National Centers for Coastal Ocean Science (within the National Ocean Service) all support work related to algal culture and/or harmful algae blooms. The Ocean Acidification Program would likely support algae research.

Description of other interagency working groups that cover research areas relevant to algae:

The Interagency Working Group on Aquaculture (IWG-A) considers research on algae to be part of its portfolio.²⁶ The Interagency Working Group on Ocean Acidification (IWG-OA) likely includes research on algae and its effect on ocean chemistry.²⁷

²⁵ NOAA, "Aquaculture Research," <u>http://noaa.maps.arcgis.com/apps/Shortlist/index.html?appid=7b4af1ef0efb425ba35d6f2c8595600f</u>.

²⁶ USDA, "The Subcommittee on Aquaculture," <u>https://www.ars.usda.gov/SCA/index.html</u>.

²⁷ NOAA, "The Interagency Working Group on Ocean Acidification," <u>https://oceanacidification.noaa.gov/_iwgoa/Home.aspx</u>.

D.4 DOC, NOAA, National Centers for Coastal Ocean Science (NCCOS)

Areas of R&D relevant to algae:

Table D.3. Areas of Algae Relevant R&D Investment by NOAA NCCOS

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	No	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	No
Fundamental biology (intracellular; molecular to cellular)	No	Siting and resources	Yes
Algae crop development	No	Regulations and standards	No
Algae cultivation system development	No	Miscellaneous	No

Description of miscellaneous scope:

NCCOS provides high-quality science, guidance, and technical support to coastal managers, empowering them to maintain healthy, resilient coastal ecosystems while supporting aquaculture development in the coastal zone. Research focuses on developing spatial products and services to support aquaculture siting and coastal management.

The <u>NCCOS Coastal Aquaculture Planning Portal</u> (CAPP) is a toolbox of coastal planning tools designed to assist managers, planners, and industry with sustainable aquaculture development.

Description of historical R&D emphasis area:

N/A

Description of historical macroalgae and microalgae eligibility:

N/A

Description of extramural funding opportunities that support the development of an algae industry: $\ensuremath{\mathrm{N/A}}$
Description of intramural funding opportunities that support the development of an algae industry: $\ensuremath{\mathrm{N/A}}$

Description of other Offices in the above agency that support research areas relevant to algae: $\ensuremath{\mathrm{N/A}}$

Description of other interagency working groups that cover research areas relevant to algae: $\ensuremath{\mathrm{N/A}}$

D.5 DOE, Office of Science (SC), Office of Basic Energy Sciences (BES)

Areas of R&D relevant to algae:

Table D.4. Areas of Algae Relevant R&D Investment by SC BES

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	No	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	No
Fundamental biology (intracellular; molecular to cellular)	Yes	Siting and resources	No
Algae crop development	No	Regulations and standards	No
Algae cultivation system development	No	Miscellaneous	N/A

Description of miscellaneous scope:

N/A

Description of historical R&D emphasis area:

The BES Biosciences programs, and their predecessor programs, have supported fundamental research to understand biological mechanisms and principles in energy-related processes in plants, algae, and microbes. Research did not target development of technology or an algae industry.

Description of historical macroalgae and microalgae eligibility:

Applicants for funding could propose fundamental research studies in microalgae and macroalgae, as appropriate, for the scientific questions to be addressed.

Description of extramural funding opportunities that support the development of an algae industry:

BES supports fundamental research to understand, predict, and ultimately control matter and energy at the electronic, atomic, and molecular levels and does not fund work to develop an algae industry. However, this fundamental research could help underpin the development of an algae industry. The BES Biosciences programs, Photosynthetic Systems and Physical Biosciences, support fundamental research to gain a mechanistic understanding of the biochemistry, chemistry, and biophysics of energy capture, conversion, and storage in natural systems.

Description of intramural funding opportunities that support the development of an algae industry: N/A. See previous response.

D.6 DOE, SC, Office of Biological and Environmental Research (BER), Biological Systems Science Division (BSSD), DOE Joint Genome Institute (JGI)

Areas of R&D relevant to algae:

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	Yes	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	No
Fundamental biology (intracellular; molecular to cellular)	Yes	Siting and resources	No
Algae crop development	No	Regulations and standards	No
Algae cultivation system development	No	Miscellaneous	Yes

Table D.5. Areas of Algae Relevant R&D Investment by BSSD and the DOE JGI

Description of "Miscellaneous" scope relevant to algae:

JGI is a DOE National Genomics User Facility supporting biological research, including algal research, by providing advanced capabilities in the areas of genomics, gene synthesis, metabolomics, data science, and informatics via annual or semiannual Community Science Program calls for proposals.²⁸

Description of historical R&D emphasis area:

The Joint Genome Institute (JGI) was created in 1997 to unite the expertise and resources in DNA sequencing, informatics, and technology development pioneered at the U.S. Department of Energy (DOE) genome centers at Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, and Los Alamos National Laboratory. The JGI invests in R&D to advance technologies and tools to sequence, assemble, annotate, and analyze algal genomes and multi-omics data sets to enable research by JGI users.

Biological and Environmental Research's (BER's) Biological Systems Science Division (BSSD) has supported research that integrates discovery- and hypothesis-driven science with technology development on plant and microbial systems relevant to national priorities in energy security and resilience. Research did not target development of an algae industry.

Description of historical macroalgae and microalgae eligibility:

The JGI provides sequencing, synthesis, and targeted metabolomics support for projects funded by BER, including those studying algae. Projects submitted to the JGI's Community Science Program call focus on large-scale genomic science projects that address questions of relevance to BER missions in sustainable biofuel and bioproducts production, global carbon cycling, and biogeochemistry and could include studies of algae. Projects related to both microalgae and macroalgae are eligible for access to the JGI's capabilities through the Community Science Program. The JGI has awarded Community Science Programs for both macroalgae and microalgae.

For BER BSSD, eligibility varied depending on the specific Funding Opportunity Announcement.

Description of extramural funding opportunities that support the development of an algae industry:

The JGI does not provide extramural funding. However, it provides users access (free of charge) to multidisciplinary state-of-the-art technologies for DNA sequencing, synthesis, and complementary omics capabilities in support of DOE mission-relevant research related to energy and environmental challenges, including algal genomics. Scientists from academia, industry, and government labs can apply for access to JGI capabilities.

BER BSSD does not fund work to develop an algae industry. However, the research supported in some projects could help underpin the development of an algae industry.

²⁸ DOE, "Joint Genome Institute User Programs," <u>https://jgi.doe.gov/user-programs/</u>.

Description of research conferences and meetings relevant to algae that our Office regularly cosponsors, attends, or organizes:

Representatives from the JGI attend:

- Advanced Bioeconomy Leadership Conference (ABLC)²⁹
- International Conference on Algal Biomass, Biofuels, and Bioproducts³⁰
- Annual Meeting of the Phycological Society of America³¹
- European Phycological Congress.³²

Description of Office-held workshops and listening days relevant to algae:

A JGI roundtable was organized with algal researchers at ABLC in San Francisco, CA, in November 2018, and an ad hoc workshop on the JGI-Los Alamos National Laboratory Algal Partnership was held in Denver, CO, in March 2019.

With the start of the algal program at JGI, the plan is to organize algal workshops in conjunction with the JGI User Meetings.

Description of Office-held project and program reviews:

BER conducts triennial reviews of JGI that cover all scientific programs, including algae.

Description of Office listserv and subscription process:

The JGI Communications Office has a mailing list to which the public can subscribe.³³

²⁹ Biofuels Digest, "Advanced Bioeconomy Leadership Conference," <u>http://biofuelsdigest.com/ablc/</u>.

³⁰ Elsevier, "International Conference on Algal Biomass, Biofuels, and Bioproducts," <u>https://www.elsevier.com/events/conferences/international-conference-on-algal-biomass-biofuels-and-bioproducts</u>.

³¹ Phycological Society of America, "Annual Meeting of the Phycological Society of America," <u>https://www.psaalgae.org/psa-annual-meeting</u>.

³² European Phycological Congress, "European Phycological Congress Meeting," http://epcseven.biol.pmf.hr/.

³³ DOE Joint Genome Institute, "Contact Us," <u>https://jgi.doe.gov/contact-us/</u>.

D.7 DOE, Office of Energy Efficiency and Renewable Energy (EERE), Bioenergy Technologies Office (BETO), Advanced Algal Systems (AAS)

Areas of R&D relevant to algae:

Table D.6. Areas of Algae Relevant R&D Investment by BETO AAS

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	No	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	No	Siting and resources	Yes
Algae crop development	Yes	Regulations and standards	Yes
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of miscellaneous scope:

BETO's AAS subprogram supports polyculture work, which could be part of "algae crop development." The value of this work to the Office is to increase productivity and culture robustness (decreased cultivation crashes) by using a mix of algae species and strains as well as native and introduced bacteria. The program also supports R&D on mixotrophic systems, which is when cultivation iterates between feeding algae CO, and organic carbon sources.

Description of historical R&D emphasis area:

AAS invests in early-applied R&D to develop technologies that deliver high-yield, low-cost, and environmentally sustainable algal biomass production, harvesting, and conversion to renewable fuel blendstocks, bioproducts, and chemical intermediates. AAS efforts emphasize delivering algal feedstocks, which are processed algae biomass, to be converted, upgraded, blended, and/or purified to produce finished fuels and bioproducts. AAS interfaces with BETO's Conversion subprogram to hand off technology development for greater investment into conversion of feedstocks to products. AAS interfaces with the Advanced Development and Optimization (ADO) subprogram to hand off technology development to ADO for integration and scale-up.

Description of historical macroalgae and microalgae eligibility:

While macroalgae has been an eligible feedstock eligible to apply for extramural funding opportunities, selections to date have been for microalgae R&D in land-based cultivation systems (open raceway ponds, photobioreactors, and hybrids of the two).

Description of extramural funding opportunities that support the development of an algae industry: BETO's AAS largely awards extramural research through an annual funding opportunity announcement (FOA) managed through EERE Exchange³⁴ and through the DOE Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.³⁵ For the purposes of this document, two links have been provided for each funding opportunity that was listed in Exchange. The "FOA text" links only to the text of the FOA. The "EERE Exchange webpage" link will have links to other information related to the FOA, such as the webinar slide decks.

Extramural funding opportunity announcements:

2010 American Recovery and Reinvestment Act (ARRA) Funding

• The consortia of projects consist of partners from academia, National Laboratories, and private industries based across the country, broadening the geographic range and technical expertise of DOE partners in the area of algal biofuels. Together, the projects represent a diversified portfolio that will help accelerate the development of algal biofuels with the objective of significantly increasing production of affordable, high-quality algal biofuels that are environmentally and economically sustainable.³⁶

Fiscal Year (FY) 2012 Advancements in Sustainable Algal Production (ASAP)

 The objective of this FOA (DE-FOA-0000615)³⁷ was to support outdoor phototrophic algae R&D in nutrient and water use in algal production systems, as well as the development of algal technology testbed facilities. Projects supported BETO goals to model pathways for significant volumes of cost-competitive algal biofuels by 2022.

³⁴ DOE, "EERE Funding Opportunity Exchange," <u>https://eere-exchange.energy.gov/</u>.

³⁵ DOE, "Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program," <u>https://science.energy.gov/sbir/</u>.

³⁶ DOE, "Department of Energy Announces \$24 Million for Algal Biofuels Research," June 28, 2010, <u>https://www.energy.gov/articles/</u> <u>department-energy-announces-24-million-algal-biofuels-research</u>.

³⁷ DOE, "DE-FOA-0000615: Advancements in Sustainable Algal Production (ASAP)," 2012, <u>https://eere-exchange.energy.gov/Default.</u> <u>aspx?Archive=1#Foald338aaba1-7e1c-4c5c-bee7-d5d2490ffd88</u>.

FY 2013 Algae Biomass Yield (ABY)

• This FOA (DE-FOA-0000811)³⁸ focused on integrating algal cultivation and preprocessing R&D from strain development to production of biofuel intermediates. Projects focused on three priority areas: improvements in algal biomass productivity, improvements in preprocessing technologies, and technical advances that enable integration of unit operations.

FY 2014 & 2015 Targeted Algal Biofuels and Bioproducts (TABB)

• The objective of this FOA (DE-FOA-0001162)³⁹ was to find alternative pathways to overcome two key barriers of commercializing algal biofuels: the high cost of producing algal biomass and the low yield of target biofuel and bioproduct feedstocks from algae. The FOA also funded R&D in improving algae productivity through carbon utilization and microbiome engineering.

FY 2015 Incubator 2

 BETO recognized there are novel and potentially disruptive ideas that were not meaningfully addressed in BETO's strategic plan or project portfolio. The Bioenergy Incubator (DE-FOA-0001320)⁴⁰ effort solicited these potentially impactful ideas to enrich the portfolio.

FY 2016 Advancements in Algal Biomass Yield, Phase 2 (ABY2)

• This FOA was directed at advancing yield targets initiated by the ABY FOA (DE-FOA-0001471).⁴¹ Projects selected under this FOA needed to demonstrate production of 2,500 gallons per acre per year of algal intermediate with a reasonable and realistic plan to produce 3,700 gallons per acre per year by the end of their performance period.

- ⁴⁰ DOE, "DE-FOA-0001320: Modification 000002: Bioenergy Technologies Incubator 2," 2015, <u>https://eere-exchange.energy.gov/Default.</u> aspx?Archive=1%23Foaldf0644206-c595-439f-920a-b1da67c2e22b#Foald52c565ad-90e8-4ab4-b25b-2519bb876218.
- ⁴¹ DOE, "DE-FOA-0001471: Advancements in Algal Biomass Yield, Phase 2 (ABY2)," 2016, <u>https://eere-exchange.energy.gov/Default.aspx?Archive=1%23Foaldb644206-c595-439f-920a-b1da67c2e22b#Foaldb49740e6-6066-4e92-892e-670b9d43b838</u>.

³⁸ DOE, "DE-FOA-0000811: Algae Biomass Yield (ABY)," 2013, <u>https://eere-exchange.energy.gov/Default.</u> <u>aspx?Archive=1%23Foaldf0644206-c595-439f-920a-b1da67c2e22b%23Foaldf0644206-c595-439f-920a-b1da67c2e22b#Foaldf0644206c595-439f-920a-b1da67c2e22b.</u>

³⁹ DOE, "DE-FOA-0001162: Targeted Algal Biofuels and Bioproducts (TABB)," 2014, <u>https://eere-exchange.energy.gov/Default.aspx?Search</u> =alga&SearchType=%23Foald561a56f3-f75c-4edc-b9f2-074b6fc76a13#Foald71d6c458-dc5c-4ed3-891b-b9d56f0e75cc.

FY 2017 Productivity Enhanced Algae and Tool-Kits (PEAK)

- The overall objective for projects selected from this FOA (DE-FOA-0001628)⁴² was to identify and test approaches to overcome species-specific, ecological, and practical challenges to achieving improved algal areal productivity and fuel yield (i.e., biomass composition). The two topic areas in this FOA were strain improvement and cultivation biology improvement.
- Regardless of topic area, projects selected under this FOA needed to also support future biological innovation efforts through integrating the development of "toolkits"—analytical/screening methods, technologies, or omics data sets that were complementary to the biological improvement(s) being pursued.
- The FOA required selected projects to participate in a cultivation readiness validation and benchmarking, or friendly "challenge," the PEAK Challenge. In the PEAK Challenge, project performers cultivated their organism(s) in an outdoor relevant environment—a field-based campaign with adequate controls and duration.

FY 2018 Efficient Carbon Utilization in Algal Systems (ECUAS)

• This FOA (DE-FOA-0001908)⁴³ supported research on increasing carbon utilization efficiencies as well as developing direct air capture technologies with the goals of increasing productivity and reducing costs.

FY 2019 Bioenergy Technologies Office Multi-Topic FOA, Cultivation Intensification Processes for Algae Area of Interest (CIPA)

• The objective of the CIPA area of interest within the FY 2019 BETO Multi-Topic FOA (DE-FOA-0002029),⁴⁴ Area of Interest 1) was to increase the harvest yield, robustness, and quality of algae cultivation for biofuels and bioproducts by overcoming challenges in translating laboratory results into successes in outdoor culturing systems.

FY 2020 Bioenergy Technologies Office Multi-Topic FOA, Algae Bioproducts and CO2 Direct-Air-Capture Efficiency (ABCDE)

• The objective of the ABCDE topic area is to lower the cost of algal biofuels through increased algae product value and/or yields (DE-FOA-0002203, Area of Interest 3).⁴⁵ This will be done by overcoming challenges at the interface between the production and processing of algal biomass through improving carbon efficiency by increasing carbon utilization in the system, and/or by employing direct-air-capture technologies.

⁴² DOE, "DE-FOA-0001628: Productivity Enhanced Algae and Tool-Kits (PEAK)," 2017, <u>https://eere-exchange.energy.gov/Default.aspx?Archive=1%23Foaldf0644206-c595-439f-920a-b1da67c2e22b%23Foald7e516e41-db54-4c51-a274-48604245e917#Foald7e516e41-db54-4c51-a274-48604245e917.</u>

⁴³ DOE, "DE-FOA-0001908: Efficient Carbon Utilization in Algal Systems (ECUAS)," 2018, <u>https://eere-exchange.energy.gov/Default.</u> aspx?Archive=1%23Foaldf0644206-c595-439f-920a-b1da67c2e22b#Foaldc8f7ecbf-2028-4bc5-bf40-13d640c4a081.

⁴⁴ DOE, "DE-FOA-0002029: "FY19 Bioenergy Technologies Office Multi-Topic FOA, Cultivation Intensification Processes for Algae Area of Interest (CIPA)," 2019, <u>https://eere-exchange.energy.gov/Default.aspx#Foald912d0039-68a7-4073-8983-2a6eb5c7cf38</u>.

⁴⁵ DOE, "DE-FOA-0002203: "FY20 Bioenergy Technologies Office Multi-Topic FOA, Algae Bioproducts and CO₂ Direct-Air-Capture Efficiency (ABCDE)," 2020, <u>https://eere-exchange.energy.gov/Default.aspx#Foald23bcb339-aa53-4821-9421-d109747cb168</u>.

FY 2020 Bioenergy Technologies Office Multi-Topic FOA, Synergistic Wastewater Integration with Microalgae (SWIM)

• The objective of the SWIM topic area is to integrate algae biomass technologies with municipal wastewater treatment to increase the energy efficiency and lower the costs of wastewater treatment while also enabling consistent yields of algal biomass that meet conversion process specifications for bioenergy, biofuels, and/or bioproducts (DE-FOA-0002203, Area of Interest 2C).⁴⁶

Extramural funding opportunities through the DOE Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs:

BETO participates in the second release of the DOE SBIR/STTR Funding Opportunity each year. The subtopics of the opportunity can vary each year. Since 2013, the Bioenergy Technologies Office has released three algae-specific topics from two different funding opportunities.

FY 2015 SBIR/STTR Phase I Release 2: Bioenergy topic with a subtopic on Solid-Liquid Separations for Algal Systems

- Solid-Liquid Separations for Algal Systems: "Algae grown in open ponds and photobioreactors are dilute (0.1–0.5 grams per liter) and currently require multiple concentration steps. Multiple separation technologies might substitute for these multiple process steps, but only if these technologies are integrated in an optimal (unit operation) fashion. The purpose of this subtopic is to support such integration."
- FOA text.⁴⁷

FY 2018 SBIR/STTR Phase I Release 2: Bioenergy topic with subtopics on Algal Breeding and Solid Liquid Separations for Algal Systems.

- Algal Breeding: "The purpose of this subtopic is to develop tools for breeding algae through traditional approaches to improve phenotypes of interest such as product yield, growth rates, harvest performance, and robustness in culture."
- Solid-Liquid Separations for Algal Systems: "The purpose of this subtopic is to integrate commercial processing technologies as a unit operation that produces slurry with 20%–30% solids from a dilute (0.5 grams/liter or less) algal feed."
- FOA Text.⁴⁸

⁴⁶ DOE, "DE-FOA-002203: "FY20 Bioenergy Technologies Office Multi-Topic FOA, Synergistic Wastewater Integration with Microalgae (SWIM)," 2020, <u>https://eere-exchange.energy.gov/Default.aspx#Foald23bcb339-aa53-4821-9421-d109747cb168</u>.

⁴⁷ DOE, "Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs," <u>https://www.energy.gov/</u> <u>sites/prod/files/2014/10/f18/eere_fy15_phase_1_release_2_topics_10-24-14.pdf</u>.

⁴⁸ FedConnect, "Opportunity: FY 2018 SBIR/STTR Phase 1 Release 2," <u>https://www.fedconnect.net/FedConnect/default.aspx?doc=DE-FOA-0001771&agency=D0E</u>.

Description of intramural funding opportunities that support the development of an algae industry: DOE has an intramural research program through the DOE National Laboratories. Currently, the Advanced Algal Systems supports research at the following National Laboratories: Argonne, Idaho, Los Alamos, Lawrence Livermore, Lawrence Berkeley, Oak Ridge, Pacific Northwest, Sandia and National Renewable Energy Laboratories. There are no publicly available links for the specific projects; however, all of the projects can be reviewed in the 2017 and 2019 Peer Review presentations and publications.^{49,50}

Description of opportunities to engage external stakeholders other than through the mechanisms above. Where appropriate, publicly available links have been provided:

Requests for Information

The Advanced Algal Systems program can use Requests for Information (RFI) to engage stakeholders on special topics. The program has released several RFIs.

- In 2012, the RFI Enhanced Algal Biofuel Intermediate Yields, was seeking information related to the development of algae production and downstream processing technology to enhance the yield of algal biofuel intermediate products.⁵¹
- In January 2019, the FY 2019 Bioenergy Technologies Multi-Topic RFI included a topic on long-term outdoor production of algae feedstocks for applied R&D purposes.⁵²
- In August 2019, the FY 2019 BETO-Wide RFI included the topic Algal Biomass Feedstock Quality and Conversion Interface for Biofuels and Bioproducts to seek information on the effects and importance of algal biomass composition (i.e. feedstock quality) on conversion efficiency and yields of biofuels and/or bioproducts.⁵³

National Algal Biofuels Technology Review

In 2016, Advanced Algal Systems updated the *National Algal Biofuels Technology Review*.⁵⁴ The document reviews the state of U.S. algal biofuels research at every step of the supply chain and serves as a reference for BETO's strategy for the development of sustainable and economical algal biofuels."

⁴⁹ DOE EERE, "2017 Project Peer Review," Washington, D.C.: Bioenergy Technologies Office, 2017, <u>https://www.energy.gov/eere/bioenergy/peer-review-2017</u>.

⁵⁰ DOE EERE, "2019 Project Peer Review," Washington, D.C., Bioenergy Technologies Office, 2019 <u>https://www.energy.gov/eere/</u> bioenergy/2019-project-peer-review.

⁵¹ DOE, "Request for Information: Enhanced Algal Biofuel Intermediate Yields (EABIY)," 2012, <u>https://eere-exchange.energy.gov/Default.as</u> <u>px?Search=algae&SearchType#Foald967b75d2-442d-4c36-b97b-cfbc8f079959</u>.

⁵² DOE, "FY 2019 Bioenergy Technologies Multi–Topic RFI," 2019, <u>https://eere-exchange.energy.gov/Default.aspx?Search=bioenergy#Foald</u> 23010be1-cd9b-428e-a545-24e68524a65b.

⁵³ DOE, "FY 2019 BETO-Wide RFI" 2019, <u>https://eere-exchange.energy.gov/Default.aspx?Search=bioenergy#Foald119c3a4a-f510-4f24-</u> <u>9607-200d4b0880f3</u>.

⁵⁴ DOE EERE, National Algal Biofuels Technology Review, Washington, D.C.: Bioenergy Technologies Office, June 2016, <u>https://www.energy.gov/sites/prod/files/2016/06/f33/national algal biofuels technology review.pdf</u>.

D.8 DOE, EERE, BETO, Advanced Development and Optimization (ADO)

Areas of R&D relevant to algae:

Table D.7. Areas of Algae Relevant R&D Investment by BETO ADO

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	No	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	No	Siting and resources	Yes
Algae crop development	Yes	Regulations and standards	No
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of miscellaneous scope:

ADO provides R&D support to facilitate the process of moving bioenergy technologies from lab to market scales. ADO's goal is to verify, by 2030, integrated systems research at engineering-scale for hydrocarbon biofuel technologies at a mature modeled minimum fuel-selling price of \$2.50 per gasoline gallon equivalent with a minimum 50% reduction in emissions relative to petroleum-derived fuels, using economically advantaged feedstocks to produce renewable fuels and bioproducts.

Description of historical R&D emphasis area:

The strategic goal of the ADO program area is to develop and test bioenergy production technologies through verified proof of performance in engineering-scale systems and relevant environments, research ways to enhance scaling and integrate bioenergy production processes, and identify innovative end uses.

Description of historical macroalgae and microalgae eligibility:

ADO transitions technologies developed by the AAS subprogram and therefore has the same historical practices as AAS.

Description of extramural funding opportunities that support the development of an algae industry: The Advanced Development and Optimization subprogram of BETO largely awards extramural research through an annual funding opportunity announcement managed through EERE Exchange (https://eere-exchange.energy.gov/). For the purposes of this document, two links have been provided for each funding opportunity that was listed on the Exchange. The "FOA text" links only to the text of the FOA. The "EERE Exchange webpage" link will have links to other information related to the FOA, such as webinar slide decks.

Extramural Funding Opportunity Announcements through Exchange:

2009 Recovery Act - Demonstration of Integrated Biorefinery Operations

The intent of this FOA (DE-FOA-0000096)⁵⁵ was to select integrated biorefinery projects that had the
necessary technical and economic performance data that validated their readiness for the next level of
scale-up. In general, "integrated biorefineries" employ various combinations of feedstocks and conversion
technologies to produce a variety of products, with the main focus on producing biofuels and bioproducts.
Coproducts or byproducts were allowed and could include additional fuels, chemicals (or other materials),
and heat and power.

FY 2012 Innovation Pilot and Demonstration Scale Production of Advanced Biofuels

The intent of this FOA (DE-FOA-0000739)⁵⁶ was to identify, evaluate, and select innovative pilot- or demonstration-scale integrated biorefineries that could produce hydrocarbon fuels that met or were likely to meet military specifications for JP-5 (jet fuel primarily for the Navy), JP-8 (jet fuel primarily for the Air Force), or F-76 (diesel). The pilot- or demonstration-scale biorefinery had to be integrated from biomass input to fuel output such that the finished product could be used directly as a fuel. Projects from this FOA included various combinations of feedstocks and conversion technologies to produce a variety of products, with the primary focus on producing biofuels.

FY 2016 Project Development for Pilot and Demonstration Scale Manufacturing of Biofuels, Bioproducts and Biopower (PD2B3)

• This FOA (DE-FOA-0001232)⁵⁷ identified, evaluated, and select applications proposed project development and execution plans for the manufacture of advanced or cellulosic biofuels ("Biofuels," as defined in the Energy Investment and Security Act of 2007 [EISA 2007] §201), bioproducts, refinery-compatible intermediates, or biopower in a domestic pilot- or demonstration-scale integrated biorefinery (IBR). Scale-up and validation of these process technologies is essential to enable the industry to build future pioneer- and commercial-scale facilities. The FOA seeks applications for projects to first design and then construct and operate IBR facilities.

⁵⁵ FedConnect, "Opportunity: Recovery Act - Demo of Integrated Biorefinery Ops," <u>https://www.fedconnect.net/FedConnect/default.aspx?R</u> <u>eturnUrl=%2fFedConnect%2f%3fdoc%3dDE-FOA-0000096%26agency%3dDDE&doc=DE-FOA-0000096&agency=DDE</u>.

⁵⁶ DOE, "DE-FOA-0000739: Innovation Pilot and Demonstration Scale Production of Advanced Biofuels," 2012, <u>https://eere-exchange.energy.gov/Default.aspx?Archive=1#Foald4fc2a5ec-3cc0-4c58-8e51-8768ef965113</u>.

⁵⁷ DOE, "DE-FOA-0001232: Project Development for Pilot and Demonstration Scale Manufacturing of Biofuels, Bioproducts and Biopower (PD2B3)," 2016, <u>https://eere-exchange.energy.gov/Default.aspx?Archive=1%23Foald751733aa-d067-485a-aeb6-6927147d81f7</u>.

FY 2017 Integrated Biorefinery Optimization

 This FOA (DE-FOA-0001689),⁵⁸ coordinated with and co-funded by USDA National Institute of Food and Agriculture, identified, evaluated, and selected applications proposing projects to address challenges encountered with the successful scale-up and reliable continuous operation of IBRs for the manufacture of advanced or cellulosic biofuels (see previous FOA for definition) and associated higher-value bioproducts. The FOA sought applications for projects focused on addressing these challenges, reducing risks, and providing resources to accelerate commercialization of biofuels and bioproducts.

FY 2019 Bioenergy Technologies Office Multi-Topic Funding Opportunity Announcement

• In this FOA (DE-FOA-0002029),⁵⁹ algae was an eligible feedstock in two areas of interest. In Area of Interest 4, Systems Research of Hydrocarbon Biofuel Technologies, BETO sought applications for integrated systems research projects—combining technology components, unit operations, or subsystems; testing those under integrated operations; and verifying the integrated process at engineering scale. Area of Interest 5, Optimization of Bio-Derived Jet Fuel Blends, focused on the identification and production of molecules (or categories of molecules) from biomass or waste resources to develop jet fuel blendstock with reduced or zero aromatics.

FY 2020 Bioenergy Technologies Multi-Topic FOA, topic area Scale Up of Bench Applications

• The topic area in this FOA (DE-FOA-0002203),⁶⁰ Scale Up of Bench Applications (SCUBA), aims to reduce the scale-up technology uncertainty and risk of integrating biorefinery technology pathways by focusing on engineering solutions for key process steps, specifically by working on the portion of a process that has the highest scale-up risk. This can include a single or multiple integrated unit operations. The goal of this topic area is to develop specialized engineering-scale equipment that will reduce technological uncertainty and risk of an eventual fully integrated engineering- or pilot-scale facility.

⁵⁸ DOE, "DE-FOA-0001689: Integrated Biorefinery Optimization," 2017, <u>https://eere-exchange.energy.gov/Default.</u> <u>aspx?Archive=1#Foald0f6d881f-f56f-4d39-86e6-df9cc53051a6</u>.

⁵⁹ DOE, "DE-FOA-0002029.0000 FY19 Bioenergy Technologies Office Multi-Topic Funding Opportunity Announcement," 2019, <u>https://eere-exchange.energy.gov/Default.aspx#Foald912d0039-68a7-4073-8983-2a6eb5c7cf38</u>.

⁶⁰ DOE, "DE-FOA-0002203: FY20 Bioenergy Technologies Multi-Topic FOA," 2020, <u>https://eere-exchange.energy.gov/Default.aspx#Foald23bcb339-aa53-4821-9421-d109747cb168</u>.

D.9 DOE, Advanced Research Projects Agency – Energy (ARPA-E)

Areas of R&D relevant to algae:

Table D.8. Areas of Algae Relevant R&D Investment by ARPA-E

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	Yes	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	Yes	Siting and resources	Yes
Algae crop development	Yes	Regulations and standards	No
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of historical R&D emphasis area:

So far, ARPA-E has primarily funded research focused on the production and conversion of macroalgae. Most of the work has been done under the Macroalgae Research Inspiring Novel Energy Resources (MARINER) program, which is supporting the development of new technologies and tools to produce macroalgal biomass at energy-relevant scales cost competitively. This work includes the design and testing of new integrated solutions for cultivation and harvest of macroalgae in a range of different geographies with correspondingly different species of macroalgae. In Phase 2 of the MARINER program, critical design elements of cultivation systems will be built and deployed in the ocean for full season test cycles. The resulting data will feed a stringent techno-economic analysis framework that has been developed in Phase 1 of the program. These efforts are supported through projects focused on the development of computational modeling tools that help in the design and operation of macroalgal farms, design and testing of new underwater and aerial monitoring systems equipped with advanced sensing modalities, and the development of genomics-based breeding tools.

Outside the MARINER program, macroalgal biomass conversion as well as production has been supported under various OPEN solicitations (OPEN 2009, OPEN 2015, and OPEN 2018). Additional work has been funded on nutrient bioextraction using macroalgae under the Solicitation on Topics Informing New Program Areas FOA.

Description of historical macroalgae and microalgae eligibility:

For ARPA-E's OPEN FOA solicitations, macroalgae and microalgae are eligible as topic areas, as long as the ultimate application focuses on energy. The MARINER program was specifically focused on macroalgae. However, there is no inherent limitation for future ARPA-E programs to include microalgae.

Description of extramural funding opportunities that support the development of an algae industry: Currently, ARPA-E is supporting the development of technologies for economically viable, scalable deployment of macroalgae (seaweeds) in the open ocean; conversion of macroalgal biomass; and utilization of macroalgal cultivation to bioextract nutrients from eutrophic regions of the oceans.

- ARPA-E MARINER Program FOA.⁶¹
- ARPA-E MARINER Program Project Descriptions.⁶²

Under ARPA-E's OPEN 2018 FOA, funding is provided for a research project to advance the conversion of macroalgal biomass via anaerobic digestion processes.

Solicitation on Topics Informing New Program Areas, Topic E: Quantification and Valorization of Nutrient Bioextraction by Seaweed (DE-FOA-0001953).⁶³

Description of intramural funding opportunities that support the development of an algae industry:

Through an interagency agreement, ARPA-E is funding NOAA's National Centers for Coastal Ocean Science to develop various geospatial information tools to aid ARPA-E performers and others outside of the program with assessment of aquaculture scalability, siting, and (pre)permitting. NOAA has delivered the National AquaMapper, an easy-to-use tool and map viewer to support offshore aquaculture planning, siting, and assessment of scalability.⁶⁴ NOAA also published OceanReports, a first-of-its-kind smart web application that revolutionizes the way ocean data are accessed, analyzed, and visualized for the entire U.S. Exclusive Economic Zone. Working with the Bureau of Ocean Energy Management and DOE, NOAA leveraged strategic partnerships across the government to unleash the power of open government data. The tool draws on over 100 data sources to analyze "ocean neighborhoods" and identify areas supporting growth of the "blue economy."

ARPA-E is working with Argonne National Laboratory to develop a module for macroalgal cultivation and conversion to fuel products within the Greenhouse gases, Regulated Emissions, and Energy use in Transportation (GREET) model framework.

⁶¹ DOE, "DE-FOA-001726: Microalgae Research Inspiring Novel Energy Resources (MARINER)," 2017, <u>https://arpa-e-foa.energy.gov/</u> Default.aspx?Archive=1#Foaldbd634121-488f-4c13-a13a-88295c643ed5.

⁶² DOE, "ARPA-E MARINER Program Project Descriptions," 2017, <u>https://arpa-e.energy.gov/?q=arpa-e-programs/mariner</u>.

⁶³ DOE, "DE-FOA-0001953: Solicitation on Topics Informing New Program Areas for ARPA-E." 2019. <u>https://arpa-e-foa.energy.gov/Default.</u> <u>aspx#Foalde8647d89-1cac-4b58-8622-1b04de8958c4</u>.

⁶⁴ NOAA, "The National AquaMapper Tool," 2017, <u>https://noaa.maps.arcgis.com/apps/webappviewer/index.</u> <u>html?id=4f12cbde0c22488196dda69d495116cc</u>.

D.10 USDA, National Institute of Food and Agriculture (NIFA)

Areas of R&D relevant to algae:

Table D.9. Areas of Algae Relevant R&D Investment by NIFA

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	Yes	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	Yes	Siting and resources	No
Algae crop development	Yes	Regulations and standards	No
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of miscellaneous scope:

Alongside research, NIFA funds agriculture education and extension projects.^{65,66}

Description of historical R&D emphasis area:

NIFA has been funding algae-based research for many years. The portfolio supports research and development on the genetic development and production of microalgae for many applications including food, phytochemicals, feed, dietary supplements, and biofuels.⁶⁷ While historical funding emphasis has primarily been in applied R&D, NIFA also invests in basic research to support a pipeline of knowledge creation that could radically change agriculture. As part of NIFA's mission to support the nation's producers, processors, and communities, NIFA also invests in process performance R&D and extension services.

⁶⁵ NIFA, "Extension," <u>https://nifa.usda.gov/extension</u>.

⁶⁶ NIFA, "Agriculture and Food Research Initiative (AFRI)," <u>https://nifa.usda.gov/program/agriculture-and-food-research-initiative-afri</u>.

⁶⁷ NIFA, "USDA and DOE Award Biomass Research and Development Grants to Reduce America's Reliance on Imported Oil," May 5, 2011, accessed April 7, 2020, <u>https://nifa.usda.gov/press-release/usda-and-doe-award-biomass-research-and-development-grants-reduce-americas-reliance</u>.

Description of historical macroalgae and microalgae eligibility:

NIFA has and continues to support R&D for macroalgae and microalgae.68

Description of extramural funding opportunities that support the development of an algae industry:

Small Business Innovation Research Program (SBIR) – Phase I69

Applicants seeking funding for upstream technologies and harvesting apply to Topic Area 8.7 (Aquaculture).
 Technologies dealing strictly with downstream processing, conversion, and product development can apply to Topic Area 8.8 (Biofuels and Bioproducts). The 2017 Request for Applications can be found here.⁷⁰

Agriculture and Food Research Initiative (AFRI)71

- AFRI Sustainable Agricultural Systems large integrated programs⁷²
- AFRI Foundational and Applied Sciences and Education and Workforce Development programs⁷³
- The foundational program Bioprocessing and Bioengineering (A1531) could be appropriate for many algae research projects that include a significant engineering component.

Aquaculture Research Competitive Grants Program (AQUA)⁷⁴ Southern Regional Aquaculture Centers Program⁷⁵

Description of other Offices in the above agency that support research areas relevant to algae:

Several USDA offices outside of NIFA also support algae research. Examples include USDA Agricultural Research Service (ARS) and USDA Rural Development (RD) (see section below). ARS is the intramural research arm of USDA, and algae research has included producing algal products from food waste in Hawaii as well as using algal turf scrubbers for nutrient remediation in the Chesapeake Bay watershed. RD has provided loan guarantees through the Biorefinery, Renewable Chemical, and Bio-based Product Manufacturing Assistance Program⁷⁶ to algae companies in the past. Other USDA offices could support algal products and companies in many ways including loan programs, marketing assistance, and export assistance, among many other programs designed to support the full spectrum of agricultural and rural development.

- ⁷² USDA, "AFRI Sustainable Agricultural Systems," <u>https://nifa.usda.gov/program/afri-sas</u>.
- ⁷³ USDA, "AFRI Education and Workforce Development Request for Applications," 2020, <u>https://nifa.usda.gov/funding-opportunity/</u> agriculture-and-food-research-initiative-education-workforce-development.
- ⁷⁴ USDA, "Special Research Grants Program Aquaculture Research," 2019, <u>https://nifa.usda.gov/funding-opportunity/special-research</u>.
- ⁷⁵ Mississippi State University, "Southern Regional Aquaculture Center," <u>http://srac.msstate.edu/theracs.html</u>.
- ⁷⁶ USDA, "Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program," 2019, <u>https://www.rd.usda.gov/programs-services/biorefinery-renewable-chemical-and-biobased-product-manufacturing-assistance</u>.

⁶⁸ NIFA, "Request for applications Small Business Innovation Research (SBIR) Program Phase I," accessed April 7, 2020," <u>https://nifa.usda.gov/funding-opportunity/small-business-innovation-research-program-phase-i</u>.

⁶⁹ USDA, "Small Business Innovation Research Program - Phase I," <u>https://nifa.usda.gov/funding-opportunity/small-business-innovation-research-program-phase-i</u>.

⁷⁰ GovTribe, "Small Business Innovation Research Program – Phase 1," <u>https://govtribe.com/opportunity/federal-grant-opportunity/small-business-innovation-research-program-phase-i-usdanifasbir006365</u>.

⁷¹ USDA, "AFRI Request for Applications," <u>https://nifa.usda.gov/afri-request-applications</u>.

Description of other interagency working groups that cover research areas relevant to algae:

Another research area relevant to algae is the Subcommittee on Aquaculture (previously known as the Interagency Working Group on Aquaculture and the Joint Subcommittee on Aquaculture).⁷⁷

Description of research conferences and meetings relevant to algae which are regularly co-sponsored, attended, or organized by the above Office:

There are none that are specific to algae. USDA regularly attends many bioproduct conferences such as the BIO World Congress and the Advanced Bioeconomy Leadership Conference (ABLC). NIFA also regularly attends the annual Aquaculture America conference sponsored by the U.S. Aquaculture Association, the World Aquaculture Society, the National Aquaculture Association, and the National Shellfisheries Association, among others.

Description of the frequency at which the above Office holds workshops or listening days relevant to algae (with titles of previous events and publicly available links):

NIFA Listens is a great opportunity for stakeholder input.⁷⁸ The first NIFA Listens event was held in 2017, and it is anticipated there will be similar input sessions held on a regular basis. NIFA and ARS also hold co-listening sessions relative to their aquaculture programs. ARS uses this as input from interested parties to develop their five-year plan. Algae is open for discussion.

Description of the above Office's project/program reviews, including attendance by other federal agencies and the public availability of review records:

NIFA holds periodic external reviews of its larger programs (e.g., AFRI) as well as its core Science Emphasis Areas (SEAs). There is a panelist selection process that can and often does include members from other federal agencies. Staff in individual programs should be contacted for schedules of any upcoming reviews.

Description of the above Office's public listserv and subscription process for receiving information relevant to algae:

The AFRI landing page⁷⁹ provides an opportunity to subscribe to a mailing list. This will enable subscribers to get notifications when new AFRI Requests for Applications are released. These will not be algae specific, but many programs will cover algae-related research. The NIFA aquaculture program has an aquaculture-related listserv that regularly sends out information germane to the aquaculture industry, including information on algae and algae-related funding opportunities.

⁷⁷ USDA, "The Subcommittee on Aquaculture," <u>https://www.ars.usda.gov/SCA/</u>.

⁷⁸ USDA, "NIFA Listens: Investing in Science to Transform Lives," <u>https://nifa.usda.gov/nifalistens</u>.

⁷⁹ USDA, "AFRI Request for Applications," <u>https://nifa.usda.gov/afri-request-applications</u>.

Description of the above Office's use of opportunities to engage external stakeholders (other than the mechanisms above):

In addition to the NIFA Listens process, external stakeholders are engaged in many ways, such as feedback received during conferences, project advisory boards, workshops, panel reviews, direct emails to program staff, and other formal and informal forums. Stakeholders that would like to provide feedback are encouraged to look at the NIFA Listens opportunity and reach out to program staff in relevant programs.

Description of research conferences and meetings relevant to algae which are regularly co-sponsored, attended, or organized by the above Office:

NIFA frequently supports travel funds for researchers and graduate students to attend research conferences, including those relevant to algae. NIFA also regularly co-sponsors conferences and meetings relevant to algae, but only those proposed by the external research community.

Description of the frequency at which the above Office holds workshops or listening days relevant to algae (with titles of previous events and publicly available links):

As of September 2019, this office has not organized any workshops specifically on algae.

Description of the above Office's project/program reviews, including attendance by other federal agencies and the public availability of review records:

Scientists and engineers from other federal agencies can and do participate in merit review panels for unsolicited proposals.

Description of the above Office's public listserv and subscription process for receiving information relevant to algae:

As of September 2019, this office does not have a public listserv.

D.11 USDA, Rural Development (RD), Rural Business-Cooperative Service, Energy Programs

Areas of R&D relevant to algae:

Table DAO America (Alza - Dalamat		
Table D.10. Areas of Algae Relevant	R&D investment by Rural E	Business-Cooperative Service, Energy Program

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	No	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	No	Siting and resources	Yes
Algae crop development	Yes	Regulations and standards	No
Algae cultivation system development	Yes	Miscellaneous	Yes

USDA RD issues loan guarantees on new, innovative, first-of-its kind commercial facilities. For example, if a business would like to produce fuels, nutraceuticals, proteins, or bioproducts, USDA RD will provide support through loan guarantees and technical assistance to construct and support operations of a first-of-its-kind facility.

Description of historical R&D emphasis area:

RD has historically invested in microalgae research to promote the development of advanced biofuels, renewable chemicals, and bio-based products. In 2009, Sapphire Energy Inc., Integrated Algal BioRefinery (IABR) Facility located near Columbus, NM, was awarded a \$54.5 million loan guarantee through the USDA RD-Cooperative Service's Biorefinery Assistance Program, to build a refined algal oil commercial facility.

Description of historical macroalgae and microalgae eligibility:

While macroalgae is eligible to receive funding, RD has historically funded microalgae projects.

Description of extramural funding opportunities that support the development of an algae industry:

RD partners with the public and private sectors in financial underwriting, R&D, and project development. In addition, RD advances the algae industry by engaging with numerous types of investors, from venture capital, project developers, private laboratories, and lenders to philanthropic and nonprofit organizations.

Description of intramural funding opportunities that support the development of an algae industry: RD partners with NIFA and ARS (as described above in the USDA NIFA section).

Description of other Offices in the above agency that support research areas relevant to algae: Refer to the USDA NIFA section above.

Description of other interagency working groups that cover research areas relevant to algae: USDA and DOE co-chair the Technical Advisory Committee and the Biomass Research and Development Board.⁸⁰

D.12 National Science Foundation (NSF), Directorate for Engineering - Chemical, Bioengineering, Environmental, and Transport Systems (CBET)

Areas of R&D relevant to algae:

<u>Table D.11.</u> Areas of Algae Relevant R&D Investment by Directorate for Engineering – Chemical, Bioengineering, Environmental, and Transport Systems

AREAS OF R&D	IN SCOPE (Yes/No)	AREAS OF R&D	IN SCOPE (Yes/No)
Fundamental biology (extracellular; microbiome to ecosystem scale)	Yes	Downstream processing and product development (harvesting, conversion of biomass to fuels and products, utilizations of waste resources for economic gains)	Yes
Fundamental biology (intracellular; molecular to cellular)	Yes	Siting and resources	No
Algae crop development	Yes	Regulations and standards	No
Algae cultivation system development	Yes	Miscellaneous	Yes

Description of miscellaneous scope:

Because the majority of the proposals the NSF receives and funds are unsolicited, the algae projects supported result in a very diverse portfolio. For a better appreciation of the types of algae projects funded by NSF, this award search tool is publicly available.⁸¹

⁸⁰ "Biomass Research and Development Board," <u>https://biomassboard.gov/</u>.

⁸¹ NSF, "Awards Simple Search," <u>https://www.nsf.gov/awardsearch/</u>.

Description of historical R&D emphasis area:

The NSF has historically funded both basic and applied research in algal ecology, physiology, genetics, and engineering. The research proposals come from the academic community, and the Proposal and Award Policies and Procedures Guide (PAPPG) details eligibility and proposal preparation.

Description of historical macroalgae and microalgae eligibility:

The NSF has funded research in both macroalgae and microalgae and eligibility is made at the individual program level.

Description of extramural funding opportunities that support the development of an algae industry:

The NSF is the funding source for approximately 24% of all federally supported basic research conducted by America's colleges and universities. To identify active awards in the development of an algae industry, please query the NSF Awards Simple Search Tool. To identify extramural funding opportunities for programs housed within specific NSF Directorates, the Directorate for Biological Sciences⁸² and the Directorate for Engineering⁸³ provide descriptions for individual programs that may be well suited to evaluate and ultimately provide resources for extramural algae research. For example, the CBET Program in Cellular and Biochemical Engineering⁸⁴ funds research in engineering photosystems and employing algal species as chassis for synthetic biology, and Engineering invests in high-tech small businesses and collaborations through the Division of Industrial Innovation and Partnerships.⁸⁵

Description of intramural funding opportunities that support the development of an algae industry: The NSF does not currently have intramural funding opportunities to support the development of an algae industry.

Description of other Offices in the above agency that support research areas relevant to algae: Many NSF programs support algae research. The best means to identify specific projects and corresponding funding mechanisms is to utilize the publicly available NSF Awards Simple Search Tool.

⁸² NSF, "Directorate for Biological Sciences," <u>https://www.nsf.gov/dir/index.jsp?org=BIO</u>.

⁸³ NSF, "Directorate for Engineering," <u>https://www.nsf.gov/dir/index.jsp?org=ENG</u>.

⁸⁴ NSF, "Cellular and Biochemical Engineering (CBE)," <u>https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=505547</u>.

⁸⁵ NSF, "Division of Industrial Innovation and Partnerships (IIP)," <u>https://www.nsf.gov/eng/iip/about.jsp</u>.

DOE/EE-2009 July 2020