

Regulatory Developments Regarding Algae Biomass

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ABSTRACT

To ensure that algae biomass as a commercial feedstock is considered appropriately by federal regulators under the Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) initiated in 2015 the Biotechnology Algae Project. OPPT has legal oversight for the production and use of intergeneric microorganisms, including cyanobacteria, eukaryotic microalgae, and their products by application of genetic engineering approaches, including processes collectively referred to as "biotechnology." EPA posted a document, [US Environmental Protection Agency Biotechnology Algae Project](#), when it rolled out the project and notes in the document that OPPT is focusing its project around biotechnology algae applications. This is an important initiative and stakeholders in this commercial space are urged to be aware of it and participate in it as appropriate.

Keywords: algae biomass, TSCA notification, biotechnology

BACKGROUND

Algae are amazing. They consume carbon dioxide and create oxygen. Their potential is great as sources of sustainable food, fuels, fertilizers, specialty oils, and many other products. Many of the secrets and potential value offered by algae are unlocked by biotechnology. The availability today of even more sophisticated technological developments, including genetic tools and related advances in synthetic biology, create even greater potential for the development of algae-derived oils and other commercial products.

Under TSCA, EPA must review "new" algae biomass chemical product notifications as a predicate to commercialization. As part of its efforts to implement TSCA, EPA scientists provide technical support for reporting on new chemical substances and microorganisms that are not yet manufactured or distributed in commerce for commercial purposes. EPA's 1997 document [Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms \(Points to Consider\)](#) assists chemical producers who intend to submit pre-manufacture microbial commercial activity notices (MCAN) or TSCA experimental release applications (TERA) for various commercial products.

EPA correctly believes the *Points to Consider* document assists submitters in identifying and organizing the information and data submitted to OPPT and reviewed as part of the required risk assessment process. An important component of EPA's biotechnology algae document is a somewhat muted statement that it is "currently updating the *Points to Consider* to accommodate the development of new information relevant to risk assessment of biotechnology products regulated under TSCA." According to EPA, the *Points to Consider* document does not currently provide specific support for those using the emerging technologies of algae production and biotechnology. EPA states that to keep its risk assessment process for biotechnology algae open and transparent, it intends "to develop a separate document on the scientific and technological issues it currently understands to be key and unique for evaluating risks from the production and use of biotechnology algae." EPA will develop its "Considerations for Biotechnology Algae" document in parallel with updating the *Points to Consider*.

EPA notes that the number of TSCA biotechnology submissions is increasing rapidly. As of June 2015, the number of submissions had already surpassed previous years' totals. According to EPA, most newer cases employ some form of biotechnology, such as the use of chemically synthesized, codon optimized genes. Importantly, EPA notes its appreciation that some of the algae submissions are from companies that "have had little or no experience with new substance review under TSCA." EPA expects that for these companies in particular, it will be useful to have clearer guidance on how to submit an MCAN or TERA that includes information to help answer the questions that EPA can be expected to ask in its evaluation of their submissions. Consolidating information on emerging technologies will make it easier for interested parties to understand both what information is needed to support risk assessments, as well as why such information is needed.

Importantly, EPA recognizes the potential of biotechnology to create new benefits for society, and, therefore, supports its development in the U.S. According to EPA, the biotechnology algae considerations document "will increase the likelihood that MCAN and TERA submitters receive expeditious EPA review of their submissions, and that any products that are approved, and ultimately commercialized, maximize their benefits to society by minimizing their potential for negative impacts on human health and the environment." EPA "understands that the development and evolution of any technology,

including biotechnology, is subject to debate within democratic societies.” EPA states that as with other emerging technologies, it “believes that the responsible development of biotechnology should include discourse around introducing biotechnology applications and products into society. EPA’s creation of a biotechnology algae considerations document can play a positive role in advancing public discourse and supporting the responsible development of biotechnology products.”

According to EPA, the updates to the *Points to Consider* document “will be enhancements of the current detailed, how-to content for submitters to think about as they prepare submissions.” EPA notes that the current document is organized to reflect the components of risk assessments for microorganisms, but this format is not optimally designed to address specific considerations informing the evaluation of biotechnology or algal technologies submitted under TSCA. The “Considerations for Biotechnology Algae,” as a separate, stand-alone document, can organize the information in a consolidated manner that can assist those developing new microbial technology applications that have emerged since EPA last revised the *Points to Consider*. EPA states that “[o]nce fully developed, [the document] will be a source of information that could be folded into the *Points to Consider*, within its current structure or in other ways, such as an addendum, or it could remain as a stand-alone complement to the *Points to Consider*.” EPA states that it expects that the process of revising the *Points to Consider* and developing a companion document on considerations for biotechnology algae will lead to the identification of technical, environmental, and social science research needs related to the introduction of such products into society.

EPA sponsored an expert workshop in October 2015 for biotechnology algae stakeholders. EPA is now considering the public input it received as it drafts its biotechnology algae considerations document. EPA expects that feedback on the biotechnology algae document will also inform its update of the *Points to Consider* document. EPA recognizes that some input may relate to issues that fall outside the scope of the document and EPA’s premanufacture review authority under TSCA. EPA expects that public awareness of its biotechnology algae document will lead to broader questions about the introduction of such organisms and other biotechnology products into society.

How the algae biomass community can best optimize the regulatory review process should be a central focus of this stakeholder community so that OPPT develops a serviceable biotechnology algae regulatory strategy that fully reflects industry’s needs and commercial sensitivities. Two issues are of significant importance. First, stakeholders need to ensure more precisely whether OPPT’s needs are broadly about biotechnology, more narrowly

focused on algae, or both. The expert workshop that was convened in October 2015 was a useful first step, but insufficient to inform EPA’s judgment.

Second, stakeholders need to provide OPPT with assistance in understanding the current state of play of and developing conventions/rules on nomenclature and the identification of species and strains for the purpose of listing genetically modified microorganisms listed on the TSCA Inventory. Key outcomes of this initiative are to ensure OPPT’s approach does not unduly burden industry members and other biotechnology stakeholders.

OBSERVATIONS

EPA’s posting of the Biotechnology Algae Project is hugely important for the industrial biotechnology communities. EPA’s announcement suggests a broader Agency initiative is underway, and is best read in the context of other relevant developments.

First, on [July 2, 2015, the White House Office of Science and Technology Policy \(OSTP\), the Office of Management and Budget \(OMB\), the U.S. Trade Representative, and the Council on Environmental Quality issued a memorandum](#) directing EPA, the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to update the [Coordinated Framework for the Regulation of Biotechnology](#). The memorandum reflects the Administration’s acknowledgement that the Framework needs to be updated to reflect the tremendous explosion of new technologies addressed by the federal family or regulatory agencies and the lack, in some instances, of a coherent regulatory framework that innovators and others can anticipate and follow in commercializing their products. More information on the update to the Coordinated Framework is available at [“Biotechnology: White House Directs EPA, FDA, and USDA to Update the Coordinated Framework for the Regulation of Biotechnology.”](#) Since July, EPA has convened several public meetings, and plans a third and final meeting at the end of March 2016. The Administration hopes to issue an updated Framework later this year, after public comment is solicited on a draft that may be circulated this summer.

Second, EPA’s updating of its *Points to Consider* document is underway and will greatly facilitate the regulatory notification process. For those of us assisting innovators with preparing MCANs and TERAs, we appreciate that the regulated community and academic research organizations have much to offer EPA with improving and updating the *Points to Consider* document. The sharp spike in MCAN submissions reflects the tremendous commercial activity in this area, and the need for more clarity, more EPA staff, and more EPA resources to manage the demand.

Third, EPA's stand-alone Biotechnology Algae Project confirms what many believe to be true: namely that most recent biotechnology submissions involve some aspect of synthetic biology. EPA expects many more down the road. The Biotechnology Algae Project presumably will capture aspects unique to these applications and focus on algal technologies. This point highlights the need for developers and commercial innovators using this technology to be prepared to explain the steps they are taking to ensure responsible commercial development and use of biotechnology, educate EPA on these measures, and participate actively in the development of new and improved guidance.

On the whole, these activities offer significant opportunities for innovators and interested others. Participation is key, especially now that the Administration is transitioning and momentum for change will need to be sustained to energize a new Administration.