



**Matt Carr**  
Executive Director  
125 St. Paul Street  
P.O. Box 369  
Preston, MN 55965-0369  
(877)531-5512  
[mcarr@algaebiomass.org](mailto:mcarr@algaebiomass.org)

---

Jeffrey Morris  
Acting Director  
Office of Pollution Prevention and Toxics (OPPT)  
Environmental Protection Agency  
1200 Pennsylvania Ave. NW.  
Washington, DC 20460

Submitted via Federal eRulemaking Portal: <http://www.regulations.gov>.

RE: EPA-HQ-OPPT-2015-0508 – Comment on EPA's Draft Algae Guidance for the Preparation of TSCA Biotechnology Submissions

November 30, 2016

Dear Deputy Director Morris,

On behalf of the Algae Biomass Organization (ABO), thank you for the opportunity to comment. ABO is the trade association for the algae industry representing the leading developers of products and ingredients from algae, cyanobacteria and other microorganisms. Our membership includes pioneering algae technology companies, research institutions and academics, technology providers, end users, and a range of other industry partners throughout the algae supply chain.

ABO and its members support an open, science-based approach to regulation of algae that ensures appropriate risk assessments are made as technologies develop. ABO members have been actively engaged with EPA under its TSCA biotechnology program for several years and have found the agency's regulatory program to be effective in assessing potential health and environmental risks while offering a responsible path to commercial development of approved technologies. EPA's development of Algae Guidance for the Preparation of TSCA Biotechnology Submissions demonstrates that EPA is actively and appropriately regulating algae under the existing coordinated framework, and is working diligently to protect the public interest while providing biotech algae developers clarity on data and other information required for biotechnology submissions.

### **Industrial Algae Production**

The industrial application of algae for the production of food and feed, fuel, chemicals and other products has the potential to deliver profound societal benefits. Algae offer a highly sustainable platform for the production of environmentally-friendly alternatives to fossil-derived transportation fuels, fertilizers and toxic chemicals; a new source of protein, oils and other nutritional components that protect fragile fish stocks and avoid deforestation while enhancing global food security; therapeutic proteins and other human and animal health solutions; and a

range of other important applications. Algae can also play a key role in on-farm, municipal, and industrial nutrient management to reduce runoff of nitrogen and other components that contribute to eutrophication, and offer an important opportunity for economically viable mitigation of greenhouse gas emissions from power plants and other industrial sources through carbon capture and utilization (CCU), as recognized by EPA in its Final Rule implementing the Clean Power Plan.

Neither algae nor the biotechnology regulated under the proposed guidance represents an inherent risk. Algae are a ubiquitous, vital component of terrestrial, aquatic and marine ecosystems, and nature's original pollution mitigation technology.

Industrial algae production in the U.S. has a more than 40-year track record of safety. Large-scale (several hundred tons of biomass produced) open pond production facilities exist for *Spirulina* (Earthrise Nutritionals LLC in California) and *Haematococcus* (Cyanotech Corp. in Hawaii). *Nannochloropsis* has been produced heterotrophically in biofermentors at commercial scale in the U.S. for over a decade – first by DSM and now a growing list of companies including TerraVia, ADM and Alltech. There is also a number of smaller facilities producing a variety of strains of microalgae in closed photobioreactors (PBRs), greenhouse enclosed ponds, and open air ponds, both lined and unlined.

Genetically engineered (GE) algae have been safely tested experimentally in open air conditions under TSCA Experimental Release Applications (TERAs) R-13-0003 through -0007 based on EPA's determination that these tests did not present unreasonable risks to human health or the environment. Microbial Commercial Activity Notice (MCAN) applications for GE algae strains from ABO members Algenol, Joule and TerraVia have also been approved by EPA, further reinforcing the safety of industrial algae strains.

The National Academies of Science 2012 review of algal biofuels sustainability<sup>1</sup> found no sustainability concerns, including environmental effects of genetically engineered organisms, to be a definitive barrier to sustainable development of algal biofuels, and that "mitigation strategies for each of those concerns have been proposed and are being developed." With respect to GE algae, the report concluded that for most production systems, "releases to the local landscape likely would result in low survival rates" and that "few rare species of algae could be displaced by invasive algae used to produce biofuel feedstocks." Henley *et al* (2012)<sup>2</sup> also conclude that most GM algal traits are unlikely to confer a selective advantage in nature, and thus would rapidly diminish, resulting in low ecological risk.

Notwithstanding the safe history and low ecological risk of GE algae, ABO supports the publication of guidance on the preparation of TSCA biotechnology submissions for algae as a means to increase the predictability, transparency and public confidence in algae biotechnology regulation. ABO supports appropriate and proportional regulation based on risk assessment that considers both hazard and probability of exposure. Risk Assessments should rely on the best

---

<sup>1</sup> *Sustainable Development of Algal Biofuels in the United States*, National Academies Press, 2012

<sup>2</sup> Henley, W.J.; R.W. Litaker; L. Novoveska; C.S. Duke; H.D. Quemada and R.T. Sayre. 2012 Initial risk assessment of genetically modified microalgae for commodity scale biofuel cultivation. *Algal research* 2:66-77

available science and the data used should be fit for purpose and integrated into the risk assessment using a weight of evidence approach.

ABO urges EPA to ensure that its approach to regulation of GE algae does not unduly burden applicants with requirements that inhibit innovation, stigmatize new technologies, or create trade barriers, as directed by the White House Office of Science and Technology Policy (OSTP).<sup>3</sup>

ABO does have some concern that the substantially expanded scope of information sought by EPA in the draft guidance may be overly burdensome to potential applicants. ABO is also concerned that the proposal to issue algae-specific guidance may be inappropriately construed by stakeholders as an indication that GE algae represent an inherent, or heightened, ecological risk relative to other GE microorganisms. ABO offers the following recommendations to address these concerns.

## **General Recommendations**

### **Purpose, Goals and Reasoning**

To ensure the proposed guidance is properly understood as a tool for clarity and transparency, and not as an indicator of inherent or heightened risk, EPA should clearly articulate in its final guidance the document's purpose and goals. EPA should identify which requirements are specific to algae (versus those required for all microorganisms), and why the agency is including these additional requirements. EPA should also provide:

- (i) Clear explanations of the specific risks being addressed by the EPA and descriptions of how those risks are assessed, including models, where used.
- (ii) The rationale for each piece of information listed in the guidance in terms of how it would inform the risk assessment, and not just for the broad categories of information as in the current draft.
- (iii) An explanation of how the data / information / studies will be weighed and integrated into the risk assessment.

### **Decision Tools**

Given the substantial additional scope of information identified in the proposed guidance for algae relative to other microorganisms, EPA should provide as much assistance as possible to submitters in identifying what information from among the listed items is necessary for any given production system. ABO therefore request that the EPA provide decision making tools to assist submitters in determining what information to provide based on the selected organism and production system. These tools could include:

- (i) Descriptions and examples of the circumstances under which information is useful or necessary to provide to the Agency.

---

<sup>3</sup> *Principles for Regulation and Oversight of Emerging Technologies*  
<http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf> . March 11, 2011.

- (ii) A decision tree to walk a submitter through the information needed based on the characteristics of the organism and containment facility being used.
- (iii) A tiered, or stratified approach to data requirements, such that algae which do not pose any significant risk (by virtue of the characteristics of the organism or the manner in which they are housed) are not subjected to further exhaustive and unnecessary testing.
- (iv) An explanation and description of the type of data required for each tier to enable a submitter to determine what level of data it should provide.
- (v) Organization of any guidance document in a manner which more closely references and tracks the information criteria required for submissions for MCANs or TERAs in EPA's regulations at 40C.F.R Part 725

ABO welcomes the opportunity to work with EPA to develop such tools.

#### Additional Recommendations

- Provide clarification on the definitions of fully contained, uncontained, and partially contained algae production systems, and data needs associated with each.
- Provide examples or guidance on the type of studies, test data or test methodologies sufficient to develop the required data
- Begin identifying genetically engineered algae that can be included on the TSCA inventory based on a history of safe use, the nature of the recipient organism, and other characteristics already in place for other microorganisms.

#### Considerations of Ecological Effects

The key risk assessment questions for algae are strain selection and survival in the receiving environment. If a proposed algae strain is native to the surrounding environment, ecological effects are not anticipated. For strains not native to the surrounding environment, the question becomes one of survival. If a strain is unsuitable for survival in the receiving environment, other risks, such as the potential to produce toxins and the potential for harmful algal blooms or other ecological effects, are mitigated.

By design, the conditions in industrial algae production systems are substantially different from those of the surrounding environment. Temperature, salinity, and other conditions are optimized to maximize productivity and minimize risk of contamination by pests. Strains are also typically optimized to thrive in the system environment, making them unsuitable for survival in the surrounding environment. Non-invasiveness tests by ABO members Algenol and Sapphire have demonstrated the inability of their respective industrial strains to become invasive. Favorable MCAN reviews for ABO members Algenol, Joule and TerraVia further reinforce the safety of industrial algae strains.

ABO agrees that it is important to build a database of environmental effects of algae and cyanobacteria strains that are intended for industrial uses subject to TSCA, and that it is

appropriate for EPA to conduct risk assessments for genetically engineered algae strains proposed for industrial production. However, regulatory risk assessments for algae should be strain-specific and should focus on whether the introduced genetic modifications change the predicted behavior or risk characteristics of the recipient strain. If the modifications are determined not to alter these characteristics, then the likelihood is low that the use of the modified strain would pose any environmental or safety risks.

The Considerations document includes a very comprehensive summary of potential environmental and health impacts that should be considered for uses of algae or cyanobacteria, and we agree it is important to document such properties of the recipient strain. However, EPA's risk assessment for GE algae should focus on whether the proposed modifications are likely to alter any of such properties.

ABO also urges EPA to continue to allow applicants to rely on genomic or proteomic analysis of proposed recipient strains to address whether such strains produce toxins or might be pathogenic or virulent. A significant literature has developed on the genes encoding toxin production or other pathogenic traits in algae and cyanobacteria, and the ability to quickly and routinely search a sequenced genome for the presence of nucleic acid sequences encoding such function can be a powerful tool in assessing the risks of using any given recipient strain in an industrial process.

It is also important to differentiate between risk assessment and risk management. That is, EPA should request specific data from applicants that would be needed to complete a risk assessment (e.g. as outlined in the Considerations document), but not all that information would necessarily lead to a conclusion that a given activity is potentially risky such that risk management and/or monitoring activities should be imposed. For example, data on environmental survival or persistence of a recipient or a modified algae strain could and should be submitted in an MCAN or TERA to the extent available, but it should not be necessary to require monitoring of environmental dispersal in all cases.

## **General Questions**

### **Considerations for Risk Assessment**

Section IV.F of EPA's Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms identifies the information about a containment system that should be provided to assess the potential for release of modified microorganisms from the containment system. The existing guidance in Section F has proven easily adaptable for contained photobioreactors. Companies such as Joule and Algenol have been able to utilize this guidance to successfully submit MCANs describing cyanobacteria photobioreactors to EPA's satisfaction.

ABO wishes to stress that the burden should not be on the submitter to "demonstrate" that a containment system is secure. Neither the TSCA statute nor the Part 725 regulations places such a burden on the applicant. EPA practice in reviewing MCANs has generally acknowledged that contained systems cannot prevent all accidental release; and the provisions in the regulations for

TERAs (Sections 725.239 through 725.288) assume that there will be release from the proposed experimentation and require that outdoor activities be managed and monitored.


Finally, ABO invites EPA to include the 2014 paper by Gressel et al.<sup>4</sup> in finalizing its Considerations for Risk Assessment of GE Algae.

### Transparency

ABO welcomes the opportunity to work with EPA and other stakeholders to continue to increase transparency on the safety of GE algae and their products. The algae industry is proud of its strong history of safety and transparency, and recognizes the importance of public support to the successful deployment of GE algae products. We would welcome the opportunity to collaborate with the agency in developing decision tools and other products that could enhance both the clarity and transparency of GE algae regulation, and stand ready to engage in the ongoing dialogue with EPA and other stakeholders. EPA may also wish to consider establishing a committee of experts in phytoplankton ecology and related fields to provide ongoing input on this important issue.

ABO thanks EPA for working with all stakeholders to ensure algae technologies are safely deployed to leverage their inherent benefits to protect and restore our environment, and feed, fuel and heal a growing population.

Sincerely,

A handwritten signature in black ink, appearing to read 'Matt Carr', with a long horizontal flourish extending to the right.

Matt Carr, PhD  
Executive Director

---

<sup>4</sup> Gressel, Jonathan, Cécile JB van der Vlugt, and Hans EN Bergmans. "Cultivated microalgae spills: Hard to predict/easier to mitigate risks." *Trends in biotechnology* 32.2 (2014): 65-69.