

Public Meeting on EPA's Draft Algae Guidance for the Preparation of TSCA Biotechnology Submissions October 27, 2016, Tempe, AZ

Charge Questions

I. Questions on Considerations of Ecological Effects of Genetically Engineered Algae

Genetically engineered (GE) microorganisms have the potential to affect the ecological dynamics of the natural environment. It has been suggested that there are several areas of ecological impacts that merit evaluation: competition, harmful algal blooms (HABs), food web dynamics, horizontal gene transfer, and releases (Henley *et al.*, 2012). The following charge questions are designed to obtain public input about which components of these areas warrant specific consideration by EPA.

1. *Survival and Competition*

- a. What types of survival and competition studies should EPA consider when GE algae are commercially grown in photobioreactors or open ponds?
- b. Please comment on whether microcosm studies using potential receiving waters are necessary for evaluating potential competitiveness and other ecological effects, or whether standardized aquatic microcosms are adequate.
- c. For open ponds systems, please identify and provide rationale for other ecological endpoints that should be considered when evaluating the potential effects of GE algae.
- d. When evaluating ecological hazards, apart from the ability of GE algae to outcompete indigenous species, please identify and provide rationale for other factors, if any, that may promote HABs in GE algae production.

2. *Food Web Dynamics*

- a. Please identify and provide the rationale for any useful data that EPA should consider when evaluating the potential effects of open pond GE algae on food web dynamics.
- b. Please identify and provide the rationale for any useful endpoints (e.g., biodiversity, growth, reproduction) that EPA should consider when evaluating trophic level effects due to the presence of GE algae.

3. *Horizontal Gene Transfer*

- a. It is hypothesized that horizontal gene transfer (HGT) could occur via exchange of genetic material through various modes of transfer. Please comment on whether our current Points to Consider or Draft Algae guidance sufficiently address HGT issues in cyanobacteria and eukaryotic algae.
- b. Please identify and provide the rationale for any other information that EPA should consider when evaluating the risks of HGT in GE algae.

4. *Releases and Worker Exposures*

- a. Based on current technological advances in process monitoring, please identify and provide the rationale for release and worker exposure estimates that EPA should use in the exposure assessment for algal systems (e.g., photobioreactors, open ponds).
- b. Please comment on which specific process parameters or unit operations should be routinely evaluated to detect these potential releases and exposures.

Suggested Reading

1. Henley, W.J., R.W. Litaker, L. Novoveská, C.S. Duke, H.D. Quemada, and R.T. Sayre. 2012. Initial risk assessment of genetically modified (GM) microalgae for commodity-scale biofuel cultivation. *Algal Research* 2:66-77.
2. Menetrez, M.Y. 2012. An overview of algae biofuel production and potential environmental impact. *Environ. Sci. Technol.* 46:7073-85.
3. Snow, A. and V.H. Smith. Genetically engineered algae for biofuels: A key role for ecologists. *Bioscience* 62:765-8.

II. General Questions

1. The Agency received very few scientific comments elaborating on the data elements of our “Considerations for Risk Assessment of GE Algae” document released in 2015. However, EPA would like to know if other data or information not captured in the current guidelines also warrant consideration. If so, please identify this information.
2. Under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (an amendment to TSCA, signed on June 22, 2016), EPA must issue affirmative findings for all new microorganisms that are subject to review under TSCA. It now requires increased transparency in relaying the basis for EPA determinations for new products of biotechnology. How may EPA collaborate with industry to increase transparency on the safety of GE algae and their products?