

U.S. EPA GM/Synbio Algae Guidance Project

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Purpose. The United States Environmental Protection Agency (EPA) is developing a project to support public dialog concerning the development and use of synthetic biology. One emerging technology over which EPA has oversight responsibility is the production and use of intergeneric cyanobacteria and eukaryotic microalgae (commonly referred to as GM algae) and their products by application of genetic engineering approaches including those called synthetic biology. It is around these applications that EPA is focusing its project.

Background. Under the Toxic Substance Control Act (TSCA), EPA provides technical guidance for those who must report on new chemical substances and microorganisms not yet in commerce. Implementing rules for new microorganisms under TSCA, in 1997 EPA promulgated the Microbial Biotechnology Rule. Connected with this effort, EPA revised its guidance document, called *Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms (Points to Consider)*. Use of the *Points to Consider* assists those who intend to submit pre-manufacture microbial commercial activity notices (MCAN) or TSCA Experimental Release Applications (TERA) for various commercial products by helping them identify and organize the information and data they need to provide to inform EPA's required risk assessments

Project Description. EPA is currently updating the *Points to Consider* to accommodate the development of new information relevant to risk assessment of GM/synbio algae. EPA wishes to keep its risk assessment process for GM/synbio algae open and transparent. To assist in engaging the public, EPA 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 GM/synbio algae. EPA will develop its "considerations for GM/synbio algae" document in concert with updating the *Points to Consider* guidance document. The former will address the specifics of GM/synbio algae technologies while the latter will be revised to address other new microbial technology applications that have emerged since the last revision of this guidance document. This separate "considerations for GM/synbio algae" document will not only be a resource for MCAN and TERA submitters, but can also—through its use as an example of an actual, practical governance tool—advance discourse around the broader societal implications of synthetic biology.

EPA expects that the process of revising the *Points to Consider* guidance document and developing a separate document on considerations for GM/synbio algae will lead to the identification of environmental and social science research needs related to the introduction of such products of synthetic biology into society. Addressing these research needs may directly support EPA's evaluation of such products under TSCA, as well as more broadly advance the responsible development and application of synthetic biology. Therefore, as EPA develops its considerations for GM/synbio algae, it is open to being informed by stakeholder participation about the societal benefits and implications of GM/synbio algae and GM/synbio algae products. Thus, EPA intends to support public engagement on its risk considerations for GM/synbio algae.