Comments submitted to: **EPA Workshop for Public Input on Considerations for Risk Assessment of Genetically Engineered Algae**. EPA Docket Number: EPA–HQ–OPPT–2015–0508

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General comment:
Drastic overhaul of our regulatory processes is long overdue and urgently needed given the pace of new techniques for manipulation of genes, including synthetic biology, as is often applied to microalgae and various microbes. Regulatory oversight is currently dangerously lacking, scattershot across different agencies, with outdated "boundaries" and limitations that prevent it from being effective. Regulatory oversight should apply to products and processes, to food and fuels, to research and commercial activities, not piecemeal. EPA should engage in independent reviews for ALL proposed uses, and assume that none are in fact truly "contained", and all are ultimately aimed towards commercial applications (MCAN would be insufficient). Those assessments and reviews should be done in holistic manner with involvement of ecologists and input from public, not dominated by industry and primarily serving their interest in speedy commercial deregulation. The old system that allows tier one and two exemptions are long outdated and should be eliminated as should the ability for companies to withold information as CBI.

Many in industry claim that there is no boundary between traditional genetic engineering and synthetic biology. The existence of a "boundary" is essentially moot. One may move across the continuum of technologies available and find that the two ends of the continuum are entirely and categorically different in spite of the lack of a clear dividing line. Synthetic biology cannot be regulated under the current processes as it introduces far more drastic changes to genomes, and is applied to microbes whose ecology and evolution over time we know rather little about.

It is time for an overhaul of biotechnology regulatory oversight, and all agencies involved should move to quickly and effectively revise structures and rules towards more appropriate methods for oversight.

Comments on charge questions 1 and 2:

1) Besides toxins and harmful algae blooms (HABS), what other effects may be associated with commercial scale production (eg invasiveness, HGT, ecological effects, effects on aquatic food webs etc.)? a) What types of data can be collected to assess these? b) How can these be detected, measured and monitored?

Engineering efforts are largely focussed on increasing productivity and creating strains that are hardy enough to withstand industrial cultivation conditions. Those in many cases are precisely the same traits that render species more competitive and invasive: ability to monopolize nutrients, grow prolifically, resist pathogens and predators etc. This is the same concern raised in debates about engineering crops for bioenergy monoculture production, as raised by the Ecological Society of America. Only consider that the ecology of microalgae is quite different from crops (see below re “paradox of the plankton”). These differences, along with the vast range of “unknowns” regarding microalgae ecology make it even far more difficult to predict or control invasiveness. Thus we should excercize even far greater precaution.

At this point in reality we may simply be unable to identify and collect the exact relevant data that would allow us to make any realistic assessment of how released GMO algae would behave, because their behavior is contingent on so many circumstantial and location-specific variables. The only reason to detect, measure and monitor is if they are released. We should avoid that, not assume that after the fact monitoring the consequences is sufficient.

2) What algal data are available to help determine the potential effects of large scale commercial production? Are there data from natural occurring or wild type algae when found or grown in high concentrations in uncontained systems that can be used to evaluate the effects of engineered algae grown commercially?

Re microalgae in the wild, the phenomenon referred to as "The Paradox of the Plankton" is relevant. A widely applicable principle of ecology is that the number of species present is generally correlated with the number of limiting resources/nutrients which translates into different "niches". Plankton have been considered a notable exception to this, hence the "paradox". Many many species can coexist in conditions thought to be rather limited in nutrient availability. What appears to be the case is that we vastly underestimated the microniches that exist in aquatic environments, from the perspective of plankton. Following is an abstract from research on the topic: Paradox of the plankton: why do so many species co-exist in a supposedly homogeneous habitat?
https://krohde.wordpress.com/article/the-paradox-of-the-plankton-xk923bc3gp4-40/
Many studies, only some discussed here, have provided evidence for an amazing complexity of the supposedly homogeneous aquatic habitats and their plankton communities. Many problems need much further work, including the effects of plankton-predators and viruses. Nevertheless, we can conclude that the paradox of the plankton can be resolved as follows (Scheffer et al. 2003 [4]): 1) homogeneity due to mixing hardly exists, and even in the open ocean meso-scale vortices and fronts result in spatial heterogeneity; 2) aquatic habitats provide many more niches for niche differentiation than originally thought (different wave lengths of white light; additional essential resources); 3) modelling of plankton communities and experimental studies have shown that even in homogeneous and constant environments plankton may never reach equilibrium, because multi-species competition may lead to oscillations and chaos, contributing to the maintenance of a great

biodiversity. Many of the predictions based on modelling have been supported by field studies. In contrast to many communities in which nonequilibrium conditions occur in largely non-saturated niche space with little interspecific competition, nonequilibrium and chaos in plankton may be caused by such competition.

The summary message is that microalgae ecology is extremely dynamic, and largely not understood. As an example of the problems posed: algae HABs may be regulated in nature largely by viruses, competitors, and changes in the nutrient availability that depend in part on the larger context of species assemblage. If algae are specifically engineered to be resistant to pathogens, and hardy in other respects, as well as prolific, we may render the natural processes for regulation of HABs ineffective.

3) Exposure considerations: What potential exposures do different containment systems pose that should be considered during a risk assessment?   How can a submitter demonstrate their containment is secure:

First of all, clearly open ponds are more risky in terms of the inevitability of release of engineered algae into the wild.   Open ponds can be visited by wildlife- ducks, racoons etc etc. who then carry the algae on to the next habitat. Microalgae are very tiny and can become aerosolized and therefore carried in the air and on the wind, in some cases even causing respiratory illnesses.   It is simply not possible to contain microalgae and many, including among the scientific community, have already expressed this concern which should be taken as basic fact.   Closed PBRs are no guarantee of containmnet, they may only somewhat delay the inevitable (and they are very expensive). Cultivation in PBRs still requires cleaning of containers, dewatering processes and various other steps where release is inevitable.

Additional comments.
There are serious concerns about the broader range impacts from an expanding algae biofuels industry: For example, demands for water, energy and nutrients are in very high demand for any algeae production systems and will likely compete with food production, result in more emissions (from fertilizer production and use among other), have impacts on biodiversity etc etc. If it proves feasible to grow algae on wastewater treatment effluents, this could be beneficial, but the many other pollutants in such waters may render it infeasible.   Meanwhile, growing algae on flu gases from power stations, for example, makes the algae industry dependent upon the ongoing operation of highly polluting practices which is hardly "sustainable".   Also, it appears that control of pathogens, invasives and predators in cultures is a major problem. The widespread use of herbicides and other chemical controls could result in very major negative impacts, along the lines of the vast increase in use of glyphosates that accompanies many GMO crops.