INSTITUTE FOR AGRICULTURE AND TRADE POLICY

Oral Statement for the Environmental Protection Agency Workshop for Public Input on Considerations for Risk Assessment of Genetically Engineered Algae: Session 3 on Advanced Genetic Engineering
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I am Steve Suppan, a Senior Policy Analyst with the Institute for Agriculture and Trade Policy (IATP) in Minneapolis, Minnesota. IATP has worked on cellulosic biofuels development policy intermittently since about 2000. We hope the following comments will help the EPA prepare its "Points to Consider" guidance to industry document on genetically engineered micro-organisms.[i]

Three European Commission Scientific Committees have in effect responded jointly to the first question for Session 3 in their 2015 "Preliminary Opinion [on] Synthetic Biology Risk Assessment Methodologies and Safety Aspects." I quote from the summary: "Currently available safety locks used in genetic engineering such as genetic safeguards (e.g. auxotrophy and kill switches) are not yet sufficiently reliable for SynBio. Notably, SynBio approaches that provide additional safety levels, such as the genetic firewalls, may improve containment compared with classical genetic engineering. However, no single technology solves all biosafety risks and many new approaches will be necessary."[ii]

The current lack of reliable biosafety containment safeguards has a direct relevance to the production of algal biomass products derived from synthetic biology. As stated in a recent review article: "The main concern with GM algae appears to be with regard to the potential escape of either viable GM algae or the relevant transgene(s) into natural ecosystems, the latter by sexual reproduction or horizontal gene transfer (HGT)."[iii] Potential avenues for escape of GM algae include aerosolizing of microalgae from open or even covered ponds; leakage from the plastic lined ponds not subject to civil engineering materials and standards; and escape via microalgae byproducts of photo-bioreactor fuel production, including the application to agricultural

fields of manure containing microalgae from livestock feed[iv] or of biosolids processed from water used in microalgae production.

The Preliminary Opinion, as well as the Presidential Commission for the Study of Bioethical Issues in synthetic biology, assume multiple genetic safeguards will be required to solve biosafety risks.[v] However, as one biosafety research team noted, "the higher the complexity of a biosafety device, the more prone it may be to disturbance and failure" because of multiple physiological burdens placed on the microbial host by the multi-device safeguard.[vi] The same researchers state that building a genetic firewall against HGT from combinations of DNA or RNA not found anywhere in nature "could lead to an effective semantic containment within decades; however, this would not stop a refactored microbe from competing at the physiological level with natural flora and fauna during environmental release."[vii] Investors in algal biofuels, including the Departments of Defense and Energy, must be required to show that the physical and genetic containment barriers of algal biofuels products and by-products prevent gene outcrossing to natural environments.

The second multi-part question 5 posed by the EPA for this session includes the question, "what biological containment methods are best employed?" and what synthetic biology containment information should industry applicants submit for commercialization of algal biofuels. IATP does not have the scientific competence to evaluate which method or methods are most likely to lead to the effective containment of synthetically engineered microalgae. However, we strongly urge the EPA to prohibit commercialization applicants from classifying containment studies and any related environmental or human/animal health data as Confidential Business Information. CBI claims by GMO product developers to U.S. regulators have crippled independent peer-reviewed research to verify safety and efficacy claims made for GMOs.[viii] The EPA should advise industry that applicant biosafety data affecting human, animal or environmental health will not be classified CBI but will be made available by the EPA for peer review.

Finally, and too briefly, we respond to the last question for this session, concerning difference in RNA and DNA that would affect the EPA's approach to synthetically engineered microbes. Synthetic biology's techniques for

interfering with RNA hopefully will not result in scientists' dismissal of non-coding RNA as "noise," just as DNA that did not code for proteins was dismissed as non-functional "junk DNA."[ix] The EPA should require submission of the RNA "noise" as well as information about the expression of gene traits by RNA editing techniques.

One team of synthetic biologists for biofuels production prefers "photosynthetic microbes growing in controlled environments . . . because they are fundamentally more engineerable and do not do as many wasteful things as plants."[x] Just because we do not understand everything that RNA does should not lead the EPA to dismiss RNA "noise" any more than we dismiss as "wasteful" those plant functions that are not readily engineered.

Thank you for the opportunity to present IATP's views on this important public policy issue.

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[i] http://www.gpo.gov/fdsys/pkg/FR-2015-08-25/html/2015-21039.htm

[ii] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_048.pdf at 6.

[iii] http://www.conacyt.gob.mx/cibiogem/images/cibiogem/comunicacion/publicaciones/CBR-V9/Shashi_vol9.pdf

[iv] E.g. http://www.scientificamerican.com/article/can-algae-feed-the-world-and-fuel-the-planet/

[v] http://bioethics.gov/node/172

[vi] Oliver Wright, Guy-Bart Stan and Tom Ellis, "Building-in biosafety for synthetic biology," *Microbiology* 159 (July 2013), 1223.

[vii] Ibid., 1227.

[viii] Kaare M Nielsen, "Biosafety Data as Confidential Business Information," *PLOS Biology* 11(3) (March 2013), 1. doi:10.1371/journal.bbio.1001499

[ix] AF Palazzo and TR Gregory (2014) "The Case for Junk DNA." PLoS Genet 10(5): e1004351. doi:10.1371/journal.pgen.1004351

[x] David Savage, Jeffrey Way and Pamela Silver, "Defossiling Fuel: How Synthetic Biology Can Transform Biofuel Production," *ACS Chemical Biology*, Vol. 3:1 (2008), 16.