INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

COMMENTS ON EPA DRAFT GUIDANCE FOR PREPARATION OF TSCA BIOTECHNOLOGY SUBMISSIONS

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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.

ICTA COMMENTS

The risk assessment guidelines need to be modified to make clear that all kinds of genetic engineering should be covered by the guidelines. The guidelines approach this by recognizing that synthetic DNA even if it copies intragenic DNA may not be identical to the original and thus recommends EPA review of the new organism. The White House memorandum on the revisions of the coordinating framework makes clear that it intends agencies to include all genetic engineered products, not just those that are intergeneric. The key language is found in the first footnote to the White House memo. https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

1 *For the purpose of this memo, "biotechnology products" refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations."*

While the EPA draft language in B.1. partially addresses this issue.[1] Making clear that ALL genetic engineering is subject to the oversight of the EPA would strengthen the document.

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

[1] See Draft Guidance at B.1. "Likewise, if the TSCA subject microorganism is wholly, or significantly synthetic, it may not sufficiently resemble any existing species such that a 'recipient microorganism' can be determined."

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?

ICTA RESPONSE:

The EPA Draft Guidance does a generally excellent job of outlining what a company must do to get its new organisms reviewed and approved by the EPA. However, the EPA has a small staff and the public should be able to review ALL significant information related to environmental and human health and safety related to these organisms.

The EPA must not allow companies to make excessive claims of confidential business information on their genetically engineered micro-organisms. All environmental effects and all human health effects must be publically disclosed. As we noted before, the EPA should consider all genetic engineered microorganisms to be new organisms under TSCA review. Any "editing" of the genome whether using genes from another organism, synthetic genes, or gene editing tools like zinc finger nucleases, TALENS or CRISPR should be subject to approval by the EPA under TSCA.

OTHER ICTA COMMENTS ON THE DRAFT GUIDANCE:

SMALL SCALE INDOOR MESOCOSMS MUST BE REQUIRED

The EPA guidelines need be expanded to require indoor mesocosms or other small scale (Phase 1) trials to demonstrate environmental and human health prior to allowing the company to have an open air outdoor experiment. Even these "Phase 1" trials must demonstrate that the organism does not pose human or environmental health challenges.

"PHASE 2" TRIALS MUST BE IN LOCATIONS THAT ACCOMPLISH GEOGRAPHICAL/ECOLOGICAL ISOLATION OF THE ORGANISM.

If an indoor trial demonstrates that the organism will not pose significant ecological or human health risks, a larger trial could be approved, but it should be located where risks to human and ecological health are minimized.

PHASE 3 TRIALS SHOULD RECEIVE PUBLIC COMMENT BEFORE FINAL EPA APPROVAL

FINALLY, only after these first smaller scale trials are completed and data from them provided to EPA and the public should the EPA approve the large scale growth of the new organism. The EPA should make its conditions for the permit public and subject to a public comment period.

EXPLICIT REVIEW OF ALTERNATIVES, INCLUDING NON-GE ALTERNATIVES

The TSCA law now clearly requires EPA to consider Alternatives when a "chemical (or microorganism) might be restricted or prohibited."

REQUIREMENTS FOR RISK EVALUATION[2] : "C) CONSIDERATION OF ALTERNATIVES.—Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect "

EPA should improve this guidance by explicitly requiring the company to review other ways that the chemicals its organism produces can be produced and comparing its products to those other products. In essence, why is this microorganism, the safest and most sustainable way to produce this chemical?

Can a non-genetically engineered microorganism produce the same results as the engineered organism under review? This should be an explicit part of the review of alternatives.

We also recommend that the EPA staff review The Principles for the Oversight of Synthetic Biology[3] as many of the points we have made are discussed in more detail in this document. The Principles has now been endorsed by over 120 civil society groups.

[2] 130 STAT. 468 PUBLIC LAW 114–182—JUNE 22, 2016
[3] http://www.icta.org/files/2016/09/ICTA_Principles_Oversight-Synthetic-Biology.pdf