Request for Information (RFI): National Biotechnology and Biomanufacturing Initiative[1]

Office of Science and Technology Policy (OSTP)

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Submitted to *biotech@ostp.eop.gov*

The Institute for Agriculture and Trade Policy (IATP) appreciates this opportunity to respond to the RFI about biotechnology and biomanufacturing solutions to achieve societal goals in food, agriculture and climate. We urge OSTP to give as much consideration to the broader systems to which any solution is applied, as to the proposed solution itself. In the case of food and agriculture solutions, the primary systems are biodiversity and the climate. We focus on three of the RFI's 17 questions.

2. Public engagement and acceptance are of critical importance for successful implementation of biotechnology solutions for societal challenges. How might social, behavioral, and economic sciences contribute to understanding possible paths to success and any hurdles? What public engagement and participatory models have shown promise for increasing trust and understanding of biotechnology?

A major source of public distrust in biotechnology is the U.S. system for exempting food and agriculture products derived from genetic engineering (GE) techniques from pre-market safety assessments. According to one analysis of this system in the U.S. Department of Agriculture, as codified in the so-call SECURE rule, "99% of GM plants will be exempt from premarket field testing and data-based risk assessment requirements."[2] This system for exempting new GE plant varieties from risk assessment, as advocated for by GE product developers, is "reconstituting the same conditions that led to the public rejection and mistrust of the first generation of GM foods."[3] First generation products were mostly feed grains for livestock, rather than products for direct human consumption, such as fresh horticulture products. As a result, and in the absence of labeling to clearly distinguish GE agriculture and food products from non-GE products,[4] public

[1] https://www.regulations.gov/document/OSTP-2022-0030-0001

[2] Jennifer Kuzma and Khara Grieger, "Community-led governance for gene-edited crops," *Science*, November 20, 2020. https://www.science.org/doi/10.1126/science.abd1512

[3] Ibid.

[4] Steve Davies, "Judge rules GMO labeling needs more than a QR code," *Agri-Pulse*, September 14, 2022. https://www.agri-pulse.com/articles/18246-gmo-labeling-needs-more-than-electronic-options-judge-rules

rejection and mistrust by retail consumers could result for products with GE traits designed to attract consumers.

Public engagement strategies that employ findings of behavioral science, whether or not directly financed by industry, may not overcome distrust of a regulatory system that eschews risk assessment for most products and that makes the "substantial equivalence" doctrine the fulcrum of risk management decisions. Focus groups to test consumer responses to different explanations used to justify an exemptive system of GE food and agriculture oversight are not likely to build trust.

Agencies routinely classify biosafety data about GM food and agriculture products as Confidential Business Information (CBI).[5] *The combination of exemptions from risk assessment and CBI classifications of a product's biosafety data requires the public to trust that any voluntary submissions of data by product developers to USDA regulatory scientists provide an adequate basis for determination of exemptive status. If the primary purpose of the exemptive system is to provide biotech product developers, their corporations and investors with regulatory certainty and predictability, public engagement strategies to foster trust in the GE products and the exemptive system will be hard to distinguish from corporate public relations.*

To increase trust and understanding of biotechnology, it is imperative that OSTP show that it has considered solutions to an identified social challenge other than those of biotechnology. In other words, OSTP should review responses to this and other RFIs using comparative technology analysis, before promoting persuasive solution responses to receive federal policy and investment. Otherwise, biotechnology, or more specifically, different techniques of genetic engineering, become the "hammer" for every challenge. For example, climate science models project as much as a 24% decrease in maize yields by 2030, while wheat yields are projected to increase by as much as 18% in "major breadbasket regions."[6] *Rather than assume that the multi-trait genetic engineering of seeds is an optimal solution to maize yield decrease and to induce public support for that solution, OSTP should develop a policy that instructs agencies to compare the evidence of other practices or technologies to meet this climate-related and other identified challenges.*

OSTP should review research into non-GE methods to cultivate wheat and other food crops in non-irrigated agriculture under the climate change challenge. For example, OSTP should instruct USDA to review data and studies that document agricultural practices to build soil microbial mass and biodiversity that can sustain crop yields in adverse, if not extreme, agri-environmental conditions with reduced use of agricultural chemicals and no use of GE seeds, usually engineered to resist proprietary pesticide products.[7] *If the purpose of the RFI is to solicit research ideas to*

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[5] Kaara M. Nielsen, "Biosafety Data as Confidential Business Information," *PLOS Biology* March 5, 2013. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3589341/

[6] Jägermeyr, J., Müller, C., Ruane, A.C. *et al.* Climate impacts on global agriculture emerge earlier in new generation of climate and crop models. *Nat Food* **2**, 873–885 (2021). https://doi.org/10.1038/s43016-021-00400-y

[7] E.g., for a review of such studies, see Jules Pretty, "Intensification for redesigned and sustainable agricultural systems," *Science*, November 23, 2018. https://www.science.org/doi/10.1126/science.aav0294

address Grand Challenges, such as the impact of climate change on agricultural production and food systems, OSTP must cast a wider net than to foster yet more research in projects and products whose repeated mono-cropping use will contribute to further eroding biodiversity and/or exacerbating climate change.

If agricultural system challenges are defined to require biotechnology solutions, it will be difficult to distinguish public engagement from corporate claims for biotechnology. The U.S. plant and animal agricultural biodiversity crisis is a Grand Challenge that cannot be "solved" by applying GE techniques to the narrow and narrowing species of "production agriculture." Indeed, if a solution is shown to further reduce biodiversity and agricultural resilience to climate change, OSTP promotion of that solution is likely to increase distrust.

12. What can the Federal Government do to support applied biosafety research and biosecurity innovation to reduce risk while maximizing benefit throughout the biotechnology and biomanufacturing lifecycles?

OSTP should develop policy to urge agencies not to subordinate biosafety and biosecurity research to the purpose of "maximizing benefit." If the results of agency biosafety and biosecurity research and/or that of agency scientific advisory board reviews document a likelihood of harm from the use of a product, then that product should not be released by the exemptive system for commercialization. OSTP's policy should be that agencies must defend the work of biosafety and biosecurity researchers even when their research advises risk managers to require biotechnology product developers to delay or even withdraw commercialization applications to the agencies.

17. What risks are associated with international biotechnology development, and how can the U.S. Government work with allies and partners to mitigate these risks?

There are several risks stemming from the current pattern of international biotechnology development. Among these are: 1) the risk of food insecurity due to the focus on applying biotechnology and the associated "technological package" of fertilizer and pesticide products to export crops, rather than to support cropping and marketing systems that are critical to domestic food security, particularly in Least Developed Countries; 2) the erosion of agricultural plant and animal biodiversity, as government and private sector research and development focus investment on a handful of species that become more vulnerable to disease with the intensification of planting and animal breeding; 3) risks to food security and robust biodiversity due to the forced adoption of the U.S. agricultural biotechnology regulatory regime through trade dispute threats,[8] international development bank loan conditionalities and diplomatic pressure on behalf U.S. corporations.

OSTP can help reduce these risks by requiring agency programs, e.g., U.S. Aid for International Development, to properly audit the performance and costs of U.S. agricultural technology transfer

[8] Sharon Anglin Treat, "Understanding the Agricultural Biotechnology Provisions in the U.S. Mexico Canada Agreement," Institute for Agriculture and Trade Policy, March 2, 2022. https://www.iatp.org/documents/understanding-agricultural-biotechnology-provisions-us-mexico-canada-agreement

and sales, e.g., in USAID support for AGRA, a public private partnership that has failed to document how it has realized claimed food security and yield increase targets.[9]

There is a large literature documenting experiments, some with field trial results, in genetically engineered plant disease resistance.[10] *Any GE plant disease resistant products that prove effective in reducing crop loss face significant technology transfer barriers, not the least of which is the cost of patent intensive products to be paid from scarce dollar reserves and/or policy conditioned loans from public and private donors. With low-income countries faced with making difficult decisions about how to spend their scarce dollar reserves, the U.S. government should not be surprised if those countries opt for lower cost solutions to crop loss caused by plant disease.*

From the viewpoint of food system building and sustainability, the U.S. government should not assume that biotechnology solutions are the most important tool in the proverbial toolbox for food security. Sometimes, more crop loss occurs for want of appropriate technology, such as simple post-harvest infrastructure and industrial refrigeration. Often, farmers seek solutions to minimize their dependence on imported, high-cost inputs, as well as to reduce their exposure to harmful chemicals.

Kofi Annan, both during and after his term as United Nations Secretary General, advocated wholistic planning for food security and rural development, particularly in Africa. In 2016, he wrote:

> American agriculture focuses on corn as a vehicle for sugar, breeds that corn for high yields rather than nutritional value, and processes it to remove whatever nutrients might still remain. This means that Americans get lots of cheap, tasty breakfast cereal that isn't good for them. The current African food system shares some of these features. The seeds available in Africa are bred for yield almost to the exclusion of other traits; the breeders who develop these seeds focus mostly on corn and wheat, so crops such as cassava and sorghum remain unimproved; and roller mills remove nutritional value in Africa just as they do in North America. But there are some reasons to be optimistic.[11]

*Some of these reasons are biotechnological, breeding plants for biofortification to improve African nutrition. Other reasons include the use of digitally transmitted education to proliferate good agricultural practices: "*The good news is that with digital education in basic conservation techniques, such as crop rotation with legumes, so-called green manure, and good water management, smallholder farmers can not only increase yields in the short term but also restore soil health over time. This is crucial, since African soils are the most depleted in the

[9] Timothy Wise, "AGRA: Still failing Africa's farmers," Institute for Agriculture and Trade Policy, March 4, 2022. https://www.iatp.org/agra-still-failing-africas-farmers

[10] E.g., Dong OX, Ronald PC. Genetic Engineering for Disease Resistance in Plants: Recent Progress and Future Perspectives. Plant Physiol. 2019 May;180(1):26-38. doi: 10.1104/pp.18.01224. Epub 2019 Mar 13. PMID: 30867331; PMCID: PMC6501101.

[11] Kofi Annan, "Food and the Transformation of Africa," Kofi Annan Foundation, February 15, 2016. https://www.kofiannanfoundation.org/combatting-hunger/food-transformation-africa/

world."[12] *According to Secretary General Annan, widespread adoption of good agricultural practices and distribution of post-harvest infrastructure, including rural roads to markets, would enable small land holder farmers to feed Africa and greatly reduce import dependence. Rather than define societal challenges in such a way as to privilege agricultural biotechnological solutions, OSTP should approach the international applications of biotechnology within a framework of epistemic humility. Long past us, we hope, are the days of explaining food crises as yield failures in a few commodities that purportedly can be remedied by technologies applied to increase yields in a few cash crops.*

Respectfully submitted,

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[12] Ibid.