

April 5, 2016

Comments on committee members for “Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System” (PIN Number DELS-BLS-15-16).

To Douglas Friedman
Responsible Staff Officer, National Academy of Sciences

We write today to submit comments to the National Research Council about the recently announced committee for its new government-sponsored project to provide advice to Congress about how to update the federal Coordinated Framework for Biotechnology.

The NRC’s committee is overwhelmed with scientists offering pro-development, industry-aligned positions, many of them having undisclosed financial conflicts of interests. At least 9 of the 13 members have conflicts of interests, ties to industry, or histories of promoting commercialization of biotechnology. These financial conflicts of interests and ideological positions creates a one-sidedness that is antithetical to good science and that stands in violation of the Federal Advisory Committee Act (FACA), which requires the NRC to form committees that are independent and balanced—and which requires conflicts of interests to be fully disclosed, which the NRC has not meaningfully done.

The heavy participation of scientists aligned with industry and primarily concerned with the development of biotechnology products is in no way balanced out by experts who advocate precaution or act as strong industry critics—as no such individuals have been invited to be committee members.

The profound lack of balance and independence in the NRC committee serves to politicize the committee in the precise manner that Congress has sought to avoid. We respectfully ask that the NRC dissolve its current committee and reformulate it with independent experts—or a balance of proponents and opponents that reflects mainstream scientific dialogue, where there is a very robust debate about the best way to regulate the products of biotechnology. At the very least, the NRC should publicize the many undisclosed conflicts of interests among most members of the committee, as required by FACA.

Failure to engage critics

The pro-development perspective that dominates the NRC committee is out of step with the broader scientific discourse where many scientists have cited the need for precaution around biotechnology development and presented criticisms about the safety or merits of industry products and practices. When NRC solicited nominations for its committee, Food & Water Watch alerted the NRC to the names of more than 300 experts and scientists who have signed on to a public statement citing safety concerns about genetically engineered crops and foods and highlighting weaknesses in regulatory assessments of these products.¹

These scientists have not taken a political or scientific position for or against the commercialization of biotechnology products, but have merely noted extenuating safety issues that have not been adequately addressed by regulators or the independent scientific community. As such, they would appear to be ideal candidates for the NRC project, given that the goal is to develop an impartial committee of scientists to advise federal regulators about how to update regulations to keep pace with development.

Food & Water Watch is aware that several other public-interest groups also nominated experts to NRC committee who are critical of industry products and practices. Given that NRC received many such nominations, it is troubling that the NRC did not engage a single strong critic to be a part of the committee and instead chose to recruit mainly industry-aligned, pro-development experts.

Finally, more than 100 public-interest groups have formulated a widely circulated document about the best way to regulate products of synthetic biology. “The Principles of Oversight for Synthetic Biology” has substantial stakeholder support and its contents speak directly to the mission of NRC’s project, which is looking at how to update regulations to keep up with new biotechnology developments like synthetic biology.² The “Principles” document takes a very critical and precautionary worldview, a viewpoint that is completely absent from the NRC’s committee, which appears to favor the other extreme, increased commercialization with very little regulatory oversight.

Not a single stakeholder supporting the “Principles” was chosen by NRC to participate in the committee, though several were nominated (including one of the authors), possibly multiple times by multiple groups. A full list of the organizations supporting the document is included at the bottom of this letter, and we recommend that the NRC recruit numerous experts from these groups.

Failure to Include Farmers

Though the coordinated framework primarily and historically has addressed the environmental release of genetically engineered organisms related to agriculture, the only farm-related expertise on the NRC committee comes from individuals who work for or with the biotechnology industry. No farmers have been invited, nor have independent farming organizations.

We recommend that NRC include the perspectives of farmers—especially the perspectives of the thousands of farmers who have suffered economic losses because of GMOs, who have abandoned GMOs because of problems with the technology, or who find their livelihoods at risk due to new biotechnology products in development. Organizations that represent organic and sustainable farming, as well as those representing farmers who have experienced the economic impacts of biotechnology on agricultural input markets and crop markets, should be included in the committee. We would be happy to connect you with organizations working in these areas.

NRC's Proposed Committee Violates FACA

In July 2015, the White House announced it was undertaking a review of the Coordinated Framework of Biotechnology, announcing that an “independent analysis” would be undertaken to help it chart a new course for the Coordinated Framework.

The EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify (1) potential new risks and frameworks for risk assessment and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood. The review will help inform future policy making. Due to the rapid pace of change in this arena, an external analysis should be completed at least every five years.³

As the National Research Council tacitly notes, its work on this project meets the definition of a Federal Advisory Committee under the FACA, which states that government agencies can only use NRC scientific opinions if they come from “fairly balanced” scientific committees free from conflicts of interests—“unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable...”⁴

NRC's committee is neither balanced nor independent, and most of the committee members have undisclosed conflicts of interests. If the NRC insists on carrying out its study with the current committee, the federal government should not use the NRC's advice or recommendations, presenting a waste of taxpayer dollars on this project.

Conflicts of Interests and Industry-Aligned Perspectives

Many of the proposed committee members work on the development of biotechnology tools and products that, in order to be successfully commercialized, may need to go through federal regulators. This presents an obvious conflict of interest given that the NRC project intends to provide guidance to federal regulators about how to regulate biotechnology products.

Beyond financial conflicts of interests, some of the committee members are also on the public record as advocating industry-friendly regulations or federal support for development of biotechnology products. Such political advocacy clearly presents an ideological position that should be balanced or removed from the NRC committee in order to conform to FACA. Yet no such balance exists.

The NRC only disclosed conflicts of interests of two committee members (notably, both of them are conflicts with the biotechnology industry), though it appears that most members, in fact, have financial conflicts of interests.

The two scientists that NRC identifies as having conflicts are, according to NRC, indispensable to the committee. That is, according to the NRC, there are no other available scientists in the world who could replace the specific expertise of these two individuals.

Looking at their biographies, it is extremely difficult to see the uniqueness of their expertise—or to overlook the fact that they both have worked for DowAgroSciences, which has a financial interest in the outcome of NRC’s work. Steven Evans currently works for DowAgroSciences, and Jeffrey Wolt previously worked for DowAgroSciences.⁵ NRC declared a conflict of interest for Wolt, not based on his previous work for the biotechnology industry, but because of financial investments he has in a biotechnology company.⁶

What NRC does not note is that Dr. Wolt’s scientific work today, as an academic at Iowa State University, appears to remain very much geared toward supporting an industry agenda around regulation of biotechnology. In February 2016, just weeks before NRC publicly named him to the committee, a journal article co-authored by Wolt was published in *Plant Biotechnology*, which strongly advocated the biotechnology industry’s favored “product-based” regulation of genetically engineered organisms as opposed to process-based regulation, widely advocated by critics and many independent scientists.⁷ Notably, Wolt declared in that article that he had no conflicts of interest, raising additional ethical questions NRC should consider when reviewing his candidacy.⁸

As noted, Evans and Wolt are not the only two scientists with conflicts of interests and industry-aligned perspectives, which seem destined to steer the NRC project toward biased findings:

-- Steven Bradbury runs a private consulting firm whose web site advertises assisting clients in “registering innovative pest management technologies, including nano-based and biotechnology products.”⁹

-- Richard Amasino has patents on biotechnology¹⁰ and has engaged in political advocacy to reduce regulations over GMO crops.¹¹

--Mary Maxon has promoted commercialization of synthetic biology products to Congress and served as the principal author of a White House document promoting synthetic biology, which was embraced by the biotechnology industry and panned by industry critics.¹² Maxon has technology patents related to biotechnology¹³ and previously worked directly for the biotechnology industry.¹⁴

-- Farren Isaacs is a synbio developer and promoter,¹⁵ who has biotechnology patents.¹⁶

--Richard Murray currently collaborates on synthetic biology development with Amgen and the U.S. military.¹⁷

--Martha Krebs previously worked for a private consulting firm and served as founding director of the California NanoSystems Institute, which works to expand development and commercialization of nanotechnology and which currently partners with private biotechnology companies.¹⁸

--Richard Johnson runs a private consulting firm called GlobalHelix that apparently has no website, making it difficult for stakeholders to meaningfully assess his fitness to serve on the NRC committee or whether he has conflicts through the corporate clients he retains. What is

known is that he is a “retired partner” at Arnold and Porter, a law firm that advocates the interests of its corporate biotechnology clients.¹⁹ Johnson serves alongside industry representatives and synbio developers on the board of BioBricks Foundation.²⁰

Summary and Recommendations

Given the very short timeline that the NRC affords the public to provide comments, Food & Water Watch had limited time to review NRC’s proposed committee members, yet we still found that at least 9 of the 13 members have conflicts of interests, ties to the biotechnology industry or histories of promoting commercialization of biotechnology. It is troubling that NRC did not disclose all financial conflicts of interests, as required by FACA. It is equally troubling that the NRC invited no opponents or strong critics to be part of the committee, instead engineering a totally one-sided panel that violates FACA’s requirement for “balance.”

NRC’s committee is neither balanced nor independent, and it cannot possibly provide meaningful, impartial advice to the federal government, which will have to decline reviewing any findings the NRC makes under the Federal Advisory Committee Act. Any reasonable person can expect the proposed NRC committee to arrive at industry-aligned, pro-development conclusions that favor commercialization of new technological applications of biotechnology and downplay safety concerns.

We respectfully ask the NRC to dissolve the current committee and form a new panel composed of independent scientists and experts—or a balance of biotechnology proponents and critics to reflect the mainstream scientific discourse on this matter. The NRC should read and seriously consider the nominations of all stakeholders involved, including the public-interest groups that took time to provide the NRC with the names of scientists and experts who may be critical of the biotechnology industry.

At the very least, the NRC must publicize the obvious conflicts of interests outlined above and publicly justify why scientists with clear conflicts are absolutely essential and irreplaceable.

If you need more information or have questions, please contact Tim Schwab at tschwab@fwwatch.org.

Thank you.



Wenonah Hauter
Executive Director

Addendum: List of more than 100 Stakeholders supporting the Principles for Oversight of Synthetic Biology:

African Biodiversity Network Agricultural Missions, Inc (AMI) (U.S.) Alliance for Humane Biotechnology (U.S.) Amberwaves (U.S.) Amigos de la Tierra España Asociacion ANDES (Peru) Asociación para la Promoción y el Desarrollo de la Comunidad CEIBA / Friends of the Earth Guatemala Basler Appell gegen Gentechnologie” (Appeal of Basle against Genetic-Manipulation) (Switzerland) Biofuelwatch (International) Biotechnology Reference Group of the Canadian Council of Churches Biowatch South Africa Brazilian Research Network in Nanotechnology, Society, and Environment - RENANOSOMA Bund für Umwelt und Naturschutz Deutschland / Friends of the Earth Germany Canadian Biotechnology Action Network (CBAN) Center for Biological Diversity (U.S.) Center for Food Safety (U.S.) Center for Genetics and Society (U.S.) Center for Humans and Nature (U.S.) Center for International Environmental Law (U.S.) Centro Ecológico (Brazil) Centre for Environmental Justice/Friends of the Earth Sri Lanka CESTA - Amigos de la Tierra, El Salvador Citizens’ Environmental Coalition (U.S.) COECOCEIBA - Friends of the Earth Costa Rica Columban Center for Advocacy and Outreach (U.S.) Community Alliance for Global Justice (CAGJ) (U.S.) Development Fund (Norway) Diverse Women for Diversity (India) Doctors for Food Safety & Biosafety (India) Eonexus (International) Ecoropa (Europe) Envirocare (Tanzania) Environmental Rights Action/Friends of the Earth Nigeria ETC Group (International) Ethiopian Society for Consumer Protection (ETHIOSCOP) European Network of Scientists for Social and Environmental Responsibility (ENSSER) Family Farm Defenders (U.S.) Federation of German Scientists Food Democracy Now! (U.S.) Food & Water Watch (U.S.) Friends of the Earth Australia Friends of the Earth Brazil Friends of the Earth Canada Friends of the Earth Cyprus Friends of the Earth Latin America and the Caribbean (ATALC) Friends of the Earth Mauritius Friends of the Earth U.S. Friends of ETC Group (U.S.) Gaia Foundation (U.K.) Gene Ethics (Australia) GeneWatch UK GLOBAL 2000/FoE Austria Global Forest Coalition (International) GM Freeze (UK) GMWatch (UK) IBON International Indian Biodiversity Forum Indigenous Peoples Council on Biocolonialism (U.S.) Initiative for Health & Equity in Society (India) Injured Workers National Network (U.S.) Institute for Agriculture and Trade Policy (U.S.) Institute for Responsible Technology (U.S.) International Center for Technology Assessment (U.S.) International Peoples Health Council (South Asia) International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers’ Associations (IUF) (International) Jamaican Council of Churches Karima Kaaithiegeni Ambaire (CBO) (Kenya) Latin American Nanotechnology & Society Network (ReLANS) Loka Institute (U.S.) MADGE Australia Inc Maendeleo Endelevu Action Program (MEAP) (Kenya) Maryknoll Office for Global Concerns (U.S.) MELCA-Ethiopia Midwest Environmental Justice Organization (U.S.) Movimiento Madre Tierra (Honduras) Mupo Foundation (South Africa) Nanotechnology Citizen Engagement Organization (U.S.) National Association of Professional Environmentalists (Friends of the Earth Uganda) Navdanya (India) NOAH Friends of the Earth Denmark Non-GMO Project (U.S.) No Patents on Life! (Germany) Northeast Organic Farming Association -- Interstate Council (NOFA-IC) (U.S.) Organic Seed Growers and Trade Association (U.S.) Otros Mundos AC/Amigos de la Tierra (México) Our Bodies Ourselves (U.S.) The Pacific Institute of Resource Management (New Zealand) Partners for the Land & Agricultural Needs of Traditional Peoples (PLANT) (U.S.) Pesticide Action Network North America Pro-Choice Alliance for Responsible Research (U.S.) Pro Natura – Friends of the Earth Switzerland Public Employees

for Environmental Responsibility (PEER) Rescope Programme (Malawi) Research Foundation for Science, Technology, and Ecology (India) Rural Coalition (U.S.) Save our Seeds (Europe) Say No to GMOs! (U.S.) Schweizerische Arbeitsgruppe Gentechnologie SAG (Swiss Working Group on Genetic Engineering) Science & Environmental Health Network (U.S.) Seed Stewards Association of Turkey Sobrevivencia – Amigos de la Tierra Paraguay Sustainability Council of New Zealand Sustainable Living Systems (U.S.) Testbiotech (Germany) Third World Network (International) Timberwatch Coalition (South Africa) Tree Is Life Trust (Kenya) United Methodist Church, General Board of Church & Society USC Canada VivAgora (France) Washington Biotechnology Action Council (U.S.) Women in Europe for a Common Future (International) World Rainforest Movement (International)

¹ Hilbeck, Angelika. “No scientific consensus on GMO safety.” *Environmental Sciences Europe*. Vol.27, Iss.4. January 24, 2015 at Introduction and Conclusion; European Network of Scientists for Social and Environmental Responsibility. “Signatories: No scientific consensus on GMO safety as of 30 October 2013.” October 30, 2013. Available at www.ensser.org/fileadmin/user_upload/signatories_as_of_131210_lv.pdf and on file at Food & Water Watch. Accessed May 19, 2014.

² Hoffman, Eric et al. “The Principles for the Oversight of Synthetic Biology.” Issued jointly by Friends of the Earth, International Center for Technology Assessment and the ETC group. 2012.

³ Executive Office of the President of the United States. “Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.” July 2, 2015 at Section III.

⁴ Federal Advisory Committee Act. 5 U.S.C. app. §15 (b)

⁵ National Academy of Sciences. “Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System.” Committee Membership Information. Available at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49773> and on file. Accessed March 29, 2016.

⁶ National Academy of Sciences. “Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System.” Committee Membership Information. Available at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49773> and on file. Accessed March 29, 2016.

⁷ Wolt, Jeffrey et al. “The regulatory status of genome-edited crops.” *Plant Biotechnology*. Vol.144, Iss.2. February 2016.

⁸ Wolt, Jeffrey et al. “The regulatory status of genome-edited crops.” *Plant Biotechnology*. Vol.144, Iss.2. February 2016.

⁹ Steven P. Bradbury & Associates. Client Services. Available at <http://www.spradbury.com/client-services/> and on file. Accessed March 29, 2016.

¹⁰ Amasino, Richard et al. “Transgenic plants with altered senescence characteristics.” Patent Number 6,359,197. March 19, 2002; Amasino, Richard et al. “Transgenic plants with altered senescence characteristics.” Patent Number 5,689,042. March 19, 2002

¹¹ “Scientists oppose plan to expand biotech regulation.” *Southwest Farm Press*. July 28, 2011; Fedoroff, Nina et al. Letter to Lisa Jackson, Administrator of Environmental Protection Agency. July 5, 2011.

¹² Maxon, Mary. Principal Deputy for Biosciences, Lawrence Berkeley National Laboratory. “The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing.” Testimony before Subcommittee on Research and Technology of Committee on Science, Space and Technology. U.S. House of Representatives. December 8, 2015; Pollack, Andrew. “White House promotes a bioeconomy.” *New York Times*. April 26, 2012.

¹³ Busby, Robert et al. U.S. Patent 6,949, 356. “Methods for improving secondary metabolite production in fungi.” September 27, 2007; Holtzman, Douglas et al. U.S. Patent 7,229,784. “Modulation of secondary metabolite production by zinc binuclear cluster proteins.” June 12, 2007.

¹⁴ Maxon, Mary. Principal Deputy for Biosciences, Lawrence Berkeley National Laboratory. “The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing.” Testimony before Subcommittee on

Research and Technology of Committee on Science, Space and Technology. U.S. House of Representatives. December 8, 2015.

¹⁵ Hathaway, Bill. “Research in the news: Yale researchers create better cellular factories to churn out novel biopolymers.” *YaleNews*. November 16, 2015; Berger, Andy. “Engineered safeguard keeps GMOs in check.” *Discover*. November 30, 2015.

¹⁶ Church, George M. et al. U.S. Patent 8,569,041. “Multiplex automated genome engineering.” October 29, 2013.

¹⁷ Murray, Richard. California Institute of Technology home page. “Cell-free expression of membrane proteins with applications to drug discovery.” Available at http://www.cds.caltech.edu/~murray/wiki/index.php/Cell-Free_Expression_of_Membrane_Proteins_with_Applications_to_Drug_Discovery and on file. Accessed March 30, 2016; “Model-guided discovery and optimization of cell-based sensors.” Available at http://www.cds.caltech.edu/~murray/wiki/index.php/Model-guided_Discovery_and_Optimization_of_Cell-based_Sensors and on file. Accessed March 30, 2016; “Biomolecular circuits for rapid detection and response to environmental events.” Available at http://www.cds.caltech.edu/~murray/wiki/index.php/Biomolecular_Circuits_for_Rapid_Detection_and_Response_to_Environmental_Events and on file. Accessed March 30, 2016.

¹⁸ “Krebs named director of energy efficient building hub at Philadelphia Navy Yard.” *PennState News*. December 18, 2013; Bartlett, Lauren. [Press Release]. “Martha Krebs appointed director of the California NanoSystems Institute and UCLA Associated Vice Chancellor for research.” *UCLA Newsroom*. March 14, 2001; California NanoSystems Institute. About CNSI. Available at <http://www.cnsi.ucla.edu/staticpages/about-us> and on file. Accessed March 30, 2016; California NanoSystems Institute. Industry Partners. Available at <http://www.cnsi.ucla.edu/staticpages/industry-partners> and on file. Accessed March 30, 2016.

¹⁹ McConnell, William. “Four law firms back Monsanto, say Syngenta’s antitrust fears groundless.” *The Street*. June 25, 2015.

²⁰ BioBricks Foundation. Board of Directors. Current list available at <https://biobricks.org/about-foundation/board-of-directors/> and on file. Accessed March 30, 2016.