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Office of Science and Technology Policy
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Submitted by via email to:
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Re: Sustainable Chemistry RFI

The Biotechnology Innovation Organization (BIO) is pleased to offer comments in response to the Office of Science and Technology Policy (OSTP) request for information on sustainable chemistry. Specifically, we seek to inform the development of a consensus definition for the term ‘‘sustainable chemistry’’ and to consider the implications of such a definition.

BIO represents 1,000 members in a biotech ecosystem with a central mission – to advance public policy that supports a wide range of companies and academic research centers that are working to apply biology and technology in the energy, agriculture, manufacturing, and health sectors to improve the lives of people and the health of the planet. BIO is committed to speaking up for the millions of families around the globe who depend upon our success. We will drive a revolution that aims to cure patients, protect our climate, and nourish humanity.

Innovations in biology and technology are generating efficient systems and beneficial products that enable society to better manage complex agricultural, environmental, energy, manufacturing, health, and food production challenges while simultaneously boosting economic well-being across the country. The value of science to advance agricultural and industrial innovation cannot be understated. The adoption of biotechnology in agriculture and industry and the development of biobased technologies has already contributed to food security, sustainability, and climate change solutions. Over the past 25 years it has enabled large shifts in agronomic practices that have led to significant and widespread environmental benefits. At the same time, biotechnology has led to a dramatic paradigm shift in the production of fuels and chemicals facilitating modern biorefineries to convert domestic sources of renewable biomass, wastes, and residues into sustainable low carbon fuels, chemicals, and biobased coproducts (food, feed, nutraceuticals, materials, plastics, etc.).

The United States historically leads the world in its ingenuity and productivity in this space and will continue to lead if the government and industry work in tandem to pave the way for innovation through sound policy and enhanced public awareness about biology's problem-solving qualities. We commend OSTP's acknowledgement that government and industry have a role to play in building and promoting the bioeconomy.

BIO supports public policies centered on innovation to incentivize the adoption of cutting-edge technologies and practices to maintain America's leadership and benefit rural economies. Further, it is crucial that the government establish risk-proportionate, transparent regulations in a timely manner that spur biological innovations and biobased technologies while protecting health and the environment. To sustain and spur the innovative contributions of BIO members, it is necessary to allow the market to operate freely. Government regulations will not be able to keep pace with the speed of innovation in this area. At the same time, it is necessary for the government to assist in the development of sustainable chemistry and to aid in providing consumers and other stakeholders with important information about the environmental and other important measures of sustainable chemistry.

BIO appreciates the opportunity to provide its comments on the information requested by OSTP regarding "sustainable chemistry" and the implications of such a definition.

OSTP Questions

1. **Definition of sustainable chemistry: OSTP is mandated by the 2021 NDAA to develop a consensus definition of sustainable chemistry. Comments are requested on what that definition should include. The definition will inform OSTP and Federal agencies for prioritizing and implementing research and development programs to advance sustainable chemistry practice in the United States. Comments are also requested on how the definition of ''sustainable chemistry'' relates to the common usage of ''green chemistry'' and whether these terms should be synonymous, exclusive, complementary, or if one should be incorporated into the other.**

The definition of "sustainable chemistry" should be flexible and broad enough to encompass a range of processes. As representatives of the biotechnology industry, BIO members utilize a range of processes to produce results that are more sustainable than past practices. We propose that the adopted definition is not overly prescriptive, so that it may encompass a wide-range of these processes. Moreover, by offering a broader definition it will not foreclose processes which may be currently un- or under-developed. The definition should aim to be inclusive of several sustainability principles so that it covers a broad range, but also narrow enough so that the supporting infrastructure is directed towards the actual stakeholders. As noted above, access to resources and guidance will help to spur future innovations, so it is important that the definition does not exclude stakeholders because it is overly prescriptive and rigid.

The definition should acknowledge that innovation in sustainable chemistry will likely outpace existing terms and frameworks. Further, as an emerging field many existing terms fail to fully capture the types of innovation present across the biotechnology industry. Specifically, BIO members would urge OSTP to exclude the current limitations in the Renewable Fuel Standard (RFS) in its definition. The RFS excludes a number of sustainable member initiatives that are innovative and designed to reduce pollution and conserve resources --- goals that we believe are directly related to the purpose of sustainable chemistry. For instance, sustainable chemistry should not exclude processes like the conversion of waste carbon resources. An example of this type of process is when one recycles carbon through biological means such as gas fermentation which can create a sustainable chemistry production system incorporating circular economic principles. Again, since a number of the processes being tested and developed in the biotechnology industry do not fit within any pre-existing definitions, we urge OSTP to avoid limitations in existing definitions that would foreclose current and future sustainable chemistries.

Accordingly, we recommend that the definition of sustainable chemistry remain technology-neutral and focused on the adoption of certain principles. As a baseline, sustainable chemistry should include processes that improve the efficiency of using natural resources. Further, the definition should include, but not be limited to, processes which prevent pollution through the reduction or elimination of hazardous substances in production, operation, and raw material use.

This approach should allow the definition to be broad enough that it aligns with goals for sustainable chemistry referenced elsewhere, such as in the United Nations Sustainable Development Goals. We understand that it may be beneficial for the definition to align with related goals, and to encourage innovation that helps to achieve those goals.

As it relates to "green chemistry" principles, OSTP observes that these terms can be viewed as interchangeable. BIO strongly urges OSTP to avoid adopting this view. While the terms overlap, sustainable is a much more flexible concept than the narrower green concept. These terms may be complementary in many cases, but by suggesting they are interchangeable a number of sustainable chemistry practices will be excluded. Green chemistry may serve as a "best practice" for stakeholders, but its goals are still mostly unachievable. However, sustainable chemistry is actionable today. Therefore, we believe that equating "green chemistry" with "sustainable chemistry" will exclude many processes that improve efficiency of natural resources and reduce or eliminate hazardous substances. Accordingly, we believe that "green chemistry" principles may be incorporated as part of "sustainable chemistry" but should not be used to exclude otherwise sustainable technologies and products.

Finally, one of the key motivators towards the creation of more sustainable chemistry is to impact climate change through the reduction of greenhouse gas emissions. For this reason, it is important that the definition can cover chemical processes that produce products with lower lifecycle greenhouse gas emissions when compared to fossil based chemical products. The reduction in greenhouse gas emissions may come from using sustainable feedstocks with biogenic carbon, from the process itself, or both. We believe that this factor may be contained within the definition of sustainable chemistry or it may be one of the outcome/output metrics used to evaluate the effectiveness of sustainable chemistry. Regardless, it is our hope that OSTP covers this specific category.

2. **Technologies that would benefit from Federal attention to move society toward more sustainable chemistry: What technologies/sectors stand to benefit most from progress in sustainable chemistry or require prioritized investment? Why? What mature technology areas, if any, should be lower priority?**

We believe a number of industries would benefit from federal prioritization. Federal attention to industries that are dependent upon virgin fossil fuels would ultimately result in significant carbon emission reductions. Many localities and states are currently taxing and banning plastic bags, but an investment in sustainable chemistry could offer a more significant and sustainable reduction of our dependence on plastics derived from fossil fuels. Another industry that would benefit from this investment is the fast-fashion industry whose use of synthetic fibers currently accounts for 1.35% of global oil consumption.[1] There is currently very little regulation of this industry or its environmental claims, so incentivizing innovation could really reduce this industry's

[1] https://www.forbes.com/sites/amynguyen/2021/07/11/time-to-go-cold-turkey--new-report-explores-fashions-harmful-addiction-to-fossil-fuel-based-fabrics-and-greenwashing/?sh=6e677475146e

consumption. A number of other industries who utilize virgin fossil fuels would benefit from investment in sustainable chemistry

We also believe that focused investment into synthetic biology would help move the needle on overall sustainability goals. Synthetic biology is a set of concepts, approaches and tools that enable the modification or creation of certain biological organisms. These engineered biological systems can be used to produce energy, manufacture chemicals, and fabricate materials.[2] Synthetic biology is still an emerging field and the extent of its potential is still largely unknown. Investment in this area can potentially contribute to a number of innovations that can span the biotechnology sphere.

3. **Fundamental research areas: What fundamental and emerging research areas require increased attention, investment, and/or priority focus to support innovation toward sustainable chemistry (e.g., catalysis, separations, toxicity, biodegradation, thermodynamics, kinetics, life-cycle analysis, market forces, public awareness, tax credits, etc.). What Federal research area might you regard as mature/robustly covered, or which Federal programs would benefit from increased prioritization?**

Federal research efforts are essential to success among many of the research areas listed. The areas provided (catalysis, separations, toxicity, biodegradation, etc.) are all critical to the development of sustainable chemistry and would benefit from increased attention. While focused efforts may generate significant advancements in any of one of these areas, we believe a more comprehensive approach may lead to more innovation across the spectrum.

At the same time, due to the increasing time pressures to take steps to avoid or limit catastrophic climate change, we believe that federal departments, agencies, and related entities should accelerate and scale-up the commercial deployment of greenhouse gas emission reducing technologies. We would agree with ramping up the federal government's investment in areas that can help to limit climate change.

Another area that would benefit from increased attention is the identification of novel natural chemicals. Companies in the biotechnology sector discover novel chemicals that must be identified (purified and elucidated via activity guided fractionation or other methods to determine the molecular structure, characteristics, etc.), named and assigned a CAS number. This process of elucidation/identification can take up to 10 years due to a lack of funding for this category of

[2] https://ebrc.org/what-is-synbio/

work. Focused efforts in this area would allow the biotechnology industry to find and utilize chemicals in nature that have been proven to work.

4. **Potential outcome and output metrics based on the definition of sustainable chemistry: What outcomes and output metrics will provide OSTP the ability to prioritize initiatives and measure their success? How does one determine the effectiveness of the definition of sustainable chemistry? What are the quantitative features characteristic of sustainable chemistry?**

As mentioned above, the term sustainable chemistry should be flexible and broad enough to represent an array of processes. Accordingly, the potential outcomes and output metrics will be equally varied. Furthermore, the term "sustainable" has no singular meaning or definition. In this context, there exists some well-known and studied metrics by which the environmental and social impacts of production methods, use phase and end-of-life can be measured, including review of energy use, water use, air and water emissions, resource intensity, toxicity, use impacts, recyclability. Many of these are already measured when looking at the life cycle analysis.

A proper assessment must review the process at the various life cycle stages: the metrics used to benchmark whether a technology meets the sustainable chemistry definition should consider the entire life cycle of the process to determine whether it results in an overall reduction of waste and/or more efficient use of natural resources. As one reviews the life cycle stages, it is important to review whether the process has resulted in a lower carbon footprint. The lifecycle analysis should consider the biogenic carbon used in the chemical processes.

The American Chemical Society provides the following broad set of principles[3] which we believe may serve as a useful resource for consideration and selection of metrics:

1. Prevention. Preventing waste is better than treating or cleaning it after it is created. Sustainable chemistry processes that result in less hazardous materials being used are effectively preventing the need for future clean-up;
2. Atom economy. This refers to the efficiency of a reaction and encourages incorporating a higher mass of the reactant atoms in order to prevent waste as unwanted by-products;
3. Less hazardous chemical syntheses. This refers to the use and generation of substances that are less toxic to human health and environment;
4. Designing safer chemicals. While challenging, it should be a goal to develop chemical products that are less toxic while preserving efficiency and functionality;

[3] https://www.acs.org/content/acs/en/greenchemistry/principles/12-principles-of-green-chemistry.html

5. Safer solvents and auxiliaries. Solvents account for a large portion of the mass in chemical operations and they account for 75% of the cumulative life cycle environmental impacts. Improving their toxicity greatly impacts the overall sustainability of a chemical;
6. Design for energy efficiency. Efforts should be made to minimize the energy consumption;
7. Use renewable feedstock. OSTP should review whether the process avoids depleting resources and l whether the process has reduced reliance on non-renewable resources;
8. Reduce derivatives. Use of derivates can typically result in additional steps and generate waste. One way to reduce their use is to incorporate enzymes that can reach with one, independent site of the molecule at a time;
9. Catalysis. The use of catalytic reagents can increase efficiencies and reduce waste in the manufacturing of chemicals;
10. Design for degradation. Degradation can eliminate risk and exposure during the chemical life cycle;
11. Real-time analysis for pollution prevention. Encourage process analysis in order to generate real-time feedback which can further enhance sustainable chemistry goals;
12. Inherent safer chemistry for accident prevention.

Using these metrics will help to assess the effectiveness of sustainable chemistry and provide a framework for determining where federal investments should be prioritized.

5. **Financial and economic considerations for advancing sustainable chemistry: How are financial and economic factors considered (e.g., competitiveness, externalized costs), assessed (e.g., economic models, full life cycle management tools) and implemented (e.g., economic infrastructure).**

Financial and economic considerations for advancing sustainable chemistry can be impacted by policy, investors, and consumers. When considering the economic factors, we believe that the full life cycle must be considered when accounting for greenhouse gas emissions. The costs of feedstock production, chemical production, use and disposal must all be taken into consideration. Accordingly, investment in tools that help to assess sustainable chemistry throughout the lifecycle will provide a better understanding of the overall cost.

6. **Policy considerations for advancing sustainable chemistry: What changes in policy could the Federal government make to improve and/or promote sustainable chemistry?**

The federal government should consider incentives to scale-up and commercialize new sustainable chemistry. This will help to balance the risks to the first to research and develop new technology. There will likely be high startup costs and up-front investments which may be offset by policies that incentive producers and/or purchasers of sustainable chemicals. As it relates to purchasers, we encourage the federal government to review its procurement policies to encourage the selection of biobased products that employ sustainable chemistry.

There are numerous areas that would benefit from review, and we suggest that federal entities review existing policies to determine whether they present any barriers to market that an emerging technology may not be able to overcome. For instance, producers of sustainable chemistry may not be able to produce certain types of studies or require different protections prior to submitting materials.

Finally, BIO requests that OSTP and the Administration implement Congress's requirement that to expand the North American Industry Classification System (NAICS) codes which were previously submitted in response to The Office of Management and Budget's (OMB) request for public input on adopting updates for the 2022 revisions of the NAICS. We seek targeted NAICS codes to properly account for the development of new biobased products and sustainable chemistry technologies. To ensure that federal agencies have access to proper statistical data, the NAICS system must be able to capture this evolving area. Currently, NAICS does not and cannot properly capture biobased manufacturing sectors. BIO urges OSTP and the Administration to complete action, called for by Congress in the 2018 Farm Bill, to develop NAICS codes for renewable chemical manufacturers and producers of biobased products. As Senators Debbie Stabenow (D-MI) and Amy Klobuchar (D-MN) noted in their referenced in their February 22, 2022, letter to the administration:

> "*The 2018 Farm Bill directed the Secretary of Agriculture and the Secretary of Commerce to jointly develop NAICS codes for renewable chemicals and biobased products. In December of 2021, OMB declined to do so, citing the need to collect additional data and instead create product codes for NAPCS. While we are grateful for this step, we encourage you to continue working with industry partners to work toward the establishment of NAICS codes. We also ask that the creation of NAPCS codes be completed swiftly and is correlated with NAICS codes for each product segment in the biobased economy. The NAPCS codes provide information on the products but fails to capture the multiple industries in which the product is sold.*"[4]

As BIO has observed in prior comments, the latest Economic Classification Policy Committee's (ECPC) recommendation not to develop NAICS ignored substantial evidence of the sector's growth and potential. ECPC argued that the framework of the NAICS makes it difficult to

[4] https://www.agriculture.senate.gov/imo/media/doc/FINAL_Stabenow%20Letter%20on%20Biopreferred.pdf

distinguish products and services solely using biobased qualifications, as the NAICS is used to collect data on inputs and outputs. However, a report from the McKinsey Global Institute analyzed the economic and social impact of biological innovation and were able to determine that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs of the global economy.[5] Further, ECPC argued that the current market size for renewable chemicals and biobased plastic resin was not significant enough to create new NAICS industry codes. We think this argument is flawed, based on the Economic Impact Analysis[6] of the U.S. Biobased Products Industry, published by the United States Department of Agriculture's (USDA) BioPreferred® Program, which found that biobased industries support nearly 5 million jobs and contributes almost half a trillion dollars to the economy. The USDA's analysis specifically points out the limitation of performing an accurate sectoral impact analysis without the establishment of NAICS codes for this sector. Since the NAICS is the standard used by federal agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to U.S. businesses, the complete inability to classify and group individual biobased, "production-oriented" businesses according to their contribution to the economy creates research limitations and it is crucial for government tracking and for the expansion of this important sector that these limitations be addressed. Until the federal government has all the metrics to understand the biotechnology industry, it will not be able to understand its value or capture the existing opportunities.

7. **Investment considerations when prioritizing Federal initiatives for study: What issues, consequences, and priorities are not necessarily covered under the definition of sustainable chemistry, but should be considered when investing in initiatives? Public Law 114–329, discussed in the background section above, includes the phrase: ''support viable long-term solutions to a significant number of challenges''. OSTP expects the final definition of sustainable chemistry to strongly consider resource conservation and other environmentally focused issues. For example, national security, jobs, funding models, partnership models, critical industries, and environmental justice considerations may all incur consequences from implementation of sustainable chemistry initiatives such as dematerialization, or the reduction of quantities of materials needed to serve and economic function.**

[5] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives
[6] https://www.biopreferred.gov/BPResources/files/BiobasedProductsEconomicAnalysis2019.pdf

Investment considerations should include federal government recommendations on growing the bioeconomy and the important role that funding for pilot scale operations can have in accelerating access and growth in commercial markets. More specifically, BIO recommends that attention be given to the recommendations on Advancing the American Bioeconomy by the National Science Foundation at this link:
https://nsf.gov/news/factsheets/Factsheet_BioEconomy_v2_D.pdf

Thank you for the opportunity to provide comments.

Sincerely,

John A. Murphy III, Esq.

Chief Policy Officer

Biotechnology Innovation Organization