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Director Shalanda Young
Office of Management and Budget
9215 New Executive Office Building
725 17th St. NW, Washington, DC 20503

Submitted Electronically VIA Federal eRulemaking Portal (www.regulations.gov).

Re: Docket ID: OMB-2023-0012; National Biotechnology and Biomanufacturing Initiative—Measuring the Bioeconomy; Request for Information Response.

Dear Madam,

The Biotechnology Innovation Organization (“BIO”) submits these comments in response to The Office of Management and Budget’s (“OMB”) request for information (“RFI”) seeking public input on how to identify, classify, and measure the bioeconomy for potential inclusion in the North American Industry Classification System (“NAICS”) and North American Product Classification System (“NAPCS”).

BIO is the world’s largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in over 30 countries. BIO is comprised of 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 millions of families around the globe who depend upon our success. BIO will drive a revolution that aims to cure patients, protect our climate, and nourish humanity. BIO represents many of the biotechnology and synthetic biology product developers in North America whose products range from life-saving health care solutions to the reduction of greenhouse gas emissions, and they use the NAICS code for statistical analysis and more reliable reporting for the sector.

I. Executive Summary

OMB requested that the public provide input on seven specific questions related to the identification, classification, and measurement of the bioeconomy. In an effort to provide the most useful responses to the RFI, we have drafted comments that directly respond to the Working Group’s questions. Our responses highlight the following:

- The bioeconomy is a growing segment of the economy and already represents a significant contribution to the economy. The bioeconomy should be measured so its total value can be understood alongside other traditional industries.
- Member industries of the bioeconomy need access to comparative metrics for government funding and private investment tracking purposes.
- The bioeconomy is uniquely connected to current and ongoing national priorities of the Biden administration. Exclusion of the bioeconomy or bundling it within non-biobased market segments will make it difficult for the federal government to track, measure, and reach these national goals.

For these reasons, BIO strongly supports developing a process for the inclusion and implementation of new biotechnology NAICS and NAPCS codes.

II. What information and what high priority concerns should the Working Group consider in making these recommendations for potential revisions to the NAICS and NAPCS that would enable characterization of the economic value of the US bioeconomy.

The Working Group should take into consideration as a high priority that the current lack of metrics counting the bioeconomy makes it challenging for the sector to fully benefit from the vast number of resources directed towards its growth and development. The bioeconomy is becoming a more important part of the economy as it is tied to a number of significant national priorities, such as fighting climate change. It is necessary to have a uniform measurement and accounting system to allow the impact of the bioeconomy to be understood to inform government grants, track the outcome of government funding, and to be discoverable by private investment community.

Another high priority consideration for the Working Group is to consider how characterizing the bioeconomy's inputs and outputs can assist in protecting the sector against its security vulnerabilities. The 2020 National Academies of Science Engineering and Medicine report "Safeguarding the Bioeconomy"¹ was created to assess the scope of the U.S. bioeconomy and to also identify potential economic and national security gaps related to the bioeconomy. The report highlights security risks related to the growth and misuse of the bioeconomy and sets forth risks related to our failure to promote the bioeconomy, protect the bioeconomy, and protect it from harms mediated by the bioeconomy. Ultimately, any efforts to monitor and protect against these potential risks requires the creation and implementation of a system that will identify the various bioeconomy inputs and outputs, so the potential areas of growth and weaknesses are clearly identifiable.

¹ National Academies of Sciences, Engineering, and Medicine. 2020. *Safeguarding the Bioeconomy*. Washington, DC. The national Academies Press. <http://doi.org/10.17226/25525>.

Furthermore, the Working Group should also consider the directive from Congress in the 2018 Farm Bill which requires the creation of NAICS codes for biobased products manufacturers.² Creation of NAICS codes should be a priority in order to move forward the initiatives put forth in the Farm Bill.

III. Which quantitative economic indicators and processes are currently used to measure the contributions of the US bioeconomy? Are these indicators reasonably accurate measures of the product components, scope, and value, of the bioeconomy; and, please explain why?

Currently, there is no comprehensive measurement system that captures the bioeconomy as a whole. As directed by Executive Order 14081, the U.S. Bureau of Economic Analysis recently issued a report to assess the feasibility of a national measurement of the bioeconomy. This report, “Developing a National Measure of the Economic Contributions of the Bioeconomy,” documents that there is no reliable, comprehensive method for measurement.³ There are a limited number of sector-specific metrics. For instance, the U.S. Department of Agriculture measures the bioeconomy as it relates to agriculture and forestry, and the U.S. Department of Energy measures the bioeconomy as it relates to U.S. biomass supply and biodiesel impacts. A related consideration involves the varying definitions of the bioeconomy that exist. The lack of consensus had led to research and reports on the bioeconomy that frequently emphasize different industries and fail to capture the full spectrum of the bioeconomy.

The “Safeguarding the Bioeconomy” report presents three methods to measure the bioeconomy as a subsector of the total economy. One approach values the Gross Value Added (“GVA”) relative to the Gross Domestic Product (“GDP”) which is the value of finished goods and services. The report suggested that this approach may have limitations, and that a more detailed delineation of products may be more useful in the bioeconomy. The second approach uses Input-Output (“I-O”) analysis to assess how the bioeconomy industry sectors interact with other industry sectors in the broader economy. This analysis looks at interdependencies between various economic sectors by identifying how a product or service is related to additional economic activities. Because biobased chemicals serve as raw materials in a variety of sectors, this approach could more accurately assess the overall contribution of bioeconomy. The third approach is the Computable General Equilibrium (“CGE”) analysis which models parts of the economic system and calibrates it to analyze certain activity against values for certain economic parameters. BIO prefers the use of actual metrics over modeled values.

These three methods are not unique to the bioeconomy. Their existence does not negate the need to develop NAICS and NAPCS codes. Each of these methods requires a delineation of the bioeconomy subsectors. Because current government and private industry designations

² Agriculture Improvement Act of 2018, Pub. L. No. 115-334, §9002(f)(1), (2018).

³ Bureau of Economic Analysis, U.S. Department of Commerce. March 2023. *Developing a National Measure of the Economic Contributions of the Bioeconomy*. <http://efaidnbmnnnibpcajpcgclefindmkaj/https://www.bea.gov/system/files/papers/bea-bioeconomy-report.pdf>.

may not align or be comprehensive for biobased services and products, relying on any existing systems means that statistics derived from them will not fully capture the bioeconomy's contributions and growth. Growing the NAICS and NAPCS systems in a more comprehensive way will result in more consistent and accurate analyses.

IV. Which industries not currently measured as unique classification in NAICS related to the bioeconomy should be considered? Similarly, which products not currently measured as a unique classification in NAPCS related to the bioeconomy should be considered? Please describe how a unique classification for such industry or product would meet the principles of NAICS and NAPCS. Please also include a description of the industry or product, with specific examples. Please also provide an explanation of how such industry or product would advance understanding of measuring the bioeconomy.

First, within the bioeconomy there are key categories to prioritize for improved inclusion in the NAICS code system. We concur with the recommendations put forward by the U.S. Department of Agriculture and support the inclusion of seven major production sectors: (1) Agriculture and Forestry; (2) Biobased Chemicals; (3) Biobased Plastic Bottles and Packaging; (4) Biorefining; (5) Enzymes; (6) Forest Products; and (7) Textiles. To this BIO would suggest the addition of carbon capture technologies that are associated with biotechnology. It is also critical for the NAICS and NAPCS systems to continue to capture the contribution of biologics and other forms of biopharmaceutical production.

We agree with Figure 3-2 (below) of the Safeguarding the Bioeconomy report which illustrates segments of the economy which have a bioeconomy component. For instance, NAICS Code 326 "Plastics and Rubber Manufacturing" should include a subsector for biobased plastic production. The chart lists sixteen distinct bioeconomy categories that we recommend for inclusion. Additionally, due to the growth in these sectors, biopesticide, plant incorporated protectants, and biostimulant production should be considered. Distinguishing amongst these agricultural inputs is especially important for tracking growth and investment in these emerging technologies.

TABLE 3-2 Illustrative Bioeconomy Segments and Their Value Encompassed by the Committee’s Definition

Segments	Classification (North American Industry Classification System [NAICS] code, where relevant)	Source of Estimate for Value Added ¹	Value Added in 2016 (millions of dollars)		
			Current	Potential	
Private Industry Sector Segments					
1.	Crop products	11111-6, 11119, 111900pt	Committee calculations; Carlson (2019)	36,740	46,141
2.	Biorefining (food)	311210, 221, 224, 225; 311300	Daystar et al. (2018)	3,023	36,830
3.	Biofuels (ethanol)	324110pt	See note 2	8,361	12,553
4.	Biopharmaceuticals	325412pt	See note 3	31,118	99,575
5.	Biologics (enzymes)	325414	Daystar et al. (2018)	16,918	16,918
6.	Other pharmaceuticals	325412pt	See note 3	93,354	24,894
7.	Biobased petrochemicals	35211	Carlson (2019)	6,726	16,304
8.	Other enzymes	32519pt	Daystar et al. (2018)	11,918	11,918
9.	Other biobased chemicals	325211, 32519, 32522, 325510, 325998, 325611, 325612, 325520, 325991, 325992, 325910, 325613	Daystar et al. (2018)	8,081	50,505
10.	Biobased plastic products	326	Daystar et al. (2018)	997	68,436
11.	Electromedical instruments	334510, 6, 7	Gross output (GO) adjusted to gross value added (GVA)	49,636	49,636
12.	Surgical and medical instruments	339112	GO adjusted to GVA	28,153	28,153
13.	Bioeconomy R&D services	541714, 541715pt	Annex 3-1 discussion	43,090	43,090
Intangible Investments Not Included in Value Added as Detailed Above					
14.	Data services/software purchases	Private bioeconomy segments listed above	National accounts and INTAN-Invest	5,615	7,880
14a. Memo:		Private health care organizations	INTAN-Invest	15,194	—
Public and Nonprofit Sector Segments					
15.	R&D	Life sciences, bioengineering, and biomedical engineering	National accounts, NCSSES surveys	44,546	44,546
16.	Software and data-related analytic services	Classification of functions of government, health	National accounts and SPINTAN project ⁴	14,190	14,190
			Total ⁵	343,730	571,569

NOTES:

1. Reports the source for the estimate of the share of national accounts value added in the “nearest” available detailed industry. The final value added estimate for each activity also includes the contribution of intangibles not in the national accounts developed from a detailed version of the estimates reported at www.intaninvest.net.

2. Estimate based on fraction of gasoline that is ethanol. Biomass electric power generation is not separately listed; available estimates suggest value added in this activity was \$635 million in 2016.

3. Estimate based on Otto et al. (2014) and the National Center for Science and Engineering Statistics Business R&D and Innovation Survey data reviewed below in the section on the direction of the bioeconomy.

4. SPINTAN (Smart Public Intangibles) refers to a European Commission Framework-financed project whose research consortium included The Conference Board. See www.spintan.net. The estimates of public- and nonprofit-sector intangibles developed for the SPINTAN project are designed to complement those for the market sector found at www.intaninvest.net.

5. Excludes line 14a.

With respect to product codes, BIO suggests giving priority to establishing NAPCS codes to delineate entirely new biobased products. For example, a NAICS code that captures a biobased process for acetone production may be adequate to capture the contribution of the bioeconomy, while entirely new classes of chemistry that are largely biobased, such as PHA and PLA polymers, warrant priority attention for both NAICS and NAPCS code development.

We believe that the inclusion of these industries aligns well with both NAICS and NAPCS principles. First, NAICS is production-oriented and focuses upon grouping identical or similar production processes together. The inclusion of these codes in no way disrupts that process. The recommendation is to include additional NAICS codes carved out the existing listed industries and provide sub-segments that relate to the bioeconomy. Doing so will provide a more accurate reflection of the economy. Secondly, one of NAICS's principles is to "give special attention to developing production-oriented classifications for: (a) new and emerging industries . . . , and (c) industries engaged in the production of advanced technologies."⁴ The bioeconomy is emerging and already contributes considerably to the economy. The bioeconomy offers promising solutions to climate issues, food supply concerns, and combating illnesses which indicates that its public and political support will only continue to grow. Existing investment into research and development highlights that this sector of the market will continue to grow. Therefore, inclusion of this sector aligns perfectly with this NAICS principle.

Additionally, measurement of the bioeconomy aligns with the NAPCS principles. The broad objectives of NAPCS include the goal to classify and define final outputs within each industry. Proper classification of the bioeconomy will allow for the outputs to be defined to include production means that are novel and potentially significant in reducing hard-to-abate sectors' emissions. This will also ensure that these outputs are properly classified.

Another objective of NAPCS is to develop a demand-based, hierarchical aggregation system which groups projects according to how they are principally used and their relationship in satisfying that principal use. The use of bioprocessing (gas fermentation of waste carbon oxides) in industrial decarbonization is new, emerging, and has market value in the form of carbon capture offsets, and inspires significant investments to deploy it. We think this is especially important since the use of certain inputs into the bioeconomy is markedly different than those same inputs into more traditional processes therefore appropriate to distinguish products using bioprocessing as well as waste biogenic or industrial carbon oxide feedstocks in their production. Accordingly, bioproducts are well suited to be aggregated by use.

Generally, we believe that the creation of additional NAICS and NAPCS codes aligns with the principles and objectives because it creates a more accurate understanding of the various inputs and outputs in the economy, how they are used, and how they contribute to the overall economy.

⁴ Executive Order 14081 Advancing Biotechnology and Biomanufacturing Innovation for A Sustainable, Safe, and Secure American Bioeconomy - Request for Information; National Biotechnology and Biomanufacturing Initiative - Measuring the Bioeconomy, 88 Fed. Reg. 25711, 25713 (April 27, 2023).

V. How might potential changes to the NAICS impact existing industry measurements, such as assessing changes in the economic output across current industries, time series measures, or data accuracy?

While the foregoing reports by the National Academies and others provide a road map for the inclusion of new biobased industry sectors and product classifications, OMB has only to look to its own experience in the successful implementation of prior changes, including the wholesale replacement of the Standard Industrial Classification System (SIC) with NAICS in 1997. On numerous occasions, OMB has already assessed a diverse number of changes relative to factors such as output, time series measures, and data accuracies in the past. Therefore, OMB is well-positioned and experienced to carry out these and other future changes to ensure that our commercial metrics track advancements in technology and manufacturing in the United States.

BIO believes the bioeconomy can and should advance under these systems without significant disruption. To mitigate these concerns, one could consider gradual (or graduated) implementation procedures, such as a pilot program that utilizes a grant opportunity to roll-out new codes, together with a mechanism to assess and verify their use. However, the primary tool may simply be affording sufficient time for the transition. We recommend providing the public with substantial advance notice of the proposed new codes, offering more opportunities for public comments as code development progresses, and a reasonable period before the effective date of implementation, such as a period of one to three years. The timing should take into account the needs of all affected sectors but also contractors, the investment community, tax preparers, and government grant programs who use the NAICS codes for classification purposes.

Interagency cooperation is another important tool for managing implementation. We suggest working with the Small Business Administration, the USDA BioPreferred Program, U.S. Department of Defense and other offices engaged in federal procurement to communicate the changes to the business community. Generally, industry classification codes are derived from information that business establishments provide on administrative, survey, or census reports. Allowing biobased industries to self-identify through agency survey tools can provide useful information regarding the relative size, contribution, and potential growth of various sectors prior to full roll-out of the codes. The Economic Census could be a useful tool to test categories prior to full implementation.

As noted earlier, changes to these systems have been rolled out well in the past. NAICS was developed under the auspices of OMB and adopted in 1997 to replace the SIC system. The United States Census' NAICS website, accessible at census.gov/naics/?28967, lists all the Federal Register Notices related to additional or revised NAICS numbers since its inception. These notices demonstrate that OMB has a well-established process for testing and advancing new NAICS codes. For instance, in 2014 OMB decided not to move forward with the Factoryless Goods Producers classification after questions on the economic census provided

inconsistent results.⁵ Despite the result, this highlights that OMB has the tools and capacity to roll-out new NACIS codes backed by sound data to support its implementation.

VI. What role can the NAPCS fill in order to advance measurement of biomanufacturing and biotechnology?

NAPCS can obtain a more accurate assessment of biobased or bioprocessed products distinct from products derived from more traditional economic sectors. For instance, the NAPCS codes can track products derived from renewable energy rather than from imported oil and natural gas. Similarly, it can help to distinguish between plastics and bioplastics (ex. beverage bottle feedstocks). The inclusion of biobased or bioprocessed products is necessary to identify outputs unique to the bioeconomy. Furthermore, inclusion of these products should generate more accurate metrics for several segments of the economy and assist with measurement of other goals. Specific measurements of the bioeconomy can help to inform whether the country is hitting its energy, carbon reduction, and other related innovative production goals such as sustainability.

VII. Biobased processes and products that are embedded in traditional industries pose challenges for differentiation and measurement. Are there methodologies that can differentiate these bioeconomy processes from current manufacturing processes to enable measurement? If yes, please explain.

When bundled together under more traditional product codes, the contribution of biobased innovations and transitions to more climate-friendly products cannot be stated with true accuracy. As explained in BIO's response in Section III above, there is not a sufficient alternative to updating the NAICS and NAPCS categories. It is important to use these uniform systems to distinguish biobased or bioprocessing operations from synthetic commodity chemical production and recognize product designations where bioprocessing is employed. Given the urgency, expense, and difficulty in transitioning to a clean economy, it is necessary for our processes and products to be consistently and easily discoverable and tracked through NAICS and NAPCS.

VIII. What potential bioeconomy measurement strategies might be considered other than revisions to and inclusion in the NAICS or NAPCS? For example, are there ways the Federal Government could better collect information to provide better measurement on biobased processes or products in current industries?

BIO believes that there is no suitable or adequate substitute for measurement through the NAICS and NAPCS. The bioeconomy is sufficiently mature or maturing to support this effort, which is mandated by Congress. These existing classification systems represent the most comprehensive and recognized approach to understanding the North American economy. We highly recommend a standardized approach to measuring the economy, including the

⁵ Notice Regarding Implementation of the Factoryless Goods Producer Classification in NAICS 2017, 79 Fed. Reg. 46558 (Aug. 8, 2014).



bioeconomy. Their purpose is to capture and better understand the economy as a whole. Relegating the bioeconomy to measurement tools outside of these national systems will make it more difficult to assess the economic impact of the bioeconomy and its role in the larger economy. Therefore, we request that other measurement tools should no longer be relied upon and advocate for the inclusion of more accurate reporting through NAICS and NAPCS.

IX. Conclusion

BIO strongly supports revisions to the NAICS and NAPCS as a necessary action to keep pace with a growing segment of the economy. We applaud efforts to gather information and research these sectors prior to making any changes, but urge OMB to move forward so that these growth markets can be fully explored and assessed, to the benefit of our nation's economic and security goals. Thank you in advance for your consideration.

Respectfully Submitted,

A handwritten signature in black ink that reads "Beth Ellikidis".

Beth Ellikidis
Vice President, Agriculture & Environment
Biotechnology Innovation Organization