Background Information

In 1986, OSTP issued the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302), which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The Coordinated Framework sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation.

In 1992, OSTP issued an update to the Coordinated Framework that set forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment (57 FR 6753). The update affirmed that Federal oversight should focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created.

In 2015, the Executive Office of the President (EOP) issued a memorandum directing EPA, FDA, and USDA to update the Coordinated Framework. The Federal government subsequently published a National Strategy for Modernizing the Regulatory System for Biotechnology in 2016; and in 2017, OSTP issued another update to the Coordinated Framework. This 2017 update clarifies current agency roles and responsibilities for the regulation of biotechnology products. It provides a table of responsibilities that lists the offices within each agency or agencies that may have regulatory responsibility for a given biotechnology product category, and relevant coordination across the agencies. In addition, it describes memoranda of understanding (MOUs) among the agencies and the types of products and information that are covered within the scope of each MOU. In 2019, E.O. 13874 recognized that advances in biotechnology have the potential to revolutionize agriculture, enhance rural prosperity, and improve the quality of American lives. The E.O. ordered additional steps to be taken to further modernize the regulatory framework.

For details on the current roles and responsibilities of agencies under the Coordinated Framework for the Regulation of Biotechnology, refer to the Unified website for Biotechnology Regulation *https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/.*

On September 12, 2022, President Biden issued Executive Order (E.O.) 14081, ''Advancing Biomanufacturing and Biotechnology Innovation for a Sustainable, Safe, and Secure Bioeconomy,'' with the goal of accelerating biotechnology innovation and growing America's bioeconomy across multiple sectors, including health, agriculture, and energy. Among other objectives, E.O. 14081 aims to support the safe use of biotechnology by clarifying and streamlining regulations in service of a science- and risk-based, predictable, efficient, and transparent regulatory system to support the safe use of products of biotechnology. E.O. 14081 directs the EPA, FDA, and USDA to:

- identify any regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework for the Regulation of Biotechnology, through engaging with developers and stakeholders and through horizon scanning for novel biotechnology products;
- provide plain-language information on the regulatory roles, responsibilities, and processes of each agency;
- provide a plan with processes and timelines to implement regulatory reform; and build upon the Unified website for Biotechnology Regulation.

As noted in the Executive Order, ''biotechnology means technology that applies to and/or is enabled by life sciences innovation or product development.'' Biotechnology products include, for example, organisms (including plants, animals, and microbes) developed through genetic engineering or the targeted or in vitro manipulation of genetic information, some products derived from such organisms, as well as products produced via cell-free synthesis, as determined by existing statutes and regulations.

Questions

Respondents are encouraged to provide relevant data or information, including case studies, regarding regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework, and regarding new and emerging biotechnology products. Respondents need not reply to all questions listed. Please identify your answers as responses to a specific question.

1. Describe any ambiguities, gaps, inefficiencies, or uncertainties regarding statutory authorities and/or agency roles, responsibilities, or processes for different biotechnology product types, particularly for product types within the responsibility of multiple agencies.

a. Describe the impact, including economic impact, of these ambiguities, gaps, inefficiencies or uncertainties.

2. Provide any relevant data or information, including case studies, that could inform improvement in the clarity or efficiency (including the predictability, transparency, and coordination) of the regulatory system and processes for biotechnology products.

3. Describe any specific topics the agencies should address in plain language on the regulatory roles, responsibilities, and processes of the agencies.

4. Describe any specific issues the agencies should consider in developing a plan to implement regulatory reform, including any updated or new regulations or guidance documents.

5. Describe any new or emerging biotechnology products (*e.g.,* microbial amendments to promote plant growth; food plants expressing non-food substances or allergens from non-plant sources) that, based on lessons learned from past experiences or other information, the agencies should pay particular attention to in their evaluation of ambiguities, gaps, or uncertainties regarding statutory authorities and/or agency roles or processes.

6. Describe any new or emerging categories of biotechnology products on the horizon that the regulatory system and processes for biotechnology products should be preparing to address. Describe any specific recommendations for regulating these new or emerging categories of biotechnology products to guide agency preparations.

7. What is the highest priority issue for the agencies to address in the short term (*i.e.,* within the next year) and in the long term?

Dated: December 15, 2022.

Rachel Wallace,

Deputy General Counsel.

[FR Doc. 2022–27599 Filed 12–19–22; 8:45 am]

BILLING CODE 3270–F1–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; National Biotechnology and Biomanufacturing Initiative

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information (RFI).

SUMMARY: The President's Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy launched a National

Biotechnology and Biomanufacturing Initiative (NBBI) to advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, and supply chain resilience, and to advance national and economic security. Biotechnology and biomanufacturing offer new opportunities to strengthen supply chains and lower prices, create more sustainable products through bio-based production, expand domestic production of goods and materials, create jobs across all of America, and spur new opportunities in agricultural communities, as some examples. This RFI seeks public input on how advances in biotechnology and biomanufacturing can help us achieve goals that were previously out of reach and what steps can be taken to ensure we have the right research ecosystem, workforce, data, domestic biomanufacturing capacity, and other components to support a strong bioeconomy.

DATES: Interested persons and organizations are invited to submit comments on or before 5 p.m. ET on January 20, 2023.

ADDRESSES: Interested individuals and organizations should submit comments electronically to *biotech@ostp.eop.gov* and include ''RFI Response: Biotechnology and Biomanufacturing Initiative'' in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline may not be taken into consideration.

Instructions: Response to this RFI is voluntary. Respondents may answer as many or as few questions as they wish. Each individual or institution is requested to submit only one response. Electronic responses must be provided as attachments to an email rather than a link. Please identify your answers by referring to a specific question number and/or letter within the response. Comments of seven pages or fewer (3,500 words) are requested; longer responses will not be considered. Responses should include the name of the person(s) or organization(s) filing the response. Responses containing references, studies, research, and other empirical data that are not widely published should include copies of or electronic links to the referenced materials. Responses containing profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

Any information obtained from this RFI is intended to be used by the Government on a non-attribution basis for planning and strategy development. OSTP will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. This RFI is not accepting applications for financial assistance or financial incentives.

Comments submitted in response to this notice are subject to the Freedom of Information Act (FOIA). No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI. Please be aware that comments submitted in response to this RFI, including the submitter's identification (as noted above), may be posted, without change, on OSTP's or another Federal website or otherwise released publicly.

FOR FURTHER INFORMATION CONTACT: Georgia Lagoudas at *biotech@ostp.eop.gov;* tel: 202–456–4444.

SUPPLEMENTARY INFORMATION:

Background: Through Executive Order 14081, the Federal Government will deliver reports to the President on how biotechnology and biomanufacturing can further societal goals related to health, climate change and energy, food and agricultural innovation, resilient supply chains, and cross-cutting scientific advances. The White House Office of Science and Technology Policy (OSTP) is tasked with developing a plan to implement the recommendations in the reports. Additionally, the Executive Office of the President and Federal agencies are tasked with the development of reports and recommendations related to the biotechnology and biomanufacturing workforce, data to support the bioeconomy, expanding domestic biomanufacturing capacity, and other components to support a strong bioeconomy. A separate request for information will be published regarding biotechnology regulation.

The Executive Order describes four categories where biotechnology and biomanufacturing can further societal goals:

(1) *Health:* biotechnology and biomanufacturing to achieve medical breakthroughs, improve health outcomes, or reduce the overall burden of disease.

(2) *Climate and energy:* biotechnology, biomanufacturing, bioenergy, and biobased products to address the causes of climate change and adapt to and mitigate the impacts of climate change, including by sequestering carbon and reducing greenhouse gas emissions.

(3) *Food and agriculture:* biotechnology and biomanufacturing for food and agricultural innovation, including by improving sustainability and land conservation; increasing food quality and nutrition; increasing agricultural yields; protecting against plant and animal pests and diseases; and cultivating alternative food sources.

(4) *Supply chain resilience:* biotechnology and biomanufacturing across economic sectors to strengthen the resilience of United States supply chains, such as addressing specific supply chain bottlenecks and developing new types of production methods.

OSTP invites input from interested stakeholders, including industry and industry association groups; academic researchers and policy analysts; civil society and advocacy groups; individuals and organizations who work on biotechnology, biomanufacturing, or related topics; and members of the public.

Information Requested: OSTP seeks responses to one, some, or all of the following questions:

Harnessing Biotechnology and Biomanufacturing R&D To Further Societal Goals

1. For any of the four categories outlined above (health, climate and energy, food and agriculture, and supply chain resilience):

a. What specific bold goals can be achieved through advances in biotechnology and biomanufacturing in the short-term (5 years) and long-term (20 years)? *In your answers, please suggest quantitative goals, along with a description of the potential impact of achieving a goal. Listed below are illustrative examples of quantitative goals:*

i. *Develop domestic bio-based routes of production, including the entire supply chain, for X% of active pharmaceutical ingredients.*

ii. *Utilize X tons of sustainable biomass annually as input to biomanufacturing processes to displace Y% of U.S. petroleum consumption.*

b. What research and development (R&D) is needed to achieve the bold goals outlined in (a), with a focus on cross-cutting or innovative advances? How would the Government support this R&D, including through existing Federal programs, creation of new areas of R&D, and/or development of new mechanisms?

c. How else can the Government engage with and incentivize the private sector and other organizations to achieve the goals outlined in (a)?

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?

Data for the Bioeconomy

3. What data types and sources, to include genomic and multiomic information, are most critical to drive advances in health, climate, energy, food, agriculture, and biomanufacturing, as well as other bioeconomy-related R&D? What data gaps currently exist?

4. How can the Federal Government, in partnership with private, academic, and non-profit sectors, support a data ecosystem to drive breakthroughs for the U.S. bioeconomy? This may include technologies, software, and policies needed for data to remain high-quality, interoperable, accessible, secure, and understandable across multiple stakeholder groups.

Building a Vibrant Domestic Biomanufacturing Ecosystem

5. What is the current state of U.S. and global biomanufacturing capacity for health and industrial sectors and what are the limits of current practice?

6. What can the Federal Government do to expand and scale domestic biomanufacturing capacity and infrastructure? What level of investment would be meaningful and what incentive structures could be employed?

7. What are barriers that must be addressed in order to better enable domestic supply chains for biomanufacturing (*e.g.,* feedstocks, reagents, consumables)?

8. How can the Federal Government partner with state and local governments to expand domestic biomanufacturing capacity, with a particular focus on underserved communities?

Biobased Products Procurement

9. What are new, environmentally sustainable biobased products that the Federal Government could purchase through its BioPreferred Program? How can the Federal Government incentivize development of new categories of sustainable biobased products?

Biotechnology and Biomanufacturing Workforce

10. How can the U.S. strengthen and expand the biotechnology and biomanufacturing workforce to meet the needs of industry today and in the future? What role can government play at the local, state, and/or Federal level?

11. What strategies and program models have shown promise for successfully diversifying access to biomanufacturing and biotechnology jobs—including those involving Historically Black Colleges and Universities, Tribal Colleges and Universities, and other Minority Serving Institutions? What factors have stymied progress in broadening participation in this workforce?

Reducing Risk by Advancing Biosafety and Biosecurity

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?

13. How can Federal agencies that fund, conduct, or sponsor life sciences research incentivize and enhance biosafety and biosecurity practices throughout the United States and international research enterprises?

Measuring the Bioeconomy

14. What quantitative indicators, economic or otherwise, are currently used to measure the contributions of the U.S. bioeconomy? Are there new indicators that should be developed?

15. How should the North American Industry Classification System and the North American Product Classification System be revised to enable characterization of the economic value of the U.S. bioeconomy? Specifically, which codes or categories do not distinguish between functionally identical bio-based and fossil fuel-based commodities?

International Engagement

16. What are opportunities for the U.S. Government to advance research and development, a skilled workforce, regulatory cooperation, and data sharing for the bioeconomy through international cooperation? Which partnerships and fora are likely key to advance these priority areas?

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

Dated: December 15, 2022.

Rachel Wallace,

Deputy General Counsel.

[FR Doc. 2022–27600 Filed 12–19–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96500; File No. SR–NASDAQ–2022–075]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Listing Rules 5605 and 5606

December 14, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 12, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to simplify implementation and compliance tracking of Listing Rules 5605 and 5606, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On December 1, 2020, the Exchange filed with the Commission a proposed rule change to adopt listing rules to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.