June 17, 2022

Vanessa Countryman
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-0609

Re: File No. S7-10-22: The Enhancement and Standardization of Climate-Related Disclosures for Investors

Dear Secretary Countryman,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the Securities and Exchange Commission's (SEC or Commission) proposed rule to require information about a registrant's climate-related risks that are reasonably likely to have a material impact on its business, results of operations, or financial condition. The requirements would include disclosure of greenhouse gas emissions, forecasted impact of climate risks on financial metrics as part of audited financial statements, board oversight of climate risk, and management operational capabilities and responsibilities on climate risk assessment and management.[1]

BIO is the world's largest life sciences trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as managing the environmental and health risks of climate change, sustainably growing nutritious food, improving animal health, enabling manufacturing processes that reduce waste and minimize water use, reducing transportation emissions through the production of sustainable fuels, and advancing the health of our families.

The biotechnology industry is instrumental in advancing society and is considered a critical technology for American economic security in the new era.[2] Accordingly, we agree that climate change is one of the defining business risks of the 21st century. The rapid swings in climate and associated costs to businesses and economies have been increasing over time, and the biotechnology industry stands at the forefront of creating new solutions to these global problems.

[1] The Enhancement and Standardization of Climate-Related Disclosures for Investors
[2] https://www.whitehouse.gov/wp-content/uploads/2022/02/02-2022-Critical-and-Emerging-Technologies-List-Update.pdf

Biotechnology has the potential to be a transformative asset in the global race to bend the arc of climate change and offers new tools that can achieve at least three billion tons of CO_2-equivalent mitigation annually by 2030 using existing technologies.[3] Accordingly, BIO supports and shares the goal of addressing climate change, however, we are concerned that this proposal imposes significant burdens on registrants, especially small companies, without adding any benefit in addressing climate change.

The primary requirement underpinning the proposed rule is the disclosure of climate-related risks *reasonably likely to be material* to a business (model), business operations, or financial conditions. Yet, the Commission has determined that all registrants, regardless of size and sector and financial ability, should nevertheless take on potential additional costs, liabilities, reorganizations, and risks to comply with this policy. This comes as independent, international climate risk standards setting bodies, such as the International Sustainability Standards Board and the Science-based Targets Initiative, have found that climate risks are not material to the biotechnology industry[4] as well as several other industries.

BIO is concerned that potential negative effects will be disproportionately borne by small companies to the detriment of small business capital formation.

These regulations have real economic costs to all companies, particularly small biotechnology companies that have no product revenues but often fall outside of the scope of smaller reporting companies due to existing public float thresholds. BIO appreciates that the Commission proposes to exempt small companies from a portion of the reporting requirements (Scope 3), acknowledging that small companies will be disproportionately affected by the proposed rule while providing limited benefit to investors.[5] However the same could be said for the other proposed requirements, yet the Commission provides few exemptions or scale-up provisions to help small companies adapt to the current wave of public company regulation.

The Commission often cited comparisons to the S&P 500[6] and even the Russell 1000[7] as evidence that the market has already moved to report on climate and that the SEC must normalize these disclosures. However, the S&P 500 and the Russell 1000 are not accurate

[3] Biotech Solutions for Climate Report
[4] SASB Climate Risk Technical Bulletin 2021
[5] "…may pose fixed costs (e.g., data gathering and verification), that would fall disproportionately on SRCs. Also, **because SRCs are a small fraction of the market, the overall benefit to investors would be limited**."
[6] S&P 500 index analyses were cited repeated throughout the proposed rule.
[7] The Commission states that Russell 1000 companies "are virtually all large-accelerated filers" and further notes that "the rate of assurance is concentrated among the larger half of the sample firms (e.g., the S&P 500 firms)."

comparators for the status of small companies in the reporting of climate risk and greenhouse gas (GHG) emissions.

Finally, BIO urges the Commission and the Administration to take a holistic approach to their regulatory agenda with a particular focus on what this wave of regulation means for small companies, the diminishing incentives to become a public company they will create, and the potentially duplicative nature of reporting that will exist once the Administration's regulatory agenda is implemented in full.

Summary of Concerns and Recommendations

- BIO is **concerned** that the Commission is implementing a suite of new regulations that are not uniformly predicated on materiality and disproportionately harm small companies.

- BIO is **concerned** that the Commission continues to cite research and statistics about the behavior and risks associated with large companies and applying those models to small companies. The Commission relies on studies and statistics that apply to the S&P 500 and then uses that sample population to justify expensive regulations on small companies. Throughout this proposed rule, the Commission acknowledged both that most *large companies* are reporting and that small companies both do not report and would thus disproportionately be affected by implementation costs.

- BIO is **concerned** that the Commission is raising the cost of being a public company with no regard to the impact these regulations will have on small companies. BIO remains concerned that regulators are replicating past episodes of regulatory overreaction that led to distortions in capital markets with which the economy (across business owners, capital providers, and labor markets) are still contending.

- BIO **recommends** that Smaller Reporting Companies (SRC) be exempt from climate risk disclosures as the Commission has already acknowledged that "the overall benefit to investors would be limited[8]" in the case of the largest and most costly aspect (Scope 3).

- BIO **recommends** that the Commission update the definition of SRC to match investor definitions of small market capitalization companies by increasing the public float threshold to $2,000,000,000.

[8] Supra note 1

- BIO **recommends** that the Commission uphold the spirit of the JOBS Act by extending the EGC designation exemptions to climate risk disclosures, including the reporting and associated assurances.

- BIO **recommends** that the Commission extends safe harbors to all climate-related disclosures as many aspects of this proposed rule will involve third-party data, service providers, estimations, and forecasts. As the Commission noted, the calculation, assessment, methodology frameworks and assurances are "still evolving."

- BIO **recommends** that the Commission do not require Regulation S-X disclosures of climate-related impact estimates on consolidated financial statements.

Summary of Responses to Key Questions[9]

Climate Risk Materiality & Disclosure

BIO is concerned that the SEC is embarking on a path to redefine the standard of materiality.

BIO was drawn to the following line in the proposal, "…the **traditional concept of materiality** already requires the disclosure of climate-related impacts that materially affect the issuer's financial condition and results of operations,[10]" which was written in summarizing submitted comments contending that materiality standards already require companies to report on climate risks if they are material to a business. Troublingly, however, it appears that with this proposal, the Commission is intending to impose rigid across-the-board rules. As traditionally understood, a company makes independent assessments of what is material.

In particular, BIO is troubled that the Commission went so far as to define materiality in the context of financial-impact reporting by defining a one percent deviation attributed to climate related externalities as the threshold for reporting in consolidated financial statements. The Commission proposes a rigid reporting standard that is not rooted in individual assessments as dictated by the traditional concept of materiality. Furthermore, the one percent threshold for line-item reporting is too low to be considered material universally across companies and industries (as we explain in the Reporting Metrics Section).

[9] Please note that given the overlapping concerns across questions posed by the Commission in the proposal BIO has chosen to respond topically to those issues relevant to BIO membership and the biotechnology sector. This response does not include questions where BIO had no position. We have attached as an appendix the responses to questions, in-line.
[10] Supra note 1

While there are precedents for a one percent threshold, such as in the reporting of excise taxes in excess of one percent of total revenues, these are related to transactions that may be material to a business but are not attributed to exogenous, macro factors. This constitutes the first such instance.

Importantly, current guidelines and Commission guidance already contemplates that companies have a duty to disclose any risk, including climate-related risks, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO urges the Commission to strongly consider updates to current guidance on climate-related risks disclosures as a pathway to meeting the purpose[11] of the proposal in a way that minimizes unintended consequences. In addition, updated guidance would enable the Commission to clarify the range of climate-related risks registrants need to evaluate for materiality, such as geographical or physical risk, without establishing such a significant set of disclosures and organizational changes as proposed.

However, most companies that already report on sustainability issues, such as climate change, already do so in separate reports that allow companies to provide said information in the context of the company's mission, operations, opportunities, and risks. This way investors have the full context of climate-related metrics within one, dedicated place instead of spread across Form 10K.

In addition, as the Commission notes, the current ecosystem of GHG emission reporting, audit, and assurance is "evolving and unique" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data." Essentially, the Commission is compelling industry to implement disclosures using service providers that are not accredited or verified by regulators to implement calculations and frameworks that have not yet been agreed upon or harmonized globally.

Finally, international standard setters, such as the Sustainability Accounting Standards Board (SASB), has already indicated that climate risks are not material for the therapeutics industry, as discussed in the next section. These results were corroborated by an internal BIO survey, which revealed that almost two-thirds of our members believe that climate change poses no material financial risk to their respective businesses. Accordingly, over two-thirds say that they do not

11 The Commission's stated purpose of the proposed rule is to *"require registrants to identify their climate-related risks that are reasonably likely to have a material impact on the registrant's business or consolidated financial statements over the short, medium, and long-term and describe the actual and potential impacts of those risks on its strategy, business model, and outlook."*

disclose climate-related risks in any report. In fact, 11% of our members reported that they have ever been urged by their investors to disclose climate change risks.

Reporting Frameworks

The Commission noted multiple times that the SASB standards are the "benchmark for financially material disclosures[12]" and "guide disclosures of financially material sustainability information by companies for their investors.[13]"

It is for this reason that, according to the International Sustainability Standards Board (ISSB), 69% of S&P 500 companies, 54% of the FTSE 100 companies, and 54% of the S&P Global 1200 use the SASB standards.[14] It is worth noting that SASB, and ISSB standards, are also based on the Taskforce for Climate-related Financial Disclosures (TCFD).

One can thus conclude that companies have chosen to implement the SASB / ISSB reporting standards because a consortium of international investors and industry experts, together, concluded on what is material for a given industry.

Simply put, the most widely implemented sustainability and climate reporting standards in the world, used by both investors and registrants, have illustrated that climate risk materiality varies across the biotechnology industry and have specifically concluded that climate risks are not material to companies developing medicines (therapeutics).

The SASB climate risk technical bulletin, in which the SASB/ISSB maps recommended materiality standards linked to the TCFD framework, includes the same climate risk categories the SEC proposes, including Acute and Chronic physical risks, transition risks and regulatory risks. This SASB Bulletin shows that climate risks, across categories, are not material risks for the therapeutics industry as illustrated in the SASB table below.

[12] Supra note 1
[13] Supra note 1
[14] https://www.sasb.org/

SECTOR	INDUSTRIES	CLIMATE RISK CATEGORY		
		PHYSICAL	TRANSITION	REGULATORY
HEALTH CARE	Biotechnology & Pharmaceuticals			
	Health Care Delivery			
	Health Care Distributors			
	Managed Care			
	Medical Equipment & Supplies			
	Drug Retailers			

SASB Climate Risk Technical Bulletin

The technical bulletin also takes the materiality analysis a step further by outlining how these identified climate risks could impact companies financially, including "including current and future effects on a company's financial condition, operating performance, and its risk profile. The financial implications of climate risk can be grouped into three general categories: income statement impacts, balance sheet impacts, and risk profile impacts.[15]"

Even within the context of a materiality assessment for the probable financial impacts of climate risk to biotechnology companies developing medicines, the SASB / ISSB consortium determined that revenue and operating costs, expected asset impairments and other balance items, and the probable financing risks, creditworthiness, and divestment risks associated with a range of climate scenarios were not financially material.

As the chart below shows, the financial impact channels of climate risks did not include the biotechnology industry in their transmission channel analysis.

SECTOR	INDUSTRY	INCOME STATEMENT	BALANCE SHEET	RISK PROFILE
HEALTH CARE	Health Care Delivery			
	Health Care Distributors			
	Managed Care			
	Medical Equipment & Supplies			
	Drug Retailers			

SASB Climate Risk Technical Bulletin

While the technical bulletin implies biotechnology falls solely within the health care sector, a complete picture of the industry must also include aspects of the renewable resources & alternative energy sector, the resource transformation sector, and certain aspects of the consumer

[15] Supra note 6

goods sector. It is critical to understand this, as to date, no reporting framework has established a single industry standard that is wholly reflective of the entire biotechnology industry. Given the reliance on such standards throughout the proposal it is important that the Commission understand that existing reporting frameworks are not universally applicable to meeting the needs of all sectors.

This challenge extends to TCFD and the GHG Protocols cited by the Commission as the standards upon which the rules have been crafted. In addition, despite current voluntary use of the TCFD and GHG Protocols, they have not been certified officially nor does the SEC oversee TCFD nor GHG Protocols in the way SEC oversees the FASB.

If the SEC wishes to require registrants to use the GHG Protocols methodology, or any other voluntary protocol, despite acknowledging the evolving landscape of GHG emissions reporting, then the Commission should take separate regulatory action to do so. All stakeholders should be provided sufficient notice and comment opportunity to respond to the proposal requiring use of the GHG Protocols or other voluntary methodology that has not been certified or otherwise subject to regulatory oversight.

Finally, BIO supports the proposal to establish an alternative reporting provision for foreign private issuers based on global sustainability reporting standards, such as those being developed by the International Sustainability Standards Board (ISSB), which would mirror the SEC's current alternative provision for financial disclosures based on IFRS accounting standards. A consistent global baseline for climate-related disclosures would benefit both international companies and investors by allowing for standardized and comparable information across jurisdictions. We recommend the SEC adopts such a provision for foreign private issuers that is aligned with material elements of the ISSB standards and/or other recognized climate-related reporting standards that may apply in the company's home jurisdiction.

Small and Emerging Companies

As drafted, the proposal raises a range of questions specific to the implementation challenges faced by small and emerging companies. Those challenges include, but are not limited to, the role of the capital formation cycle and the nature of the R&D pipelines in the industry. In recognition of those challenges BIO strongly supports the exemption of SRCs from all climate-related reporting. BIO also encourages the Commission to extend EGC exemptions from all climate-related reporting.

Emerging biotechnology companies will be forced to spend hundreds of thousands of dollars each to *seek* materiality, restate financial statements, calculate GHG emissions and intensity, implement board-level oversight, restructure organizational operating structures, and seek audit and assurances with unestablished frameworks to cater to a risk that is not found to be material for the therapeutics (medicine) industry and has yet to be determined for other aspects of the broader biotechnology industry.

Additionally, the Commission acknowledges that small companies largely do not already have systems in place to report on climate-related financial disclosures[16] and goes on to state,

> "To the extent that they are not already gathering the information required to be disclosed under the proposed rules, registrants may need to *re-allocate in-house personnel, hire additional staff, and/or secure third-party consultancy services. Registrants may also need to conduct climate-related risk assessments, collect information or data, measure emissions (or, with respect to Scope 3 emissions, gather data from relevant upstream and downstream entities), integrate new software or reporting systems, seek legal counsel, and obtain assurance on applicable disclosures*.[17]"

The Commission further acknowledges that small companies will shoulder the greatest financial burden and estimates that compliance would cost between \$490,000 to \$640,000 to implement in the first year with \$120,000 to \$180,000 in estimated internal costs and \$350,000 to \$460,000 in estimated outside professional services costs.[18] But these do not include estimates for hiring additional staff, acquiring and integrating new systems, and the costs of new board and

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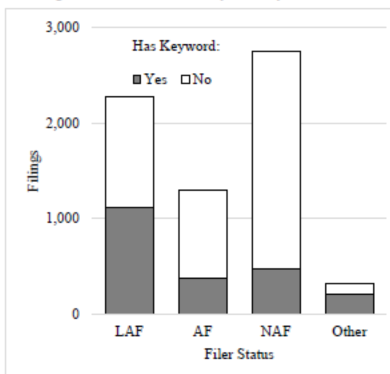

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management structures dedicated to climate reporting. In fact, a survey of BIO members showed that 71% of BIO members would be forced to hire third-party consultants, and 56% believed that the Commission has underestimated these expected costs with 40% expecting to pay between $500,000 and $1,000,000.

The Commission also mentions that service providers have estimated that "low maturity" companies, or those that have "no formal understanding of GHG emissions calculations and have no related policies or programs in place[19]" should expect to bear higher costs associated with seeking professional services in GHG emissions reporting.

Separately, the nature of an emerging biotechnology company's consolidated financial statements would make the proposed new line items required by the proposal confusing for investors, auditors, and assurance providers alike.

Small and emerging companies in the biotechnology industry may not have product revenues for years, if ever, and must raise capital throughout their lifecycle to finance ongoing R&D pipelines. Revenue recognition accounting, as it is applied in the emerging biotechnology industry, may lead to highly volatile and incomparable climate-related financial metrics. The most common revenue recognized in this sector is that from capital raising (either via partnerships or follow-on issuances), and companies do not raise money every year.

The desire for an appropriate alternative, such as total assets[20] as recommended by the Commission in the proposed rule, may compel further confusion. Total assets, which in the biotechnology industry consists of mostly cash and cash equivalents, are the main assets of a small biotechnology company and these fluctuate across the sector to address R&D funding needs, which would make the Commission's intention for consistency very difficult to achieve. (This is further explained in Reporting Metrics Section below.)

Aligning the dynamic nature of R&D pipeline financing with the requirements of the regulation, as proposed, may challenge a small biotechnology company's ability to meet the Commission's intended goals. Cash levels in the biotechnology industry are not uniform or consistent, even across companies leveraging similar types of science. This spectrum of cash levels and burn rates is part of the fundamental analysis of the industry, which is calculated by most biotechnology

[19] Id.
[20] "If the registrant has no revenue for a fiscal year, it would be required to calculate its GHG intensity with another financial measure (*e.g.*, total assets), with an explanation of why the particular measure was used. Similarly, if the registrant does not have a unit of production, it would be required to calculate its GHG intensity with another measure of economic output, depending on the nature of its business (*e.g.*, data processing capacity, volume of products sold, or number of occupied rooms) with an explanation of why the particular measure was used." – Supra note 1

specialist investors and analysts. Similar analyses are conducted by analysts for other industries. With such a diversity of cash levels and cash burn rates, the application of climate-related forecasted impacts on financial statements will not be consistent or comparable.

Furthermore, and crucially, BIO supports an alternative threshold for climate-related reporting. As discussed in Question 137, the Commission should align the statutory definition of SRC with the market definition by updating the public float threshold to $2,000,000,000. Defining SRC as companies with less than $100,000,000 in revenue and less than $2,000,000,000 in public float, (a) keeps with the revenue threshold of SRC, and (b) aligns current definition of SRC with market practice for small companies, which is defined as a company with market capitalization (public float) less than $2,000,000,000. The same public float threshold should also apply to emerging growth companies, which would help to align further regulatory definitions with market definitions and practice.

Data Collection and Reporting

As the Commission notes, the current ecosystem of GHG emission reporting is "evolving and unique[21]" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data.[22]" Because the Commission is compelling industry to implement disclosures in a shifting landscape with a multitude of service providers that have not been validated or verified by regulators, both investors and registrants would be better served with maximum flexibility and protections under safe harbors given the inherent need to rely on estimation and forecasting.

The Commission acknowledges that the current landscape is fraught with liability across the entire reporting, auditing, and attestation of climate risk disclosures and yet the Commission is only providing narrow safe harbors. The Commission writes,

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[21] "Although we are proposing certain minimum standards for attestation services, this proposal does not aim to create or adopt a specific attestation standard for assuring GHG emissions, just as this proposal does not define a single methodology for calculating GHG emissions. This is because both the reporting and attestation landscapes are currently evolving, and it would be premature to adopt one approach and potentially curtail future innovations in these two areas. The evolving nature of GHG emissions calculations and attestation standards could suggest that it may also be premature to require assurance."

[22] "Nevertheless, *the evolving and unique nature of GHG emissions reporting involves and, in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data.* As such, requiring a third party's attestation over these disclosures would provide investors with an additional degree of reliability regarding not only the figures that are disclosed, but also the key assumptions, methodologies, and data sources the registrant used to arrive at those figures."

> "Nevertheless, the evolving and unique nature of GHG emissions reporting involves and, in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data."

There is too much willful reliance on third-party service providers that have not been vetted, accredited, or certified by regulators as trustworthy providers of assessments, verifications, and services for the greatest change in accounting and corporate reporting in a generation. Estimates based on various unapproved sources and unapproved methodologies without appropriate safe harbors is dangerous for registrants.

BIO is concerned that the Commission has not adequately provided for exemptions and phase-in periods for small companies to adapt to the proposed reporting requirements. In fact, 67% of BIO members surveyed said that they currently do not report on carbon emissions, and a similar majority have significant concerns with the ability to collect and accurately report without significant liability. This challenge is compounded by the evolving nature of the reporting and attestation landscape.

As the Commission noted through the Economic Analysis section, there is an expectation for implementation prices to fall over time. The Commission should extend lengthier phase-ins and more exemptions to allow for the market to settle on standards and for prices adjust.

This brief respite and on-ramp will also provide small companies with the confidence that those service providers that remain in the market have been validated by large, seasoned filers and investors alike to provide accurate, adequate, and accepted services. This is crucial as the Commission provides very limited safe harbors for the use of so many third-party providers of data and services that will be required to comply with these new regulations.

Where reporting is determined to be material and necessary, registrants should generally be allowed to report according to their existing reporting schedule, which is by fiscal year. However, the Commission should align to the greatest extent feasible with existing GHG reporting timelines as it relates to registrants already required to report emissions data. For example, the reporting deadline for the Greenhouse Gas Reporting Program (GHGRP) administered by the Environmental Protection Agency (EPA) is March 31st.

Scope 3 Emissions in Biotechnology

As discussed above, the biotechnology ecosystem is concentrated with small, pre-revenue companies that are heavily focused on research and development. Compelling these companies to implement new and costly corporate structures to monitor non-material risks to their respective organizations is already quite the undertaking and falls far afield of the SEC's mandates. However, the Scope 3 emissions portion of the proposed rule would impose the most significant burden on these companies, and, indeed, most companies. Accordingly, BIO agrees that smaller reporting companies (as defined herein) should be exempt, and BIO supports the safe harbors for Scope 3 disclosures. BIO also vigorously recommends that emerging growth companies be provided with these exemptions.

Effectively, the Commission is requiring that corporate managers become experts in and responsible for the analysis of the climate economics and emissions drivers of adjacent industries. Historically, that has been an investor's job.

Companies will be now responsible for forecasting the emissions of companies in other industries, hypothesizing the expected emissions path of those companies, and incorporating these estimates into internal forecasts to report to investors. While this is the business model for some companies, most companies find the risks and liabilities involved are significant.

BIO is concerned that the Commission is forcing companies to shoulder the burden, responsibility, and liability for accumulating, forecasting, reporting, and independently assuring emissions forecasts based on estimates from adjacent industries. It seems that investors do not have any responsibility in analyzing companies and industries when it comes to emissions and climate risks.

For example, downstream of the biotechnology industry is, literally, the entire world, which includes governments. Medicine and food must reach every corner of the world, from metropolitan centers to the most desolate places on earth. What is more material for a company in this scenario, the fact that medicine and food reached these patients or estimates of the emissions it took to reach these rural communities, including emissions estimates from all the international organizations (who do not report on their emissions) that are part of the delivery?

Any biotechnology therapeutics company that sells medicine to the United Kingdom's National Health Service (NHS) or the U.S. government's Tricare program, for example, will struggle with creating and reporting Scope 3 estimates, assumptions, and methodologies. The sale is material, but the value chain emissions tied to the NHS's transportation and use of the medicine is not.

For instance, should a startup biotechnology company in Arizona that gains the UK's NHS as a customer be forced to estimate and report on the percentage of the NHS's 25 million tons of CO_2-equivalents that pertain to their product?[23] The fraction would be negligible, but the amount of capital, time, and other resources required would be significant. More importantly, what value does that exercise add to investors of the biotechnology company?

Nowhere in the NHS's decarbonization plan does the NHS determine that the production and value chain of small molecule or biological medicine developers contribute significantly to its emissions.[24] Hence, in this representative example, the NHS's emissions and its decarbonization plan are not material to the small biotech's operations or future finances. Why then would the SEC compel biotherapeutics companies that count the NHS as a customer to hire consultants to estimate and report on Scope 3 emissions stemming from having the NHS as a customer?

Finally, a survey of BIO's members confirmed the difficulty of gathering this information. A full 100% of survey respondents reported that it would be difficult to collect Scope 3 data from their global suppliers and would require hiring third parties. In addition, the survey revealed widespread concern among BIO members that the Commission's proposed safe harbors for Scope 3 emissions reporting would NOT mitigate liability.

Safe Harbors

BIO strongly urges the Commission to enshrine all proposed climate-related disclosures in the Private Securities Litigation Reform Act (PSLRA) safe harbors, including GHG emissions, GHG intensity, transition plans and targets, internal strategies, financial impacts, and other proposed disclosures, statements, and supplemental information.

The Commission outlined numerous times within the proposed rule that most aspects of the proposed reporting requirements is "still evolving," including the audit and assurance aspects of the proposed rule. The Commission should therefore exclude the proposed rules from ICFR requirements until such time as the Commission has established appropriate guidelines for audit and assurance. Finally, the Commission should keep with the spirit of the JOBS Act and include climate-related disclosures and financial-impact disclosures in the emerging growth company exemption.

[23] https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(20)30271-0/fulltext?rss=yes, and NHS "Delivering a 'Net Zero' National Health Service" report, October 2020

[24] The NHS focuses on anesthetic gases and inhalers as its largest emitters from the medicines category (as is the case for all hospital systems).

Further, as noted elsewhere in these comments, the biotechnology industry's nuance will make certain proposed metrics unusable for generalist investors, and, we fear, may cause consternation and possible litigation attributed to nothing more than a lack of understanding of the sector. For these reasons as well, the Commission should broaden the safe harbors to include all climate-related financial disclosures. Should the Commission go so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors.

Climate-Related Risk & Opportunity

As discussed above, the material nature of climate-related risks will be different for various sectors of the biotechnology industry. In addition, for some registrants' climate-related opportunities are foundational to the operation of the company. As such, registrants should have the option to identify and illustrate the relationship between climate-related risk and opportunities, identified as material, as it relates to significant changes made to, its products or services, supply chain or value chain, activities to mitigate or adapt to climate-related risks, including adoption of new technologies or processes, expenditure for research and development, and any other significant changes or impacts.

Furthermore, existing guidelines and Commission guidance already require companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. To require all registrants to disclose or discuss the process for identifying, assessing, and managing climate-related risks, as proposed could be both duplicative and challenge traditional interpretations of materiality. For those registrants that determine climate-related risk is material to their business such process related disclosure should be optional.

BIO urges the Commission to take into consideration that the wide range of enumerated climate-related risk considerations included in the proposal, as drafted, may result in creation of new risk for registrants particularly in the realm of liability and cost. For this reason, it is imperative that the Commission adhere to the current standards of materiality and allow companies to report only on material effects of climate change on financial statements.

In furtherance of that goal, BIO encourages the Commission to ensure that there is no overlap in reporting requirement across federal and state government agencies. To the extent that there is overlap, such as with the EPA, the Commission should work with other federal and state agencies to ensure common reporting standards are in place and shared across agencies. Insofar as there is overlap, registrants should not have to disclose to two separate agencies. Further, if

the EPA has established a requirement for registrants to disclose certain emissions, which are then published for public consumption, then there is no need for the Commission to require further disclosures of risks and calculations that are not material for securities regulators to hold. Should the Commission determine there remains a need for specific emissions disclosures on financial statements they should be predicated on materiality and not reliant on arbitrary thresholds especially.

Additionally, the Commission should refrain from including definitions discussed in the proposal that may already be widely understood in the context of existing GHG emissions reporting. For example, the EPA already provides guidance on the definition of Scope 1, Scope 2, and Scope 3 emissions. As a result, the SEC does not need to further define terms such as “upstream costs.” The proposed examples provided regarding the financial impact metrics clarified how to contemplate reporting in the event a climate-related event or climate trend is found to be material enough to warrant disclosure.

Should the Commission finalize components of the climate-related risks disclosure and reporting proposal, BIO would urge that in addition to adhering to current standards of materiality that the Commission focus required disclosure on common elements across registrants and sectors of the economy. For example, not all registrants will have established or seek to establish a price of carbon. In addition, the Commission should ensure that required disclosure does not duplicate existing pathways of communication between registrants and investors or investor analysts. Current guidelines and standards already require registrants to provide disclosures on the risks and events, such as climate-related events, that alter capital expenditures and the cost of capital. As such, registrants already raise with investors when the cost of capital changes and the impact of those changes on specific, material line items.

Reporting Metrics

BIO supports and strongly recommends that the Commission continue using the materiality standard, as it is traditionally understood, for company reporting on the effects of climate-related events and transition activities on financial statements and operations, including if there are material changes to how companies estimate, calculate, or develop assumptions and methodologies for any material disclosure. The Commission must ensure that the means of such reporting not be undermined by mandated use of metrics that are arbitrary or have a significant potential for causing confusion with generalist investors. For example, the SEC should ensure that required metrics not be duplicative or involve significant overlap as would occur in reporting both financial impact metrics and as specific expenditure metrics.

While the Commission has used various thresholds to trigger different reporting requirements, the Commission's proposed requirement of a one percent threshold trigger constitutes the Commission creating a new definition of materiality, which is intended to supersede the current definition that has been established by case law and subvert a company's shareholders as the stakeholders responsible for dictating what is material to them. BIO is concerned that the SEC is endeavoring to uproot the established interpretations of materiality.

BIO contends that a one-percent impact may not be material for every company of every size in every industry. BIO stresses the need for the Commission to adhere to the current standards of materiality and allow companies to report only on material effects of climate change on financial statements. Historically, a one-percent deviation of any consolidated financial statement line item would never reach the level of materiality for a broad investment public. Furthermore, a one-percent expenditure is seldomly critiqued by investors. Why, then, should registrants be compelled to report a trigger that historically would never be considered important by an investor?

As proposed, BIO further contends that the climate-related financial statement metrics and GHG intensity metrics have significant potential to cause confusion among generalist investors and will require registrants to provide calculations and metrics that have been traditionally part of the roles and responsibilities of an industry analyst / investor.

Requiring registrants to calculate GHG intensity as proposed, will not provide for adequate or uniform comparisons across biotechnology companies for all investors. Only specialist investors will be able to understand the volatility of the contemplated ratios and how to truly compare between biotechnology companies (as is currently the case).

Biotechnology companies with no revenue or units of production will be put into a disadvantageous position as the denominator of such calculations is inherently volatile and entirely predicated upon the cash raising cycle. For these reasons, BIO strongly urges the Commission continue using the materiality standard for climate-related company reporting and agrees that companies with no revenues or units of production should not disclose GHG intensity.

For context, alternative asset metrics, such as total assets, are highly volatile and cyclical line items as they are comprised of cash, cash equivalents, and short-term investments. These line items are not uniform or consistent across the biotechnology industry, even among companies leveraging similar types of science or companies in the same therapeutic category (e.g., oncology) for those developing medicines.

Small biotechnology companies, which spend heavily on R&D, use cash at an accelerated rate and raise new funds frequently but not in defined patterns or amounts. This spectrum of cash levels and burn rates is part of the fundamental analysis of the industry, which is calculated by most biotechnology specialist investors and analysts. Similar analyses are conducted by analysts for other industries. With such a diversity of cash levels and cash burn rates, the application of climate-related forecasted impacts on financial statements will not be consistent or comparable.

Since the denominator of these proposed intensity metrics will be composed of these highly volatile and highly cyclical line items, this means that over time, by virtue of the business model and industry, emissions, emissions-intensity, and climate-related financial metrics will deteriorate[25] until capital is raised once again.

In other words, climate-related financial disclosures will ebb and flow with the capital raising cycle. Most generalist investors will not know this nuance when it comes to investing in biotechnology companies and has the potential to detract generalists from the biotechnology sector as it will introduce yet another layer of complexity.

Furthermore, the Commission does not require companies to conduct a DuPont analysis, intrinsic value calculations, return on invested capital, return on capital employed, liquidity ratios, current ratios, or any other ratio that helps analysts and investors understand and compare financial statements. While many companies may provide some of these ratios, they are not mandated by securities regulators. This should also be applied to climate-related financial metrics as they are not material to all companies, may cause significant confusion for generalist investors researching technical industries, and will leave companies open to liability.

BIO urges the Commission to ensure that, where material, reporting metrics do not create an unnecessary shift in regulatory burden onto reporting companies. The Commission, for the first time, has requested that companies specifically analyze, discuss, forecast, and report on how an exogenous shock and/or macro factor (climate change) will impact their respective businesses and consolidated financial statements over various time horizons. The analysis of macro factors on financial statements is the job of investors and industry analysts. Registrants should not be made to do this level of analysis for investors, assuming the liabilities in the process.

[25] As the denominator (cash level) falls and numerator (emissions) stays basically unchanged, the ratio increases and sends a false signal to investors that the company may be emitting more GHGs or GHG intensity may be increasing over time, even though nothing has really changed except for cash levels ("total assets").

As it relates to filing of historic data, BIO understands that starting points matter. However, BIO contends that asking small companies to submit historical years is a significant and costly burden. If disclosures of methodologies are already included as part of the disclosures, then investor should be able to extrapolate. BIO remains concerned that the Commission is requiring registrants to fulfill the analytical role traditionally completed by industry analysts and investors. Furthermore, private companies seeking to IPO should not have to provide climate-related disclosure in Form S-1 as many companies will be using capital raised in an IPO to fulfill all of these requirements. There is little expectation for venture capital investors to provide funding to finance the creation of organizational structures that are required to satisfy a different pool on investors.

Attestation

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant transition periods to allow registrants, auditors, and attestation providers to catch-up to demand and settle on market standards, which are currently not present.

Attestation requirements, where required, should be phased-in in-line with the spirit of the JOBS Act emerging growth company exemptions. In addition, the requirement should be limited to seasoned issuers and those companies with more than $1,000,000,000,000 in revenue and more than $2,000,000,000 in public float, which (a) keeps with the revenue threshold of SRCs and EGCs, and (b) aligns current definition of SRC with market practice for small companies, which is defined as a company with market capitalization (public float) less than $2,000,000,000.

BIO strongly supports the establishment of global standards for attestation engagement and reporting prior to requiring registrants to utilize them in reporting to shareholders and filing with the Commission. This will go a long way to limit liability and create a level-playing field for all registrants. BIO strongly supports that these standards be created by a recognized body that follows due process procedures, including feedback from all stakeholders, and them making these standards available at no cost. If the Commission is endeavoring to formalize the reporting of climate-related risks, then the Commission should ensure that the reporting, auditing, and attestation frameworks that will be used are standardized, transparent, and well-understood by all stakeholders.

Organizational Structure

While the overall impact of climate-related risk disclosure will vary across registrants and sectors of the economy, BIO remains concerned regarding the burden specifically being imposed on the makeup, compensation, and expertise of boards and management structures. Registrants should be able to, if needed, demonstrate board level commitment without the Commission mandating climate-related expertise be housed within the board. Biotechnology firms, especially small and emerging companies, need to ensure a wide range of highly specialized expertise is demonstrated among a small number of individuals. Current efforts by the Commission to embed multiple new areas of specialized expertise in these boards will create additional barriers for companies already having difficulty identifying individuals to serve.

The proposed rule for board-level involvement and oversight seems more appropriate as a requirement for index inclusion. This is the most efficient mechanism for ensuring that larger companies have board representation for this matter. For example, S&P 500, Dow Jones Industrial Average, MSCI, Russell, Wilshire, and CRSP Indices can mandate that in order to be included in their respective index, a company must fit the market capitalization and board structure requirements.

In addition, the Commission should ensure that any board- or management-level requirements included in the proposal, if finalized, be framed to ensure that a company's management is focused on matters that are material to the operations and finances of the company. The SEC should not mandate that every company in the United States be required to expand management structures to accommodate concerns that are not material to a company.

The Impact of Regulation on Small Business Capital Formation

BIO urges the Commission to view their regulatory agenda with the hindsight of lessons learned from past waves of regulation, the consequences they had for capital formation and capital markets, the significant costs to small companies and the knock-on effects to local economies, and the eventual need to roll back regulations to more meaningful and more effective levels. This proposed rule will compel action which will increase the cost of capital for smaller companies and increase capital expenditure on greenhouse gas emissions and climate risk service providers. This is in addition to the costs and liability already proposed by the Commission's other proposed rules.

The net consequence of heavy regulatory reporting burdens for public companies are two-fold. (1) Fewer companies will join public markets (particularly since climate risk disclosure are

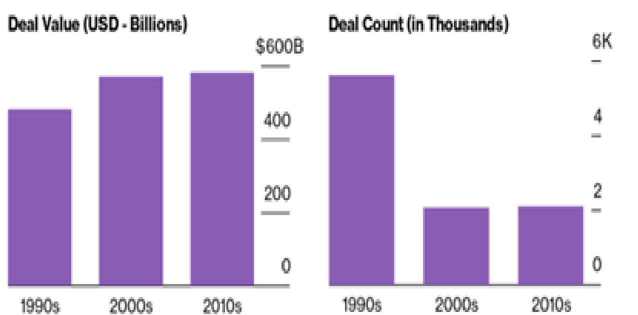
required for Form S-1 with no phase-in or protections from an emerging growth company designation), and (2) the companies that do become public will be large in order to absorb the burdens associated with being a public company.

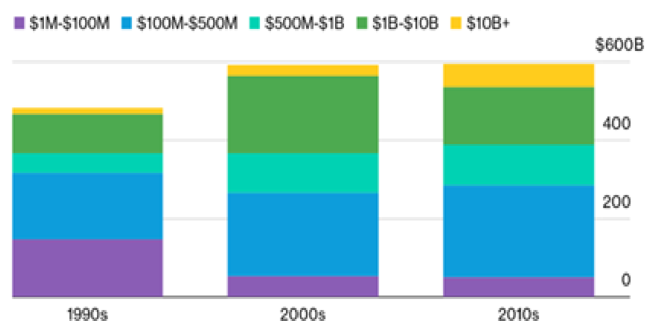
Put another way, more regulation means you create larger companies. This is a natural consequence of requiring more capital to support a larger, more costly operating structure to meet the demands of regulators. This was the result of Sarbanes-Oxley. Similarly, in the wake of Dodd-Frank, financial institutions and asset managers became much larger.

As the chart below illustrate, in the wake of Sarbanes-Oxley the number of IPOs fell but deal values increased. This means that fewer companies went public, but those that did tended to be large. Put another way, the consequence of regulatory waves is the creation of larger companies and industry consolidation to absorb effectively costs and operations.

From the 1990s to the 2000s the number of IPOs fell by more than 60 percent.[26] Another way to look at it is by breaking down the deal values by offer size where one can note that since the 1990s the number of companies seeking $1 million to $100 million collapsed.[27]

Congress had to enact new legislation, most crucially the JOBS Act of 2012, to reignite the IPO market, particularly for smaller companies. This is concerning, given that support for legislation like the JOBS Act is no longer as bipartisan as it once was.





[26] https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-three-decades-of-ipo-deals-1990-2019
[27] Id

The current wave of regulation is threatening to repeat the earlier cycles in capital markets and capital formation. It will become necessary for Congress to enact new ways to incentivize going public because of the significant cost and onerous, duplicative, reporting associated with being a reporting company. Such a feat will be exponentially more difficult in today's climate than when the JOBS Act was first enacted.

While each of the Commission's proposed rules have merit and address serious issues, BIO is concerned that the Commission is not analyzing the aggregate effects and consequences of the entire regulatory agenda.

Conclusion

BIO thanks the Commission both for undertaking this important work and for the opportunity to provide feedback and comments on the proposed rule. BIO remains highly concerned with the financial impact of the proposed rule on small reporting and emerging growth companies. BIO recommends that the Commission align the definition of smaller reporting company with the investor definition of small company (market cap less than $2,000,000,000) and provide for exemptions. BIO is concerned that the proposed rule is highly reliant on an ecosystem of service providers that have not been accredited or certified by regulators as adequate providers of the data, systems, consulting services, audit, attestation, and governance advice that is required for this proposed rule to be successful. As such, BIO recommends that the full climate disclosure proposed rule qualify for safe harbors. BIO is also concerned with the consolidated financial statement reporting proposals as (a) a one-percent threshold is a negligible fluctuation for most companies, (b) is imposing artificially one percent as a materiality threshold, and (c) intensity metrics and other financial-related ratios are too volatile for the biotechnology industry and should be omitted from the final rule. BIO looks forward to working with the Commission on these important issues.

Responses to Key Questions

Please note that included below are answers to questions to which BIO had comments. We do not include questions where BIO had no position.

1. Should we add a new subpart to Regulation S-K and a new article to Regulation S-X that would require a registrant to disclose certain climate-related information, as proposed? Would including the climate-related disclosure in Regulation S-K and Regulation S-X facilitate the presentation of climate information as part of a registrant's regular business reporting? Should we instead place the climate-related disclosure requirements in a new regulation or report? Are there certain proposed provisions, such as GHG emissions disclosure requirements, that would be more appropriate under Regulation S-X than Regulation S-K?

Most companies that already report on sustainability issues, such as climate change, already do so in separate reports that allow companies to provide said information in the context of the company's mission, operations, opportunities, and risks. This way investors have the full context of climate-related metrics within one, dedicated place instead of spread across Form 10K. Furthermore, BIO contends that GHG emissions are not material to a company's operations or financials, and should not be included in Regulation S-K or Regulation S-X.

Reporting on GHG emissions stretches the Commission's established criteria for materiality, creates enumerable risks for small companies, and will introduce significant costs on small companies to comply. This last point is particularly salient given that the Commission is also asking small companies to undertake the same operational, organizational, and exogenous costs on several other proposed rules.

It seems odd that the Commission would select one specific exogenous factor causing structural problems to the global business environment and then compelling registrants to calculate, analyze, forecast, and report deeply using uncertified methods to execute the proposed rule. There are many exogenous factors that are changing the business environment in ways that will reshape global trade, innovation, and international competition for decades to come. It seems odd that the Commission has chosen climate change.

GHG emissions and intensity ratios have no need to be included within consolidated financial statements as these ratios (intensity per unit of revenue or unit of production) are arbitrary and, as demonstrated in the comments above, irrelevant in the biotechnology industry. Further, emissions are not financially material. These metrics will not provide for adequate or uniform comparisons across emerging biotechnology companies for the broad investor public. Only specialist investors will be able to understand the volatility of the contemplated ratios and how to truly compare between emerging biotechnology companies (as is currently the case).

Furthermore, the Commission does not require companies to conduct a DuPont analysis, intrinsic value calculations, return on invested capital, return on capital employed, liquidity ratios, current ratios, or any other ratio that helps analysts and investors understand and compare financial statements. These ratios have been and should continue to be conducted by investors, and not compelled by regulation to be reported by companies. This is a fundamental job of any analyst, but not for corporate financial reporting.

4. Do our current reporting requirements yield adequate and sufficient information regarding climate-related risks to allow investors to make informed decisions? In lieu of, or in addition to the proposed amendments, should we provide updated guidance on how our existing rules may elicit better disclosure about climate-related risks?

Yes. Current guidelines and Commission guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO vigorously agrees that the Commission should update current guidance on climate-related risks disclosures as the proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

5. Should we require a registrant to present the climate-related disclosure in an appropriately captioned, separate part of the registration statement or annual report, as proposed? Should this disclosure instead be presented as part of the registrant's MD&A?

As the Commission notes, the current ecosystem of GHG emission reporting, audit, and assurance is "evolving and unique" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data."

Because the Commission is compelling industry to implement disclosures in a shifting landscape with a multitude of service providers that have not been validated or verified by regulators, both investors and registrants would be better served in having any climate-related disclosure enshrined in the MD&A, which is covered by the safe harbors necessary to protect registrants while providing investors with any climate-related financial or operating information that may be material to their company or industry group.

7. Should we permit a registrant to provide certain of the proposed climate-related disclosures in Commission filings other than the annual report or registration statement? For example, should we permit a registrant to provide information about board and management oversight of climate-related risks in its proxy statement?

Small companies, particularly those in the biotechnology industry, should not be required to have board or management structures entirely dedicated to climate risk assessments, strategy, and planning. This should not be included in any regulatory filings as biotechnology boards are

already constrained by exogenous factors (such as the dearth of talent in the life sciences with subject matter expertise that also meet diversity statistics).

If shareholders vote for such reporting, then the company should have such information included in proxy statements. Until such time as shareholders conclude that such information is relevant to them, as owners of a going interest, then companies should not be compelled to do so via regulation. As evidenced by the SASB climate risk technical bulletin, climate risks are not material for certain industries, such as biotechnology.

8. Should we require a registrant to disclose any climate-related risks that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements, which may manifest over the short, medium, and long term, as proposed? If so, should we specify a particular time period, or minimum or maximum range of years, for "short," "medium," and "long term?" For example, should we define short term as 1 year, 1-3 years, or 1-5 years? Should we define medium term as 5-10 years, 5-15 years, or 5-20 years? Should we define long-term as 10-20 years, 20-30 years, or 30-50 years? Are there other possible years or ranges of years that we should consider as the definitions of short, medium, and long term? What, if any, are the benefits to leaving those terms undefined? What, if any, are the concerns to leaving those terms undefined? Would the proposed provision requiring a registrant to specify what it means by the short, medium, and long term mitigate any such concerns?

Current guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.

It seems odd that the Commission, for the first time, has requested that companies specifically analyze, discuss, forecast, and report on how exogenous shocks will impact their respective businesses and consolidated financial statements over various time horizons. The current inflationary environment, supply chain shocks, the long-term consequences of the pandemic, and ongoing geopolitical turmoil (in Europe as well as the broader retreat of globalization) also have significant long-term ramifications. Yet the Commission has not mandated that companies create separate line-item forecasts, consult with outside experts, nor create entirely new reporting structures to account and brief investors. The Commission is leaving these structural shifts to the business environment for investors to navigate on their own. It seems odd that the Commission would select one specific exogenous factor causing structural problems to the global business environment and then compel every registrant listed in the United States to analyze and forecast across three different time horizons that can be arbitrarily determined by registrants.

10. We define transition risks to include legal liability, litigation, or reputational risks. Should we provide more examples about these types of risks? Should we require more specific disclosures about how a registrant assesses and manages material legal liability,

litigation, or reputational risks that may arise from a registrant's business operations, climate mitigation efforts, or transition activities?

BIO is concerned that the unintended consequence of the proposed rule is that it will introduce many of these risks.

11. Some chronic risks might give rise to acute risks, e.g., drought (a chronic risk) that increases acute risks, such as wildfires, or increased temperatures (a chronic risk) that increases acute risks, such as severe storms. Should we require a registrant to discuss how the acute and chronic risks they face may affect one another?

Not all registrants are climate experts, nor should they be required to hire external professionals to conduct this assessment.

13. If a registrant determines that the flooding of its buildings, plants, or properties is a material risk, should we require it to disclose the percentage of those assets that are in flood hazard areas in addition to their location, as proposed? Would such disclosure help investors evaluate the registrant's exposure to physical risks related to floods? Should we require this disclosure from all registrants, including those that do not currently consider exposure to flooding to be a material physical risk? Should we require this disclosure from all registrants operating in certain industrial sectors and, if so, which sectors? Should we define "flood hazard area" or provide examples of such areas? If we should define the term, should we define it similar to a related definition by the Federal Emergency Management Agency ("FEMA") as an area having flood, mudflow or flood-related erosion hazards, as depicted on a flood hazard boundary map or a flood insurance rate map? Should we require a registrant to disclose how it has defined "flood hazard area" or whether it has used particular maps or software tools when determining whether its buildings, plants, or properties are located in flood hazard areas? Should we recommend that certain maps be used to promote comparability? Should we require disclosure of whether a registrant's assets are located in zones that are subject to other physical risks, such as in locations subject to wildfire risk?

Current guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.

The Commission, and investors, do not need every registrant to report on flood hazards if flood hazards are not material to the business or consolidated financial statements of a company. The Commission risks following in the steps of the conflict mineral or mining disclosures as these are not material to the majority of companies.

14. If a material risk concerns the location of assets in regions of high or extremely high water stress, should we require a registrant to quantify the assets (*e.g.*, book value and as a

percentage of total assets) in those regions in addition to their location, as proposed? Should we also require such a registrant to disclose the percentage of its total water usage from water withdrawn in high or extremely high water stressed regions, as proposed? If so, should we include a definition of a "high water stressed region" similar to the definition provided by the World Resource Institute as a region where 40-80 percent of the water available to agricultural, domestic, and industrial users is withdrawn annually? Should we similarly define an "extremely high water stressed area" as a region where more than 80 percent of the water available to agricultural, domestic, and industrial users is withdrawn annually? Are there other definitions of high or extremely high water stressed areas we should use for purposes of this disclosure? Would these items of information help investors assess a registrant's exposure to climate-related risks impacting water availability? Should we require the disclosure of these items of information from all registrants, including those that do not currently consider having assets in high water-stressed areas a material physical risk? Should we require these disclosures from all registrants operating in certain industrial sectors and, if so, which sectors?

Current guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.
The Commission, and investors, do not need every registrant to report on water stress concerns if water stress concerns are not material to the business or consolidated financial statements of a company. The Commission risks following in the steps of the conflict mineral or mining disclosures as these are not material to the majority of companies.

17. Should we include the negative impacts on a registrant's value chain in the definition of climate-related risks, as proposed? Should we define "value chain" to mean the upstream and downstream activities related to a registrant's operations, as proposed? Are there any upstream or downstream activities included in the proposed definition of value chain that we should exclude or revise? Are there any upstream or downstream activities that we should add to the definition of value chain? Are there any upstream or downstream activities currently proposed that should not be included?

Value-chain definitions should exclude outsourcing of processes that have never been part of a registrant's operations at current or future scale, outsourcing of operations as mandated by regulation as well as counterparts that are governments, state-owned enterprises, government-affiliated enterprises, intergovernmental institutions, international institutions, private companies, and nonprofit and/or not-for-profit enterprises.

19. Should we require a registrant to describe the actual and potential impacts of its material climate-related risks on its strategy, business model, and outlook, as proposed? Should we require a registrant to disclose impacts from climate-related risks on, or any resulting significant changes made to, its business operations, including the types and locations of its operations, as proposed?

Current guidelines and Commission guidance already requires companies to disclose any risk, including climate-related risk, that have had or are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

20. Should we require a registrant to disclose climate-related impacts on, or any resulting significant changes made to, its products or services, supply chain or value chain, activities to mitigate or adapt to climate-related risks, including adoption of new technologies or processes, expenditure for research and development, and any other significant changes or impacts, as proposed? Are there any other aspects of a registrant's business operations, strategy, or business model that we should specify as being subject to this disclosure requirement to the extent they may be impacted by climate-related factors?

Current guidelines and Commission guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

22. Should we require a registrant to discuss whether and how it considers any of the described impacts as part of its business strategy, financial planning, and capital allocation, as proposed? Should we require a registrant to provide both current and forward-looking disclosures to facilitate an understanding of whether the implications of the identified climate related risks have been integrated into the registrant's business model or strategy, as proposed? Would any of the proposed disclosures present competitive concerns for registrants? If so, how can we mitigate such concerns?

Current guidelines and Commission guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

23. Should we require the disclosures to include how the registrant is using resources to mitigate climate-related risks, as proposed? Should the required discussion also include

how any of the metrics or targets referenced in the proposed climate-related disclosure subpart of Regulation S-K or Article 14 of Regulation S-X relate to the registrant's business model or business strategy, as proposed? Should we require additional disclosures if a registrant leverages climate-related financing instruments, such as green bonds or other forms of "sustainable finance" such as "sustainability-linked bonds," "transition bonds," or other financial instruments linked to climate change as part of its strategy to address climate-related risks and opportunities? For example, should we require disclosure of the climate-related projects that the registrant plans to use the green bond proceeds to fund? Should we require disclosure of key performance metrics tied to such financing instruments?

Current guidelines and Commission guidance already requires companies to disclose any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. Registrants also disclose and discuss significant capital projects and expenditures. BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

24. If a registrant has used carbon offsets or RECs, should we require the registrant to disclose the role that the offsets or RECs play in its overall strategy to reduce its net carbon emissions, as proposed? Should the proposed definitions of carbon offsets and RECs be clarified or expanded in any way? Are there specific considerations about the use of carbon offsets or RECs that we should require to be disclosed in a registrant's discussion regarding how climate related factors have impacted its strategy, business model, and outlook?

The purchase of carbon offsets would already be disclosed in consolidated financial statements, their utility to an organization would be described in footnotes, and their link to corporate strategy would be discussed in MD&A.

25. Should we require a registrant to provide a narrative discussion of whether and how any of its identified climate-related risks have affected or are reasonably likely to affect its consolidated financial statements, as proposed? Should the discussion include any of the financial statement metrics in proposed 17 CFR 210.14-02 (14-02 of Regulation S-X) that demonstrate that the identified climate-related risks have had a material impact on reported operations, as proposed? Should the discussion include a tabular representation of such metrics?

Current guidelines and Commission guidance already requires companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO emphatically

stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

28. To the extent that disclosure that incorporates or is based on an internal carbon price constitutes forward-looking information, the PSLRA safe harbors would apply. Should we adopt a separate safe harbor for internal carbon price disclosure? If so, what disclosures should such a safe harbor cover and what should the conditions be for such a safe harbor?

BIO highly encourages that the Commission extends safe harbors to all climate-related disclosures as every aspect of this proposed rule will involve third-party data, service providers, estimations, and forecasts as well as uncertified and unvalidated audit and attestation frameworks. As the Commission noted, the calculation, assessment, methodology frameworks and assurances are "still evolving" and therefore represents a significant liability for registrants, especially small companies.

29. Should we require all registrants to disclose an internal carbon price and prescribe a methodology for determining that price? If so, what corresponding disclosure requirements should we include in connection with such mandated carbon price? What methodology, if any, should we prescribe for calculating a mandatory internal or shadow carbon price? Would a different metric better elicit disclosure that would monetize emissions?

No. Most companies do not require the creation and disclosure of an internal carbon price.

30. Should we require a registrant to disclose analytical tools, such as scenario analysis, that it uses to assess the impact of climate-related risks on its business and consolidated financial statements, and to support the resilience of its strategy and business model, as proposed? What other analytical tools do registrants use for these purposes, and should we require disclosure of these other tools? Are there other situations in which some registrants should be required to conduct and provide disclosure of scenario analysis? Alternatively, should we require all registrants to provide scenario analysis disclosure? If a registrant does provide scenario analysis disclosure, should we require it to follow certain publicly available scenario models, such as those published by the IPCC, the IEA, or NGFS and, if so, which scenarios? Should we require a registrant providing scenario analysis disclosure to include the scenarios considered (e.g., an increase of global temperature of no greater than 3 º, 2 º, or 1.5 ºC above pre-industrial levels), the parameters, assumptions, and analytical choices, and the projected principal financial impacts on the registrant's business strategy under each scenario, as proposed? Are there any other aspects of scenario analysis that we should require registrants to disclose? For example, should we require a registrant using scenario analysis to consider a scenario that assumes a disorderly transition? Is there a need for us to provide additional guidance regarding scenario

analysis? Are there any aspects of scenario analysis in our proposed required disclosure that we should exclude? Should we also require a registrant that does not use scenario analysis to disclose that it has not used this analytical tool? Should we also require a registrant to disclose its reasons for not using scenario analysis? Will requiring disclosure of scenario analysis if and when a registrant performs scenario analysis discourage registrants from conducting scenario analysis? If so, and to the extent scenario analysis is a useful tool for building strategic resilience, how could our regulations prevent such consequences?

Current guidelines and Commission guidance already requires companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

31. Would the PSLRA forward-looking statement safe harbors provide adequate protection for the proposed scenario analysis disclosure? Should we instead adopt a separate safe harbor for scenario analysis disclosure? If so, what disclosures should such a safe harbor cover that would not be covered by the PSLRA safe harbors and what should the conditions be for such a safe harbor?

All climate-related disclosures, be they related to the business or the consolidated financial statements of a company, should be enshrined in existing safe harbors.

32. Should we adopt a provision similar to 17 CFR 229.305(d) that would apply the PSLRA forward-looking statement safe harbor to forward-looking statements made in response to specified climate-related disclosure items, such as proposed Item 1502 and Item 1505 (concerning targets and goals) of Regulation S-K? If so, which proposed items should we specifically include in the safe harbor?

All climate-related disclosures, be they related to the business or the consolidated financial statements of a company, should be enshrined in existing safe harbors.

34. Should we require a registrant to describe, as applicable, the board's oversight of climate-related risks, as proposed? Should the required disclosure include whether any board member has expertise in climate-related risks and, if so, a description of the nature of the expertise, as proposed? Should we also require a registrant to identify the board members or board committee responsible for the oversight of climate-related risks, as proposed? Do our current rules, which require a registrant to provide the business experience of its board members, elicit adequate disclosure about a board member's or executive officer's expertise relevant to the oversight of climate-related risks?

BIO vehemently disagrees with this proposed requirement. The biotechnology industry already has tremendous difficulty in filing board seats with those that have expertise in biotechnology, clinical trials, and in the sub-specialty of the therapeutic target of the company.

For example, finding board members that have successful track records running clinical trials and raising capital for companies in amyloid-targeting therapeutics in the treatment of Alzheimer's disease is remarkably difficult. In addition to this expertise of the therapeutic area (neurology with a focus on dementia), sector (biotechnology), and board role (audit, etc), small biotechnology companies must also work towards finding diverse candidates to fill these board-level roles in an industry that suffers a structural deficit in talent, due to nationally low participation rates in STEM education, and specifically in board-ready candidates from diverse backgrounds. Finally, with such limited pools of talent, there is significant competition and added complexity from proxies, who limit the number of boards on which a director can sit. While this may be pertinent for larger companies, it is a significant problem for smaller companies.

The Commission is adding to this complexity with the need for climate change expertise. In a separate proposed rule, the Commission is compelling the same need for cybersecurity expertise. This is not feasible for small biotechnology companies.

The proposed rule for board-level involvement and oversight seems more appropriate as a requirement for index inclusion. This is the most efficient mechanism for ensuring that larger companies have board representation for this matter. For example, S&P 500, Dow Jones Industrial Average, MSCI, Russell, Wilshire, and CRSP Indices can mandate that in order to be included in their respective index, a company must fit the market capitalization and board structure requirements.

35. Should we require a registrant to disclose the processes and frequency by which the board or board committee discusses climate-related risks, as proposed?

BIO vehemently disagrees with this proposed requirement. The biotechnology industry already has tremendous difficulty in filing board seats with those that have expertise in biotechnology, clinical trials, and in the sub-specialty of the therapeutic target of the company. The Commission is adding to this complexity with the need for climate change expertise. In a separate proposed rule, the Commission is compelling the same need for cybersecurity expertise. This is not feasible for small biotechnology companies.

The proposed rule for board-level involvement and oversight seems more appropriate as a requirement for index inclusion. This is the most efficient mechanism for ensuring that larger companies have board representation for this matter.

36. Should we require a registrant to disclose whether and how the board or board committee considers climate-related risks as part of its business strategy, risk management, and financial oversight, as proposed? Would the proposed disclosure raise competitive harm concerns? If so, how could we address those concerns while requiring additional information for investors about how a registrant's board oversees climate-related risks?

BIO vehemently disagrees with this proposed requirement. The biotechnology industry already has tremendous difficulty in filing board seats with those that have expertise in biotechnology, clinical trials, and in the sub-specialty of the therapeutic target of the company. The Commission is adding to this complexity with the need for climate change expertise. In a separate proposed rule, the Commission is compelling the same need for cybersecurity expertise. This is not feasible for small biotechnology companies.

The proposed rule for board-level involvement and oversight seems more appropriate as a requirement for index inclusion. This is the most efficient mechanism for ensuring that larger companies have board representation for this matter.

37. Should we require a registrant to disclose whether and how the board sets climate-related targets or goals, as proposed? Should the required disclosure include how the board oversees progress against those targets or goals, including whether it establishes any interim targets or goals, as proposed? Would the proposed disclosure raise competitive harm concerns? If so, how could we address those concerns while requiring additional information for investors about how a registrant's board oversees the setting of any climate-related targets or goals?

BIO vehemently disagrees with this proposed requirement. The biotechnology industry already has tremendous difficulty in filing board seats with those that have expertise in biotechnology, clinical trials, and in the sub-specialty of the therapeutic target of the company. The Commission is adding to this complexity with the need for climate change expertise. In a separate proposed rule, the Commission is compelling the same need for cybersecurity expertise. This is not feasible for small biotechnology companies.

The proposed rule for board-level involvement and oversight seems more appropriate as a requirement for index inclusion. This is the most efficient mechanism for ensuring that larger companies have board representation for this matter.

38. Should we require a registrant to describe, as applicable, management's role in assessing and managing climate-related risks, as proposed? Should the required disclosure include whether certain management positions or committees are responsible for assessing and managing climate-related risks and, if so, the identity of such positions or committees, and the relevant expertise of the position holders or members in such detail as necessary to fully describe the nature of the expertise, as proposed? Should we require a registrant to identify the executive officer(s) occupying such position(s)? Or do our current rules, which

require a registrant to provide the business experience of its executive officers, elicit adequate disclosure about management's expertise relevant to the oversight of climate-related risks?

BIO vehemently disagrees with this proposed requirement. A company's management should be focused on matters that are material to the operations and finances of the company. In biotechnology, as noted throughout this comment letter, climate risks and any associated risks to the consolidated financial statements of a biotechnology have been found by the SASB / ISSB (which are built upon TCFD) to not be material to the biotechnology industry. This is the case for several industry groups and a myriad of companies within these groups. As such, the SEC should not mandate that every company in the United States be required to expand management structures in order to accommodate concerns that are not material to a company.

39. Should we require a registrant to describe the processes by which the management positions or committees responsible for climate-related risks are informed about and monitor climate-related risks, as proposed? Should we also require a registrant to disclose whether and how frequently such positions or committees report to the board or a committee of the board on climate-related risks, as proposed?

A company's management should be focused on matters that are material to the operations and finances of the company. In biotechnology, as noted throughout this comment letter, climate risks, and any associated risks to the consolidated financial statements of a biotechnology company, have been found by the SASB / ISSB (which are built upon TCFD) to be not material to the biotechnology industry. This is the case for several industry groups and a myriad of companies within these groups. As such, the SEC should not mandate that every company in the United States be required to expand management structures in order to accommodate concerns that are not material to a company.

40. Should we specifically require a registrant to disclose any connection between executive remuneration and the achievement of climate-related targets and goals? Is there a need for such a requirement in addition to the executive compensation disclosure required by 17 CFR 229.402(b)?

BIO vehemently disagrees with this proposal. A company's executives should be compensated according to its shareholders and should be tied to the long-term effectiveness of executives.

41. As proposed, a registrant may disclose the board's oversight of, and management's role in assessing and managing, climate-related opportunities. Should we require a registrant to disclose these items?

BIO vehemently disagrees with this proposed requirement.

42. Should we require a registrant to describe its processes for identifying, assessing, and managing climate-related risks, as proposed?

BIO disagrees that this should be a requirement. BIO contends that biotechnology companies should not be required to spend capital and time on social concerns that are not material to the industry or the company.

43. When describing the processes for identifying and assessing climate-related risks, should we require a registrant to disclose, as applicable, as proposed:
• How the registrant determines the relative significance of climate-related risks compared to other risks?
• How it considers existing or likely regulatory requirements or policies, such as emissions limits, when identifying climate-related risks?
• How it considers shifts in customer or counterparty preferences, technological changes, or changes in market prices in assessing potential transition risks?
• How the registrant determines the materiality of climate-related risks, including how it assesses the potential size and scope of an identified climate-related risk?

Are there other items relevant to a registrant's identification and assessment of climate-related risks that we should require it to disclose instead of or in addition to the proposed disclosure items?

BIO contends that the above proposed requirements will require registrants in the biotechnology sector to hire a significant number of outside consultants and counsels to fulfill regulatory requirements that are not material to the industry. Existing guidance already requires companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.

BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

44. When describing the processes for managing climate-related risks, should we require a registrant to disclose, as applicable, as proposed:
• How it decides whether to mitigate, accept, or adapt to a particular risk?
• How it prioritizes climate-related risks?
• How it determines to mitigate a high priority risk? Are there other items relevant to a registrant's management of climate-related risks that we should require it to disclose instead of or in addition to the proposed disclosure items?

BIO contends that the above proposed requirements will require registrants in the biotechnology sector to hire outside consultants to fulfill regulatory requirements that are not material to the industry. Existing guidelines and Commission guidance already require companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.

BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

45. Should we require a registrant to disclose whether and how the processes described in response to proposed 17 CFR 229.1503(a) are integrated into the registrant's overall risk management system or processes, as proposed? Should we specify any particular aspect of this arrangement that a registrant should disclose, such as any interaction between, and corresponding roles of, the board or any management committee responsible for assessing climate-related risks, if there is a separate and distinct committee of the board or management, and the registrant's committee in charge, generally, of risk assessment and management?

BIO contends that the above proposed requirements will require registrants in the biotechnology sector to hire outside consultants to fulfill regulatory requirements that are not material to the industry. Existing guidelines and Commission guidance already require companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.

BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

51. To the extent that disclosure about a registrant's transition plan constitutes forward looking information, the PSLRA safe harbors would apply. Should we adopt a separate safe harbor for transition plan disclosure? If so, what disclosures should such a safe harbor cover and what should the conditions be for such a safe harbor?

BIO strongly urges the Commission to enshrine all proposed climate-related disclosures in the PSLRA safe harbors, including any transition plan, if registrants choose to compose and release them. The Commission outlined numerous times within the proposed rule that every aspect of the proposed reporting requirements is "still evolving," including the audit and assurance aspects

of the proposed rule. Due to the fluid nature of the industry that is expected to underwrite these disclosures on behalf of registrants, the Commission should broaden the safe harbors to include all climate-related disclosures. Further, as noted in the comments above, the biotechnology industry's nuance will make certain proposed metrics unusable for generalist investors, and, we fear, may cause consternation and possible litigation attributed to nothing more than a lack of understanding of the sector. For these reasons as well, the Commission should broaden the safe harbors to include all climate-related disclosures finalized.

52. Should we require a registrant to provide contextual information, including a description of significant inputs and assumptions used, and if applicable, policy decisions made by the registrant to calculate the specified metrics, as proposed? Should we revise the proposed requirement to provide contextual information to require specific information instead? We provide some examples of contextual information disclosure in Sections II.F.2 and II.F.3 below. Would providing additional examples or guidance assist registrants in preparing this disclosure?

Given that the landscape of third-parties service providers is still fluid, the Commission should allow for broader interpretations.

53. The proposed rules would specify the basis of calculation for the climate-related financial statement metrics. Is it clear how to apply these accounting principles when calculating the proposed climate-related financial statement metrics, or should we provide additional guidance? Should we require a registrant to report these metrics with reference to its consolidated financial statements, as proposed? If not, how should registrants report these metrics? If we were to establish accounting principles (e.g., the basis for reporting these metrics) in a manner that differs from the principles applicable to the rest of the consolidated financial statements, would the application of those principles to the proposed metrics make climate-related disclosures less clear, helpful, or comparable for investors?

As noted in the comments above, BIO contends that the climate-related financial statement metrics have significant potential to cause confusion among generalist investors. BIO is also confused as to why registrants are being required to provide calculations and metrics that have been traditionally part of the roles and responsibilities of an industry analyst / investor. For these reasons, BIO strongly urges the Commission to tie these calculations to materiality. Notably, industry analysts, investors, and registrants, as part of the SASB/ISSB deliberation process, concluded that the climate-related disclosures are not material for the biotechnology industry.

55. The proposed rules would require disclosure for the registrant's most recently completed fiscal year and for the corresponding historical fiscal years included in the registrant's consolidated financial statements in the filing. Should disclosure of the climate-related financial statement metrics be required for the fiscal years presented in the registrant's financial statements, as proposed? Instead, should we require the financial statement metrics to be calculated only for the most recently completed fiscal year

presented in the relevant filing? Would requiring historical disclosure provide important or material information to investors, such as information allowing them to analyze trends? Are there other approaches we should consider?

BIO understands that starting points matter. However, BIO contends that asking small companies to submit historical years is a significant burden for small companies. If disclosures of methodologies are already included as part of the disclosures, then investor should be able to extrapolate. BIO remains concerned that the Commission is requiring registrants to fulfill the analytical role traditionally completed by industry analysts and investors.

56. Should information for all periods in the consolidated financial statements be required for registrants that are filing an initial registration statement or providing climate-related financial statement metrics disclosure for historical periods prior to the effective date or compliance date of the rules? Would the existing accommodation in Rules 409 and 12b-21 be sufficient to address any potential difficulties in providing the proposed disclosures in such situations?

BIO understands that starting points matter. However, BIO contends that asking small companies to submit historical years is a significant burden for small companies. Private companies seeking to IPO should not have to provide climate-related disclosure in Form S-1 as many companies will be using capital raised in an IPO to fulfill all of these requirements. There is little expectation for venture capital investors to provide funding to finance the creation of organizational structures that are required to satisfy a different pool on investors.

59. Should we require registrants to disclose the financial impact metrics, as proposed? Would presenting climate-specific financial information on a separate basis based on climate related events (severe weather events and other natural conditions and identified physical risks) and transition activities (including identified transition risks) elicit decision-useful or material information for investors? Are there different metrics that would result in disclosure of more useful information about the impact of climate-related risks and climate-related opportunities on the registrant's financial performance and position?

As noted in the comments above, BIO contends that the climate-related financial statement metrics have significant potential to cause confusion among generalist investors. BIO is also confused as to why registrants are being required to provide calculations and metrics that have been traditionally part of the roles and responsibilities of an industry analyst / investor. For these reasons, BIO strongly urges the Commission to tie these calculations to materiality. Notably, industry analysts, investors, and registrants, as part of the SASB/ISSB deliberation process, concluded that the climate-related disclosures are not material for the biotechnology industry.

60. Would the impact from climate-related events and transition activities yield decision useful information for investors? Would the climate-related events (including the examples provided) and transition activities result in impacts that are easier to quantify or

disaggregate than climate-related risks more generally? Would a registrant be able to quantify and provide the proposed disclosure when the impact may be the result of a mixture of factors (e.g., a factory shutdown due to an employee strike that occurs simultaneously with a severe weather event)? If there are situations where disaggregation would not be practicable, should we require a registrant to disclose that it was unable to make the required determination and why, or to make a reasonable estimate and provide disclosure about the assumptions and information that resulted in the estimate?

As described above, the utility of the climate-related disclosures would have little value to biotechnology investors (as already verified by the SASB standards) and would create confusion for generalists reviewing climate-related disclosures for the biotechnology industry.

61. Alternatively, should we not require disclosure of the impacts of identified climate related risks and only require disclosure of impacts from severe weather events and other natural conditions? Should we require a registrant to disclose the impact on its consolidated financial statements of only certain examples of severe weather events and other natural conditions? If so, should we specify which severe weather events and other natural conditions the registrant must include? Would requiring disclosure of the impact of a smaller subset of climate-related risks be easier for a registrant to quantify without sacrificing information that would be material to investors?

BIO contends that existing guidelines and Commission guidance already require companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements.

BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed. The proposed rule is fraught with liability, costs, organizational structure, and disclosures that are not material for a myriad of economic sectors and companies.

62. Should impact from climate-related opportunities be required, instead of optional, as proposed? We are proposing to require a registrant that elects to disclose the impact of an opportunity to do so consistently (e.g., for each fiscal year presented in the consolidated financial statements, for each financial statement line item, and for all relevant opportunities identified by the registrant). Are there any other requirements that we should include to enhance consistency? Should we only require consistency between the first fiscal period in which opportunities were disclosed and subsequent periods?

Many biotechnology companies have a core mission of developing novel products that are low carbon-intensity or replacements for petroleum-based products. This does not, however, mean that climate change is material to a company who is developing these new products. These companies should not be required to restate their mission and how their strategic plans flow

through the financial statements in pursuit of that mission. Investors in these companies should already understand the value proposition and opportunity of the product offerings. This would constitute an overlap in disclosures for these companies.

64. Are the proposed requirements for calculating and presenting the financial impact metrics clear? Should the analysis be performed and disclosed in a manner other than on a line-by-line basis referring to the line items of the registrant's consolidated financial statements?

As noted in the comments above, BIO is concerned with the proposal to compel companies to report financial impacts of risks that have not been found to be material for the biotechnology industry by international consortiums of standard-setters, investors, and companies (such as the SASB/ISSB). As noted in the comments, the line-by-line basis of reporting will further complicate what is already a specialist sector for investing. The biotechnology industry is comprised mostly of small companies that will require significant third-party data and service providers to report on these line items at significant cost to the entire biotechnology ecosystem and innovation economy.

65. We are proposing to allow a registrant to aggregate the absolute value of negative and positive impacts of all climate-related events and, separately, transition activities on a financial statement line item. Should we instead require separate quantitative disclosure of the impact of each climate-related event or transition activity? Should we require separate disclosure of the impact of climate-related opportunities that a registrant chooses to disclose?

The analysis of macro factors on financial statements is the job of investors and industry analysts. Registrants should not be made to do this level of analysis for investors, assuming the liabilities in the process.

66. The proposed financial impact metrics would not require disclosure if the absolute value of the total impact is less than one percent of the total line item for the relevant fiscal year. Is the proposed threshold appropriate? Should we use a different percentage threshold (e.g., three percent, five percent) or use a dollar threshold (e.g., less than or greater than $1 million)? Should we use a combination of a percentage threshold and a dollar threshold? Should we only require disclosure when the financial impact exceeds the threshold, as proposed, or should we also require a determination of whether an impact that falls below the proposed quantitative threshold would be material and should be disclosed?

The Commission has used various thresholds to trigger different reporting requirements. The Commission's imposition of a one percent threshold trigger constitutes the Commission creating a new definition of materiality, which is intended to supersede the current definition that has been established by case law and subvert a company's shareholders as the stakeholders

responsible for dictating what is material to them. BIO is concerned that the SEC is endeavoring to uproot the established interpretations of materiality.

BIO also contends that a one-percent impact may not be material for every company of every size in every industry. BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements. Historically, a one-percent deviation of any consolidated financial statement line item would never reach the level of materiality for a broad investment public. A one-percent expenditure is seldomly critiqued by investors. Why, then, should registrants be compelled to report a trigger that would historically never be considered important by an investor? This threshold is arbitrary.

68. Instead of including a quantitative threshold, as proposed, should we require disaggregated disclosure of any impact of climate-related risks on a particular line item of the registrant's consolidated financial statements? Alternatively, should we just use a materiality standard?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements. Historically, a one-percent deviation of any consolidated financial statement line item would never reach the level of materiality for a broad investment public. A one-percent expenditure is seldomly critiqued by investors. Why, then, should registrants be compelled to report a trigger that would historically never be considered important by an investor?

69. Should we require a registrant to disclose changes to the cost of capital resulting from the climate-related events? If so, should we require a registrant to disclose its weighted average cost of capital or any internal cost of capital metrics? Would such disclosure elicit decision-useful or material information for investors?

Current guidelines and standards already require registrants to provide disclosures on the risks and events that alter capital expenditures and the cost of capital. Registrants already discuss to investors when the cost of capital changes, and the impact of those changes on specific, material line items.

70. We have not proposed defining the term "upstream costs" as used in the proposed examples for the financial impact metrics and elsewhere. Should we define that term or any others? If so, how should we define them?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

71. Are the proposed examples in the financial impact metrics helpful for understanding the types of disclosure that would be required? Should we provide different or additional examples or guidance?

BIO stresses the need for a materiality-based disclosure regime. However, the examples were helpful in understanding how to contemplate reporting in the event a climate event or climate trends is found to be material enough to warrant disclosure.

72. Should we require registrants to disclose the expenditure metrics, as proposed? Would presenting the expenditure metrics separately in one location provide decision-useful information to investors? Is there a different type of metric that would result in more useful disclosure of the expense or capitalized costs incurred toward climate-related events and transition activities or toward climate-related risks more generally?

Current guidelines and standards already require registrants to provide disclosures on the risks and events that alter capital expenditures and capital projects. Registrants already disclose to investors when expenses are material to the company, and thoroughly explain the costs or expected costs to shareholders.

73. Would the disclosure required by the expenditure metrics overlap with the disclosure required by the financial impact metrics? If so, should we require the disclosure to be provided pursuant to only one of these types of metrics?

There is significant overlap involved in reporting financial impact metrics as well as specific expenditure metrics.

74. Should the same climate-related events (including severe weather events and other natural conditions and identified physical risks) and transition activities (including identified transition risks) that we are proposing to use for the financial impact metrics apply to the expenditure metrics, as proposed? Alternatively, should we not require a registrant to disclose expenditure incurred towards identified climate-related risks and only require disclosure of expenditure relating to severe weather events and other natural conditions? Should we require a registrant to disclose the expenditure incurred toward only certain examples of severe weather events and other natural conditions? If so, should we specify which severe weather events and other natural conditions the registrant must include? Would requiring disclosure of the expenditure relating to a smaller subset of climate-related risks be easier for a registrant to quantify without sacrificing information that would be material to investors?

There is significant overlap involved in reporting financial impact metrics as well as specific expenditure metrics. Current guidelines and standards already require registrants to provide disclosures on the risks and events that alter capital expenditures and capital projects. BIO

stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

75. Should the proposed rules instead require a registrant to disclose the aggregate amounts of expensed and capitalized costs incurred toward any climate-related risks? Should expenditures incurred towards climate-related opportunities be optional based on a registrant's election to disclose such opportunities, as proposed?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

76. Should we apply the same disclosure threshold to the expenditure metrics and the financial impact metrics? Is the proposed threshold for expenditure metrics appropriate? Should we use a different percentage threshold (e.g., three percent, five percent) or use a dollar threshold (e.g., less than or greater than $1 million)? Should we use a combination of a percentage threshold and a dollar threshold? Should we only require disclosure when the amount of climate-related expenditure exceeds the threshold, as proposed, or should we also require a determination of whether an amount of expenditure that falls below the proposed quantitative threshold would be material and should be disclosed? Should we require separate aggregation of the amount of expense and capitalized costs for purposes of the threshold, as proposed? Should we require separate aggregation of expenditure relating to the climate-related events and transition activities, as proposed?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements. Historically, a one-percent deviation of any consolidated financial statement line item would never reach the level of materiality for a broad investment public. A one-percent expenditure is seldomly critiqued by investors. Why, then, should registrants be compelled to report a trigger that would historically never be considered important by an investor?

77. Instead of including a quantitative threshold, as proposed, should we require disaggregated disclosure of any amount of expense and capitalized costs incurred toward the climate-related events and transition activities, during the periods presented? Alternatively, should we just use a materiality standard?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

79. The proposed rule does not specifically address expensed or capitalized costs that are partially incurred towards the climate-related events and transition activities (e.g., the expenditure relates to research and development expenses that are meant to address both the risks associated with the climate-related events and other risks). Should we prescribe a particular approach to disclosure in such situations? Should we require a registrant to

provide a reasonable estimate of the amount of expense or capitalized costs incurred toward the climate-related events and transition activities and to provide disclosure about the assumptions and information that resulted in the estimate?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

80. Are the proposed terms and examples used in the expenditure metrics helpful for understanding the types of disclosures that would be required? Should we provide different or additional examples?

BIO stresses the need for a materiality-based disclosure regime. However, the examples were helpful in understanding how to contemplate reporting in the event a climate event or climate trends is found to be material enough to warrant disclosure.

81. Should we require disclosure of financial estimates and assumptions impacted by the climate-related events and transition activities (including disclosed targets), as proposed? How would investors use this information?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

82. Should we instead require disclosure of only significant or material estimates and assumptions that were impacted by the climate-related events and transition activities? Alternatively, should we require disclosure of only estimates and assumptions that were materially impacted by the climate-related events and transition activities?

BIO highly supports and strongly recommends that the Commission continue using the materiality standard for company reporting on the effects of climate change on financial statements and operations.

83. Should we instead require disclosure of financial estimates and assumptions impacts by a subset of climate-related events and transition activities, such as not requiring disclosure related to identified climate-related risks or only requiring disclosure with respect to a subset of severe weather events and natural conditions? If so, how should the subset be defined?

BIO stresses the need for the Commission to adhere to the current standards of materiality and allowing companies to report only on material effects of climate change on financial statements.

84. Should we instead utilize terminology and thresholds consistent with the critical accounting estimate disclosure requirement in 17 CFR 229.303(b)(3), such as "estimates made in accordance with generally accepted accounting principles that involve a significant

level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations of the registrant"? If so, should we only require disclosures of whether and how the climate-related events and transition activities impacted such critical accounting estimates? Should we require only a qualitative description of how the estimates and assumptions were impacted by the climate-related events and transition activities, as proposed? Should we require quantitative disclosures as well? If so, should we require such disclosure only if practicable or subject to another qualifier?

BIO recommends that the Commission using materiality as the standard for companies reporting on the effects of climate change on financial statements and operations.

85. Should the disclosure of financial estimates and assumptions impacted by climate-related opportunities be optional, as proposed?

BIO strongly recommends that the Commission using materiality as the standard for companies reporting on the effects of climate change on financial statements and operations. This may involve optionality of certain or all sections of the proposed rule.

86. For the proposed financial statement metrics, should we require a registrant to disclose material changes in estimates, assumptions, or methodology among fiscal years and the reasons for those changes? If so, should we require the material changes disclosure to occur on a quarterly, or some other, basis? Should we require disclosure beyond a discussion of the material changes in assumptions or methodology and the reasons for those changes? Do existing required disclosures already elicit such information? What other approaches should we consider?

BIO strongly supports the Commission using materiality as the standard for companies reporting on the effects of climate change on financial statements and operations, including if there are material changes to how companies estimate, calculate, or develop assumptions and methodologies for any material disclosure.

87. We are proposing to require the financial statement metrics to be disclosed in a note to the registrant's audited financial statements. Should we require or permit the proposed financial statement metrics to be disclosed in a schedule to the financial statements? If so, should the metrics be disclosed in a schedule to the financial statements, similar to the schedules required under Article 12 of Regulation S-X, which would subject the disclosure to audit and ICFR requirements? Should we instead require the metrics to be disclosed as supplemental financial information, similar to the disclosure requirements under FASB ASC Topic 932-235-50-2 for registrants that have significant oil- and gas-producing activities? If so, should such supplemental schedule be subject to assurance or ICFR requirements?

As noted in the comments above, BIO contends that climate-related financial disclosures are not material to the biotechnology industry and may confuse non-specialist investors as cash raising cycles will be the dominant factor in these proposed disclosures. If the Commission goes so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors.

88. Instead of requiring the financial statement metrics to be disclosed in a note to the registrant's audited financial statements, should we require a new financial statement for such metrics? For example, should a "consolidated climate statement" be created in addition to the consolidated balance sheets, statements of comprehensive income, cash flows, and other traditional financial statements? Would including the proposed metrics in a new financial statement provide more clarity to investors given that the metrics are intended to follow the structure of the existing financial statements (including the line items)? What complications or unintended consequences may arise in practice if such a climate statement is created?

As noted in the comments above, BIO contends that climate-related financial disclosures are not material to the biotechnology industry and may confuse non-specialist investors as cash raising cycles will be the dominant factor in these proposed disclosures. If the Commission goes so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors.

89. Should we require the disclosure to be provided outside of the financial statements? Should we require all of the disclosure to be provided in the proposed separately captioned item in the specified forms?

As noted in the comments above, BIO contends that climate-related financial disclosures are not material to the biotechnology industry and may confuse non-specialist investors as cash raising cycles will be the dominant factor in these proposed disclosures. If the Commission goes so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors.

90. Should we require any additional metrics or disclosure to be included in the financial statements and subject to the auditing and ICFR requirements as described above? For example, should any of the disclosures we are proposing to require outside of the financial statements (such as GHG emissions metrics) be included in the financial statements? If so, should such metrics be disclosed in a note or a schedule to the financial statements? If in a schedule, should such schedule be similar to the schedules required under Article 12 of Regulation S-X and subject to audit and ICFR requirements? Should we instead require the metrics to be disclosed as supplemental financial information in a supplemental schedule? If so, should such supplemental schedule be subject to assurance or ICFR requirements?

As noted in the comments above, BIO contends that climate-related financial disclosures are not material to the biotechnology industry and may confuse non-specialist investors as cash raising cycles will be the dominant factor in these proposed disclosures. If the Commission goes so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors.

The Commission has noted that the industry for audit and assurance of climate-related financial disclosures is not mature and very much still in flux. The Commission should therefore exclude the proposed rules from ICFR requirements until such time as the Commission has established appropriate guidelines for audit and assurance. BIO also contends that non-financial metrics, such as GHG emissions, have no place in financial statements. Finally, the Commission should keep with the spirit of the JOBS Act and include climate-related disclosures and financial-impact disclosures in the emerging growth company exemption.

91. Under the proposed rules, PCAOB auditing standards would be applicable to the financial statement metrics that are included in the audited financial statements, consistent with the rest of the audited financial statements. What, if any, additional guidance or revisions to such standards would be needed in order to apply PCAOB auditing standards to the proposed financial statement metrics? For example, would guidance on how to apply existing requirements, such as materiality, risk assessment, or reporting, be needed? Would revisions to the auditing standards be necessary? What additional guidance or revisions would be helpful to auditors, preparers, audit committee members, investors, and other relevant participants in the audit and financial reporting process?

As noted in the comments above, BIO contends that climate-related financial disclosures are not material to the biotechnology industry and may confuse non-specialist investors as cash raising cycles will be the dominant factor in these proposed disclosures. If the Commission goes so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors. The Commission has noted that the industry for audit and assurance of climate-related financial disclosures is not mature and very much still in flux. The Commission should therefore exclude the proposed rules from ICFR requirements until such time as the Commission has established appropriate guidelines for audit and assurance. Finally, the Commission should keep with the spirit of the JOBS Act and include climate-related disclosures and financial-impact disclosures in the emerging growth company exemption.

94. Should we require a registrant to disclose its GHG emissions both in the aggregate, per scope, and on a disaggregated basis for each type of greenhouse gas that is included in the Commission's proposed definition of "greenhouse gases," as proposed? Should we instead require that a registrant disclose on a disaggregated basis only certain greenhouse gases, such as methane (CH4) or hydrofluorocarbons (HFCs), or only those greenhouse gases that are the most significant to the registrant? Should we require disaggregated disclosure of one or more constituent greenhouse gases only if a registrant is obligated to separately

report the individual gases pursuant to another reporting regime, such as the EPA's greenhouse gas reporting regime or any foreign reporting regime? If so, should we specify the reporting regime that would trigger this disclosure?

BIO encourages the Commission to ensure that there is no overlap in reporting requirement across federal and state government agencies. To the extent that there is overlap, the Commission should work with other federal and state agencies to ensure common reporting standards are in place and shared across agencies. Insofar as there is overlap, registrants should not have to disclose to two separate agencies. Further, if the EPA has established a requirement for registrants to disclose certain emissions, which are then published for public consumption, then there is no need for the Commission to require further disclosures of risks and calculations that are not material for securities regulators to hold.

98. Should we require a registrant to disclose its Scope 3 emissions for the fiscal year if material, as proposed? Should we instead require the disclosure of Scope 3 emissions for all registrants, regardless of materiality? Should we use a quantitative threshold, such as a percentage of total GHG emissions (e.g., 25%, 40%, 50%) to require the disclosure of Scope 3 emissions? If so, is there any data supporting the use of a particular percentage threshold? Should we require registrants in particular industries, for which Scope 3 emissions are a high percentage of total GHG emissions, to disclose Scope 3 emissions?

BIO is significant concerns on the inclusion of Scope 3 emissions. As noted in the comments above, Scope 3 emission are not material nor will they provide investors with any actionable or relevant information about the biotechnology industry, especially for emerging biotechnology companies. The proposed rule contemplates the inclusion of emissions estimates from sovereign nations, national health systems, intergovernmental institutions, and other such customers of the biotechnology industry, which makes their inclusion irrelevant. BIO further encourages the Commission to use the standards of materiality in their attempt to curb carbon emissions.

100. Should Scope 3 emissions disclosure be voluntary? Should we require Scope 3 emissions disclosure in stages, e.g., requiring qualitative disclosure of a registrant's significant categories of upstream and downstream activities that generate Scope 3 emissions upon effectiveness of the proposed rules, and requiring quantitative disclosure of a registrant's Scope 3 emissions at a later date? If so, when should we require quantitative disclosure of a registrant's Scope 3 emissions?

BIO strongly encourages the Commission to make Scope 3 emissions disclosure predicated on materiality or optional. As noted throughout this comment letter, climate-related risks have been found to be immaterial to the biotechnology industry. Further, the proposed definitions of Scope 3 make their disclosures invalid and insignificant for an investor in the biotechnology sector.

BIO emphatically stresses the need for the Commission to update current guidance on climate-related risks disclosures instead of imposing such a significant set of disclosures and organizational changes as proposed.

104. Should we, as proposed, allow a registrant to provide their own categories of upstream or downstream activities? Are there additional categories, other than the examples we have identified, that may be significant to a registrant's Scope 3 emissions and that should be listed in the proposed rule? Are there any categories that we should preclude, *e.g.*, because of lack of accepted methodologies or availability of data? Would it be useful to allow registrants to add categories that are particularly significant to them or their industry, such as Scope 3 emissions from land use change, which is not currently included in the Greenhouse Gas Protocol's Scope 3 categories? Should we specifically add an upstream emissions disclosure category for land use?

BIO contends that Scope 3 reporting is inappropriate and immaterial for the biotechnology industry. BIO remains concerned that the Commission is de facto outsourcing securities regulatory compliance to an uncertified third-party provider of non-securities-related information.

105. Should we require the calculation of a registrant's Scope 1, Scope 2, and/or Scope 3 emissions to be as of its fiscal year end, as proposed? Should we instead allow a registrant to provide its GHG emissions disclosures according to a different timeline than the timeline for its Exchange Act annual report? If so, what should that timeline be? For example, should we allow a registrant to calculate its Scope 1, Scope 2, and/or Scope 3 emissions for a 12-month period ending on the latest practicable date in its fiscal year that is no earlier than three months or, alternatively, six months prior to the end of its fiscal year? Would allowing for an earlier calculation date alleviate burdens on a registrant without compromising the value of the disclosure? Should we allow such an earlier calculation date only for a registrant's Scope 3 emissions? Would the fiscal year end calculations required for a registrant to determine if Scope 3 emissions are material eliminate the benefits of an earlier calculation date? Should we instead require a registrant to provide its GHG emissions disclosures for its most recently completed fiscal year one, two, or three months after the due date for its Exchange Act annual report in an amendment to that report?

Registrants should be allowed to report according to their existing reporting schedule, which is by fiscal year.

109. Should we require a registrant to disclose the intensity of its GHG emissions for the fiscal year, with separate calculations for (i) the sum of Scope 1 and Scope 2 emissions and, if applicable (ii) its Scope 3 emissions (separately from Scopes 1 and 2), as proposed? Should we define GHG intensity, as proposed? Is there a different definition we should use for this purpose?

In requesting that registrants calculate GHG intensity, the Commission is requesting that registrants take on the responsibility typically held by industry analysts and investors. Companies should not be made to make calculations and compose metrics on behalf of investors. As described in the comments above, GHG intensity metrics will not be useful for generalist investors analyzing the biotechnology sector as the denominator is inherently volatile in biotechnology and entirely predicated upon the cash raising cycle.

111. Should we require the disclosed GHG intensity to be expressed in terms of metric tons of CO2e per unit of production, as proposed? Would such a requirement facilitate the comparability of the disclosure? Should we require a different economic output measure of GHG intensity and, if so, which measure? For example, should GHG intensity be expressed in terms of metric tons of CO2e per number of employees? Should we require the GHG intensity to be expressed per unit of production relevant to the registrant's business (rather than its industry)? Is further guidance needed on how to comply with the proposed requirement? Would requiring GHG intensity to be expressed in terms of metrics tons of CO2e per unit of production require disclosure of commercially sensitive or competitively harmful information?

In requesting that registrants calculate GHG intensity, the Commission is requesting that registrants take on the responsibility typically held by industry analysts and investors. Companies should not be made to make calculations and compose metrics on behalf of investors. As described in the comments above, GHG intensity metrics will not be useful for generalist investors analyzing the biotechnology sector as the denominator is inherently volatile in biotechnology and entirely predicated upon the cash raising cycle.

112. Should we require a registrant with no revenue or unit of production for a fiscal year to disclose its GHG intensity based on, respectively, another financial measure or measure of economic output, as proposed? Should we require such a registrant to use a particular financial measure, such as total assets, or a particular measure of economic output, such as total number of employees? For registrants who may have minimal revenue, would the proposed calculation result in intensity disclosure that is confusing or not material? Should additional guidance be provided with respect to such instances?

BIO strongly agrees that companies with no revenues or units of production should not disclose GHG intensity. As discussed in the comments above, biotechnology companies will be put into a disadvantageous position should they be required to report GHG intensity as the denominator of such calculations will hold no value for most investors and confuse novice investors.

115. Should we require a registrant to disclose the methodology, significant inputs, and significant assumptions used to calculate its GHG emissions metrics, as proposed? Should we require a registrant to use a particular methodology for determining its GHG emission metrics? If so, should the required methodology be pursuant to the GHG Protocol's Corporate Accounting and Reporting Standard and related standards and guidance? Is

there another methodology that we should require a registrant to follow when determining its GHG emissions? Should we base our climate disclosure rules on certain concepts developed by the GHG Protocol without requiring a registrant to follow the GHG Protocol in all respects, as proposed? Would this provide flexibility for registrants to choose certain methods and approaches in connection with GHG emissions determination that meet the particular circumstances of their industry or business or that emerge along with developments in GHG emissions methodology as long as they are transparent about the methods and underlying assumptions used? Are there adjustments that should be made to the proposed methodology disclosure requirements that would provide flexibility for registrants while providing sufficient comparability for investors?

In requesting that registrants calculate GHG intensity, the Commission is requesting that registrants take on the responsibility typically held by industry analysts and investors. Companies should not be made to make calculations and compose metrics on behalf of investors. As described in the comments above, GHG intensity metrics will not be useful for generalist investors analyzing the biotechnology sector as the denominator is inherently volatile in biotechnology and entirely predicated upon the cash raising cycle.

116. Should we require a registrant to disclose the organizational boundaries used to calculate its GHG emissions, as proposed? Should we require a registrant to determine its organizational boundaries using the same scope of entities, operations, assets, and other holdings within its business organization as that used in its consolidated financial statements, as proposed? Would prescribing this method of determining organizational boundaries avoid potential investor confusion about the reporting scope used in determining a registrant's GHG emissions and the reporting scope used for the financial statement metrics, which are included in the financial statements? Would prescribing this method of determining organizational boundaries result in more robust guidance for registrants and enhanced comparability for investors? If, as proposed, the organizational boundaries must be consistent with the scope of the registrant's consolidated financial statements, would requiring separate disclosure of the organizational boundaries be redundant or otherwise unnecessary?

In requesting that registrants calculate GHG intensity, the Commission is requesting that registrants take on the responsibility typically held by industry analysts and investors. Companies should not be made to make calculations and compose metrics on behalf of investors. As described in the comments above, GHG intensity metrics will not be useful for generalist investors analyzing the biotechnology sector as the denominator is inherently volatile in biotechnology and entirely predicated upon the cash raising cycle.

117. Except for calculating Scope 3 emissions, the proposed rules would not require a registrant to disclose the emissions from investments that are not consolidated, proportionately consolidated, or that do not qualify for the equity method of accounting. Should we require such disclosures for Scopes 1 and 2 emissions, and if so, how?

BIO stresses the need for materiality-based disclosures. As such, investment emissions should only be disclosed if they are material to a business.

125. Should we permit a registrant to use reasonable estimates when disclosing its GHG emissions as long as it also describes the assumptions underlying, and its reasons for using, the estimates, as proposed? Should we permit the use of estimates for only certain GHG emissions, such as Scope 3 emissions? Should we permit a registrant to use a reasonable estimate of its GHG emissions for its fourth fiscal quarter if no actual reported data is reasonably available, together with actual, determined GHG emissions data for its first three fiscal quarters when disclosing its GHG emissions for its most recently completed fiscal year, as long as the registrant promptly discloses in a subsequent filing any material difference between the estimate used and the actual, determined GHG emissions data for the fourth fiscal quarter, as proposed? If so, should we require a registrant to report any such material difference in its next Form 10-Q if domestic, or in a Form 6-K, if a foreign private issuer? Should we permit a domestic registrant to report any such material difference in a Form 8-K if such form is filed (rather than furnished) with the Commission? Should any such reasonable estimate be subject to conditions to help ensure accuracy and comparability? If so, what conditions should apply?

As the Commission notes, the current ecosystem of GHG emission reporting is "evolving and unique" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data." Because the Commission is compelling industry to implement disclosures in a shifting landscape with a multitude of service providers that have not been validated or verified by regulators, both investors and registrants would be better served with maximum flexibility and protections under safe harbors for what is essentially a exercise in estimation and forecasting.

126. Should we require a registrant to disclose, to the extent material, any use of third-party data when calculating its GHG emissions, regardless of the particular scope of emissions, as proposed? Should we require the disclosure of the use of third-party data only for certain GHG emissions, such as Scope 3 emissions? Should we require the disclosure of the use of third- party data for Scope 3 emissions, regardless of its materiality to the determination of those emissions? If a registrant discloses the use of third-party data, should it also be required to identify the source of such data and the process the registrant undertook to obtain and assess the data, as proposed?

As the Commission notes, the current ecosystem of GHG emission reporting is "evolving and unique" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data." Because the Commission is compelling industry to implement disclosures in a shifting landscape with a multitude of service providers that have not been

validated or verified by regulators, both investors and registrants would be better served with maximum flexibility and protections under safe harbors for what is essentially a exercise in estimation and forecasting.

127. Should we require a registrant to disclose any material change to the methodology or assumptions underlying its GHG emissions disclosure from the previous year, as proposed? If so, should we require a registrant to restate its GHG emissions data for the previous year, or for the number of years for which GHG emissions data has been provided in the filing, using the changed methodology or assumptions? If a registrant's organizational or operational boundaries, in addition to methodology or assumptions, change, to what extent should we require such disclosures of the material change, restatements or reconciliations? In these cases, should we require a registrant to apply certain accounting standards or principles, such as FASB ASC Topic 250, as guidance regarding when retrospective disclosure should be required?

BIO strongly supports the Commission using materiality as the standard for companies reporting on the effects of climate change on financial statements and operations, including if there are material changes to how companies estimate, calculate, or develop assumptions and methodologies for any material disclosure.

128. Should we require a registrant to disclose, to the extent material, any gaps in the data required to calculate its GHG emissions, as proposed? Should we require the disclosure of data gaps only for certain GHG emissions, such as Scope 3 emissions? If a registrant discloses any data gaps encountered when calculating its Scope 3 emissions or other type of GHG emissions, should it be required to discuss whether it used proxy data or another method to address such gaps, and how its management of any data gaps has affected the accuracy or completeness of its GHG emissions disclosure, as proposed? Are there other disclosure requirements or conditions we should adopt to help investors obtain a reasonably complete understanding of a registrant's exposure to the GHG emissions sourced by each scope of emissions?

As the Commission notes, the current ecosystem of GHG emission reporting is "evolving and unique" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data." Because the Commission is compelling industry to implement disclosures in a shifting landscape with a multitude of service providers that have not been validated or verified by regulators, both investors and registrants would be better served with maximum flexibility and protections under safe harbors for what is essentially a exercise in estimation and forecasting.

129. When determining the materiality of its Scope 3 emissions, or when disclosing those emissions, should a registrant be required to include GHG emissions from outsourced activities that it previously conducted as part of its own operations, as reflected in the

financial statements for the periods covered in the filing, in addition to emissions from activities in its value chain, as proposed? Would this requirement help ensure that investors receive a complete picture of a registrant's carbon footprint by precluding the registrant from excluding emissions from activities that are typically conducted as part of operations over which it has ownership or control but that are outsourced in order to reduce its Scopes 1 or 2 emissions? Should a requirement to include outsourced activities be subject to certain conditions or exceptions and, if so, what conditions or exceptions?

BIO has significant concerns on the inclusion of Scope 3 emissions. As noted in the comments above, Scope 3 emission are not material nor will they provide investors with any actionable or relevant information about the biotechnology industry, especially for emerging biotechnology companies. The proposed rule contemplates the inclusion of emissions estimates from sovereign nations, national health systems, intergovernmental institutions, and other such customers of the biotechnology industry, which makes their inclusion irrelevant. BIO further encourages the Commission to use the standards of materiality in their attempt to curb carbon emissions.

130. Should we require a registrant that must disclose its Scope 3 emissions to discuss whether there was any significant overlap in the categories of activities that produced the Scope 3 emissions? If so, should a registrant be required to describe any overlap, how it accounted for the overlap, and its effect on the total Scope 3 emissions, as proposed? Would this requirement help investors assess the accuracy and reliability of the Scope 3 emissions disclosure?

BIO has significant concerns on the inclusion of Scope 3 emissions. As noted in the comments above, Scope 3 emission are not material nor will they provide investors with any actionable or relevant information about the biotechnology industry, especially for emerging biotechnology companies. The proposed rule contemplates the inclusion of emissions estimates from sovereign nations, national health systems, intergovernmental institutions, and other such customers of the biotechnology industry, which makes their inclusion irrelevant. BIO further encourages the Commission to use the standards of materiality in their attempt to curb carbon emissions.

131. Should we permit a registrant to present its Scope 3 emissions in terms of a range as long as it discloses its reasons for using the range and the underlying assumptions, as proposed? Should we place limits or other parameters regarding the use of a range and, if so, what should hose limits or parameters be? For example, should we require a range to be no larger than a certain size? What other conditions or guidance should we provide to help ensure that a range, if used, is not overly broad and is otherwise reasonable?

BIO strongly encourages the Commission to make Scope 3 emissions disclosure predicated on materiality. As noted throughout this comment letter, climate-related risks have been found to be immaterial to the biotechnology industry. Further, the proposed definitions of Scope 3 make their disclosures invalid and insignificant for an investor in the biotechnology sector.

132. Should we require a registrant to follow a certain set of published standards for calculating Scope 3 emissions that have been developed for a registrant's industry or that are otherwise broadly accepted? For example, should we require a registrant in the financial industry to follow PCAF's Global GHG Accounting & Reporting Standard for the Financial Industry when calculating its financed emissions within the "Investments" category of Scope 3 emissions? Are there other industry-specific standards that we should require for Scope 3 emissions disclosure? Should we require a registrant to follow the GHG Protocol's Corporate Value Chain (Scope 3) Accounting and Reporting Standard if an industry-specific standard is not available for Scope 3 emissions disclosure? If we should require the use of a third-party standard for Scope 3 emissions reporting, or any other scope of emissions, how should we implement this requirement?

BIO is concerned with the sheer amount of outsourcing the Commission has used in the development of the proposed rule as well as the amount of outsourcing the Commission is compelling that registrants use in complying with the proposed rule.

133. Should we provide a safe harbor for Scope 3 emissions disclosure, as proposed? Is the scope of the proposed safe harbor clear and appropriate? For example, should the safe harbor apply to any registrant that provides Scope 3 disclosure pursuant to the proposed rules, as proposed? Should we limit the use of the safe harbor to certain classes of registrants or to registrants meeting certain conditions and, if so, which classes or conditions? For example, should we require the use of a particular methodology for calculating and reporting Scope 3 emissions, such as the PCAF Standard if the registrant is a financial institution, or the GHG Protocol Scope 3 Accounting and Reporting Standard for other types of registrants? Should we clarify the scope of persons covered by the language "by or on behalf of a registrant" by including language about outside reviewers retained by the registrant or others? Should we define a "fraudulent statement," as proposed? Is the level of diligence required for the proposed safe harbor (i.e., that the statement was made or reaffirmed with a reasonable basis and disclosed in good faith) the appropriate standard? Should the safe harbor apply to other climate-related disclosures, such as Scopes 1 and 2 emissions disclosures, any targets and goals disclosures in response to proposed Item 1505 (discussed below), or the financial statement metrics disclosures required pursuant to Proposed Article 14 of Regulation S-X? Should the safe harbor apply indefinitely, or should we include a sunset provision that would eliminate the safe harbor some number of years, (e.g., five years) after the effective date or applicable compliance date of the rules? Should the safe harbor sunset after certain conditions are satisfied? If so, what types of conditions should we consider? What other approaches should we consider?

BIO strongly urges the Commission to enshrine all hypothesized climate-related disclosures in the PSLRA safe harbors, including any transition plan, if registrants choose to compose and release them. The Commission outlined numerous times within the proposed rule that every aspect of the proposed reporting requirements is "still evolving," including the audit and

assurance aspects of the proposed rule. Due to the fluid nature of the industry that is expected to underwrite these disclosures on behalf of registrants, the Commission should broaden the safe harbors to include all climate-related disclosures. Further, as noted in the comments above, the biotechnology industry's nuance will make certain proposed metrics unusable for generalist investors, and, we fear, may cause consternation and possible litigation attributed to nothing more than a lack of understanding of the sector. For these reasons as well, the Commission should broaden the safe harbors to include all climate-related disclosures finalized.

134. Should we provide an exemption from Scope 3 emissions disclosure for SRCs, as proposed? Should the exemption not apply to a SRC that has set a target or goal or otherwise made a commitment to reduce its Scope 3 emissions? Are there other classes of registrants we should exempt from the Scope 3 emissions disclosure requirement? For example, should we exempt EGCs, foreign private issuers, or a registrant that is filing or has filed a registration statement for its initial public offering during its most recently completed fiscal year from the Scope 3 disclosure requirement? Instead of an exemption, should we provide a longer phase in for the Scope 3 disclosure requirements for SRCs than for other registrants?

Yes, BIO strongly supports the exemption of SRC from Scope 3 reporting. BIO also supports EGC exemptions from reporting Scope 3 emissions. As discussed in the comment above, most biotechnology companies would continue to qualify as SRCs if it were not for arbitrary public float thresholds. The reason they would continue to qualify as SRCs is because they have no product revenues and the only revenue recognized is from capital raising efforts. These kinds of R&D-intensive companies have decentralized operations and expenses that are demanded by regulators (for safety and to avoid conflicts of interest) and investors (for cost efficiency and the avoidance of conflicts of interest). For this reason, SRCs and EGCs should be exempt from reporting Scope 3 emissions.

135. Should we require accelerated filers and large accelerated filers to obtain an attestation report covering their Scope 1 and Scope 2 emissions disclosure, as proposed? Should we require accelerated filers and large accelerated filers to obtain an attestation report covering other aspects of their climate-related disclosures beyond Scope 1 and 2 emissions? For example, should we also require the attestation of GHG intensity metrics, or of Scope 3 emissions, if disclosed? Conversely, should we require accelerated filers and large accelerated filers to obtain assurance covering only Scope 1 emissions disclosure? Should any voluntary assurance obtained by these filers after limited assurance is required be required to follow the same attestation requirements of Item 1505(b)–(d), as proposed?

BIO is concerned that the Commission is distorting the market. The Commission writes,

"Although we are proposing certain minimum standards for attestation services, this proposal does not aim to create or adopt a specific attestation standard for assuring GHG emissions, just as this proposal does not define a single methodology for calculating GHG emissions. This is

because both the reporting and attestation landscapes are currently evolving, and it would be premature to adopt one approach and potentially curtail future innovations in these two areas. The evolving nature of GHG emissions calculations and attestation standards could suggest that it may also be premature to require assurance."

The Commission acknowledges in the above that the current landscape is fraught with liability across the entire reporting, auditing, and attestation of climate risk disclosures and the yet the Commission is mandating that companies implement the proposed rule with minimal safe harbors. The Commission has proposed these reporting, auditing, and attestation requirements with no regard for the liability and costs that companies, especially small companies, will incur as a result.

136. If we required accelerated filers and large accelerated filers to obtain an attestation report covering Scope 3 emissions disclosure, should the requirement be phased-in over time? If so, what time frame? Should we require all Scope 3 emissions disclosure to be subject to assurance or only certain categories of Scope 3 emissions? Would it be possible for accelerated filers and large accelerated filers to obtain an attestation report covering the process or methodology for calculating Scope 3 emissions rather than obtaining an attestation report covering the calculations of Scope 3 emissions? Alternatively, is there another form of verification over Scope 3 disclosure that would be more appropriate than obtaining an attestation report?

Attestation should be phased-in in-line with the spirit of the JOBS Act emerging growth company exemptions.

137. Should the attestation requirement be limited to accelerated filers and large accelerated filers, as proposed? Alternatively, should the attestation requirement be limited to a subset of accelerated filers and large accelerated filers? If so, what conditions should apply? Should the attestation requirement only apply to well-known seasoned issuers? Should the attestation requirement also apply to other types of registrants? Should we create a new test for determining whether the attestation requirements apply to a registrant that would take into account the resources of the registrant and also apply to initial public offerings? For example, should we create a test similar to the SRC definition, includes a separate determination for initial registration which statements, but using higher public float and annual revenue amounts?

The attestation requirement should be limited to seasoned issuers and those companies with more than $1,000,000,000,000 in revenue and more than $2,000,000,000 in public float, which (a) keeps with the revenue threshold of SRCs and EGCs, and (b) aligns current definition of SRC with market practice for small companies, which is defined as a company with market capitalization (public float) less than $2,000,000,000.

138. Instead of requiring only accelerated filers and large accelerated filers to include an

attestation report for Scope 1 and Scope 2 emissions, should the proposed attestation requirements also apply to registrants other than accelerated filers and large accelerated filers? If so, should the requirement apply only after a specified transition period? Should such registrants be required to provide assurance at the same level as accelerated filers and large, accelerated filers and over the same scope of GHG emissions disclosure, or should we impose lesser requirements (*e.g.*, only limited assurance and/or assurance over Scope 1 emissions disclosure only)?

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant transition periods to allow registrants, auditors, and attestation providers to catch-up to demand and settle of market standards, which are currently not present.

139. Should we require accelerated filers and large accelerated filers to initially include attestation reports reflecting attestation engagements at a limited assurance level, eventually increasing to a reasonable assurance level, as proposed? What level of assurance should apply to the proposed GHG emissions disclosure, if any, and when should that level apply? Should we provide a one fiscal year transition period between the GHG emissions disclosure compliance date and when limited assurance would be required for accelerated filers and large accelerated filers, as proposed? Should we provide an additional two fiscal year transition period between when limited assurance is first required and when reasonable assurance is required for accelerated filers and large accelerated filers, as proposed?

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant flexibility to allow registrants, auditors, and attestation providers to catch-up to demand and settle of market standards, which are currently not present.

140. Should we provide the same transition periods (from the Scopes 1 and 2 emissions disclosure compliance date) for accelerated filers and large accelerated filers, as proposed? Instead, should different transition periods apply to accelerated filers and large accelerated filers? Should we provide transition periods with different lengths than those proposed? Should we require the attestation to be at a reasonable assurance level without having a transition period where only limited assurance is required? Should we instead impose assurance requirements to coincide with reporting compliance periods?

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant transition periods to allow registrants, auditors, and attestation providers to catch-up to demand and settle of market standards, which are currently not present.

141. Under prevailing attestation standards, "limited assurance" and "reasonable assurance" are defined terms that we believe are generally understood in the marketplace, both by those seeking and those engaged to provide such assurance. As a result, we have not proposed definitions of those terms. Should we define "limited assurance" and "reasonable assurance" and, if so, how should we define them? Would providing definitions in this context cause confusion in other attestation engagements not covered by the proposed rules? Are the differences between these types of attestation engagements sufficiently clear without providing definitions?

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant transition periods to allow registrants, auditors, and attestation providers to catch-up to demand and settle of market standards, which are currently not present.

142. As proposed, there would be no requirement for a registrant to either provide a separate assessment and disclosure of the effectiveness of controls over GHG emissions disclosure by management or obtain an attestation report from a GHG emissions attestation provider specifically covering the effectiveness of controls over GHG emissions disclosure.

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant flexibility to allow registrants, auditors, and attestation providers to catch-up to demand and settle of market standards, which are currently not present.

Should we require accelerated filers and large accelerated filers to provide a separate management assessment and disclosure of the effectiveness of controls over GHG emissions disclosure (separate from the existing requirements with respect to the assessment and effectiveness of DCP)? Should we require management to provide a statement in their annual report on their responsibility for the design and evaluation of controls over GHG emissions disclosure and to disclose their conclusion regarding the effectiveness of such controls? Instead of, or in addition to, such management assessment and statement, should we require the registrant to obtain an attestation report from a GHG emissions attestation provider that covers the effectiveness of such GHG emissions controls as of the date when the accelerated filer or large accelerated filer is required to comply with the reasonable assurance requirement under proposed Item 1505(a)? If so:

(i) Would it be confusing to apply either such requirement in light of the existing DCP requirements that would apply to the proposed GHG emissions disclosure?

(ii) Would a separate management assessment and statement on the effectiveness of controls over GHG emissions provide meaningful disclosure to investors beyond the existing requirement for DCP?

(iii) Should we specify that the separate management assessment and statement must be provided by the accelerated filer's or large accelerated filer's principal executive and principal financial officers, or persons performing similar functions? Should we clarify

which members of the accelerated filer or large accelerated filer's management should be involved in performing the underlying assessment?

(iv) What controls framework(s) would the effectiveness of the registrant's controls over GHG emissions disclosure be evaluated against, if any?

(v) For the GHG emissions attestation provider, what requirements should be applied to such GHG emissions disclosure controls attestation requirement? For example, what attestation standards should apply? Should other service provider(s) in addition to or in lieu of the GHG emissions attestation provider be permitted to provide such attestation over the effectiveness of the GHG controls?

(vi) (vi) Should we limit such a requirement to accelerated filers and large accelerated filers only or should it apply to other registrants as well?

(vii) (vii) What would be the potential benefits and costs of either approach?

(viii) (viii) Should we require a certification on the design and evaluation of controls over GHG emissions disclosures by officers serving in the principal executive and principal financial officer roles or persons performing similar functions for an accelerated filer or large accelerated filer? Would a certification requirement have any additional benefits or impose any additional costs when compared to a requirement for management to assess and disclose in a statement in the annual report the effectiveness of controls over GHG emissions?

BIO vehemently disagrees with this proposed requirement. A company's management should be focused on matters that are material to the operations and finances of the company. In biotechnology, as noted throughout this comment letter, climate risks and any associated risks to the consolidated financial statements of a biotechnology have been found by the SASB / ISSB (which are built upon TCFD) to not be material to the biotechnology industry. This is the case for several industry groups and a myriad of companies within these groups. As such, the SEC should not mandate that every company in the United States be required to expand management structures in order to accommodate concerns that are not material to a company.

143. We considered whether to require registrants to include the GHG emissions metrics in the notes or a separate schedule to their financial statements, by amending Regulation S-X instead of Regulation S-K.

(i) Would there be benefits to including this information in a registrant's financial statements? For example, would requiring the GHG emissions disclosure to be included in the financial statements improve the consistency, comparability, reliability, and decision-usefulness of the information for investors? Would it facilitate the integration of GHG metrics and targets into the registrant's financial analysis? Would such placement cause registrants to incur significantly more expense in obtaining an audit of the disclosure? If so, please quantify those additional expenses where possible. (ii) Should we require a registrant to include the GHG emissions disclosure in its audited financial statements so that the disclosure would be subject to the existing requirements for an independent audit and ICFR? If so, we seek comment on the following aspects of this alternative: (a) If GHG emissions disclosure is subject to ICFR, or an internal control framework similar to ICFR,

would GHG emissions disclosure be more reliable compared to what is currently proposed? What are the benefits or costs? (b) Should the GHG emissions disclosure be included in a note to the registrant's financial statements (e.g., in the note where the proposed financial statement metrics as discussed above in Section II.F would be included) or in a schedule, or somewhere else? If the GHG emissions disclosure was required in the financial statements, should it be subject to a reasonable assurance audit like the other information in the financial statements? If in a schedule, should the GHG emissions disclosure be disclosed in a schedule similar to those required under Article 12 of Regulation S-X, which would subject the disclosure to audit and ICFR requirements? Should we instead require the metrics to be disclosed as supplemental financial information, similar to the disclosure requirements under FASB ASC Topic 932-235-50-2 for registrants that have significant oil- and gas producing activities? If so, should such supplemental schedule be subject to ICFR requirements? Instead of requiring the GHG emissions disclosure to be included in a note to the registrant's audited financial statements, should we require a new financial statement for such metrics? (c) PCAOB auditing standards apply to the audit of a registrant's financial statements. If GHG emissions disclosure is included in a supplemental schedule to the financial statements, should we allow other auditing standards to be applied? If so, which ones? What, if any, additional guidance or revisions to such standards would be needed in order to apply them to the audit of GHG emissions disclosure? (d) What are the costs and benefits of employing registered public accounting firms to perform audits of GHG emissions disclosure and related attestation of internal controls? Are there potential cost savings in employing registered public accountants that currently perform audits of financial statements and attestation of ICFR to review GHG emissions disclosure and any related internal controls? If we require GHG emissions disclosure to be presented in the financial statements, should we permit entities other than registered public accounting firms to provide assurance of this information, as proposed for the current attestation requirements under Regulation S-K? If not limited to registered public accounting firms, who should be permitted to provide assurance of GHG emissions disclosure? Should we permit environmental consultants, engineering firms, or other types of specialists to provide assurance? What are the costs and benefits of such approach? Would the reliability of the audits and therefore the information disclosed be affected if assurance providers other than registered public accounting firms are permitted to conduct these audits? Please provide supporting data where possible. If we should allow for assurance providers that are not registered public accounting firms, what qualifications and oversight should they have, and what requirements should we impose on them? Should we direct the PCAOB to develop a separate registration process for service providers that are not otherwise registered? What expertise, independence and quality control standards should apply? (e) What would be the other potential benefits and costs of such an approach?

GHG emissions ratios have no need to be included within consolidated financial statements as these ratios (intensity per unit of revenue or unit of production) are arbitrary and, as demonstrated in the comments above, irrelevant in the biotechnology industry. These metrics

will not provide for adequate or uniform comparisons across biotechnology companies for all investors. Only specialist investors will be able to understand the volatility of the contemplated ratios and how to truly compare between biotechnology companies (as is currently the case).

Furthermore, the Commission does not require companies to conduct a DuPont analysis, intrinsic value calculations, return on invested capital, return on capital employed, liquidity ratios, current ratios, or any other ratio that helps analysts and investors understand and compare financial statements. These ratios have been and should continue to be driven by investors, and not compelled by regulation to be reported by companies. This is a fundamental job of any analyst, but not for corporate financial reporting.

Finally, given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant flexibility to allow registrants, auditors, and attestation providers to catch-up to demand and settle of market standards, which are currently not present. BIO has significant concerns on the liabilities and significant costs that small companies will incur as a result of moving to

154. Should we require the attestation engagement and related attestation report to be provided pursuant to standards that are publicly available at no cost and are established by a body or group that has followed due process procedures, including the broad distribution of the framework for public comment, as proposed? Is the requirement of "due process procedures, including the broad distribution of the framework for public comment" sufficiently clear? Would the attestation standards of the PCAOB, AICPA, and IAASB meet this due process requirement? Are there other standards currently used in the voluntary climate-related assurance market or otherwise in development that would meet the due process and publicly availability requirements? For example, would verification standards commonly used by non-accountants currently, such as ISO 14064-3 and the AccountAbility's AA1000 Series of Standards, meet the proposed requirements? Are there standards currently used in the voluntary climate-related assurance market or otherwise under development that would be appropriate for use under the Commission's climate-related disclosure rules although they may not strictly meet the proposed public comment requirement? If so, please explain whether those standards have other characteristics that would serve to protect investors?

BIO strongly supports the establishment of global standards for attestation engagement and reporting prior to requiring registrants to utilize them in reporting to shareholders and filing with the Commission. This will go a long way to limit liability and create a level-playing field for all registrants. BIO strongly supports that these standards be created by a recognized body that follows due process procedures, including feedback from all stakeholders, and them making these standards available at no cost. If the Commission is endeavoring to formalize the reporting of climate-related risks, then the Commission should ensure that the reporting, auditing, and

attestation frameworks that will be used are standardized, transparent, and well-understood by all stakeholders.

159. If we require or permit a registrant to use the GHG Protocol as the methodology for determining GHG emissions, would the provisions of the GHG Protocol qualify as "suitable criteria" against which the Scope 1 and Scope 2 emissions disclosure should be evaluated?

BIO is concerned with the amount of outsourcing that has been done in the developed of the proposed rule. Unlike the FASB, the SEC nor the EPA oversee GHG Protocols in the way SEC oversees the FASB. If the SEC wishes to permit or require registrants to use the GHG Protocols methodology, then the Commission should officially oversea their development and implementation in the same way that the Commission oversees FASB.

174. Should we apply the PSLRA statutory safe harbors as they currently exist to forward looking statements involving climate-related targets and goals, or other climate-- related forward looking information? Should we instead create a separate safe harbor for forward climate-related information, including targets and goals ? Should we looking adopt an exception to the PSLRA statutory safe harbors that would extend the safe harbor s to climate-related forward-looking disclosures made in an initial public offering registration statement?

BIO strongly urges the Commission to enshrine all proposed climate-related disclosures in the PSLRA safe harbors, including GHG emissions, GHG intensity, plans, goals, targets, strategies, financial impacts, and other proposed disclosures.

The Commission outlined numerous times within the proposed rule that every aspect of the proposed reporting requirements is "still evolving," including the audit and assurance aspects of the proposed rule. Due to the fluid nature of the industry that is expected to underwrite these disclosures on behalf of registrants, the Commission should broaden the safe harbors to include all climate-related disclosures.

Further, as noted in the comments above, the biotechnology industry's nuance will make certain proposed metrics unusable for generalist investors, and, we fear, may cause consternation and possible litigation attributed to nothing more than a lack of understanding of the sector. For these reasons as well, the Commission should broaden the safe harbors to include all climate-related disclosures finalized.

175. Should the proposed climate-related disclosures be required in Exchange Act reports and registration statements, as proposed? Should we exempt SRCs from all of the proposed climate-related disclosure rules instead of exempting them solely from Scope 3 emissions disclosure requirements, as proposed? Should we exempt SRCs from certain other proposed climate-related disclosure requirements and, if so, which requirements?

For example, in addition to the proposed exemption from Scope 3 emissions disclosure, should we exempt SRCs from the proposed requirement to disclose Scopes 1 and 2 emissions? Are there certain types of other registrants, such as EGCs or business development companies ("BDCs"), that should be excluded from all or some of the proposed climate-related disclosure rules?

BIO strongly supports the exemption of SRC from all climate-related reporting. BIO also supports EGC exemptions from all climate-related reporting.

As discussed in the comment above, most biotechnology companies would continue to qualify as SRCs if it were not for arbitrary public float thresholds. The reason they would continue to qualify as SRCs is because they have no product revenues and the only revenue recognized is from capital raising efforts. These kinds of R&D-intensive companies have decentralized operations and expenses that are demanded by regulators (for safety and to avoid conflicts of interest) and investors (for cost efficiency and the avoidance of conflicts of interest).

Furthermore, and crucially, BIO supports an alternative threshold for climate-related reporting. As discussed in Question 137, the Commission should align the statutory definition of SRC with the market definition by updating the public float threshold to $2,000,000,000. Defining SRC as companies with less than $100,000,000 in revenue and less than $2,000,000,000 in public float, (a) keeps with the revenue threshold of SRC, and (b) aligns current definition of SRC with market practice for small companies, which is defined as a company with market capitalization (public float) less than $2,000,000,000. The same public float threshold should also apply to emerging growth companies, which would help to align further regulatory definitions with market definitions and practice. This would help investor protections as investors would be able to clearly understand that emerging growth companies are small companies.

189. An International Sustainability Standards Board (ISSB) has recently been created, which is expected to issue global sustainability standards, including climate-related disclosure standards. If we adopt an alternative reporting provision, should that provision be structured to encompass reports made pursuant to criteria developed by a global sustainability standards body, such as the ISSB? If so, should such alternative reporting be limited to foreign private issuers, or should we extend this option to all registrants? What conditions, if any, should we place on a registrant's use of alternative reporting provisions based on the ISSB or a similar body?

We support the proposal to establish an alternative reporting provision for foreign private issuers based on global sustainability reporting standards, such as those being developed by the International Sustainability Standards Board (ISSB), which would mirror the SEC's current alternative provision for financial disclosures based on IFRS accounting standards. A consistent global baseline for climate-related disclosures would benefit both international companies and investors by allowing for standardized and comparable information across jurisdictions. We recommend the SEC adopts such a provision for foreign private issuers that is aligned with

material elements of the ISSB standards and/or other recognized climate-related reporting standards that may apply in the company’s home jurisdiction