

PCP Report - Biotechnology

(Completion rate: 29.41%)

Public Comment on the proposed set of material sustainability issues and Key Performance Indicators for the Biotechnology Industry

The purpose of this survey is to obtain public feedback on the proposed set of material sustainability issues and associated key performance indicators (KPIs) for the Biotechnology Industry. Exposure Drafts of material sustainability issues and associated KPIs for each industry can be found [here](#). These issues and KPIs were developed by SASB through a rigorous research and industry engagement process. If you wish to learn more about the process, please follow [this link](#). The issues and KPIs form the basis for the recommended sustainability disclosures companies publicly listed in U.S. should include in their annual reports (Form 10-K or Form 20-F for foreign private issuers). This reporting framework will be supported by Technical Protocols to ensure proper and consistent accounting. SASB has developed Industry Briefs for all six industries in the Health Care sector. These documents provide background information on the industry and include evidence of materiality for each issue. Industry Briefs can be found [here](#). Important note: SASB has identified a set of issues deemed material for an industry. Ultimately, determination of materiality is the responsibility of entities preparing annual reports and could differ from the set of material issues identified by SASB, given the specific circumstances of a company's operations. Please begin this survey only after you have thoroughly reviewed the Exposure Draft for the Biotechnology Industry. You may provide comments on as many industries as you would like by following the appropriate survey links found [here](#). The results from the survey will be made publicly available once the public comment period ends. Should you have any technical difficulties with the survey, please contact Trent Boorman at: [REDACTED]

Basic information

Please provide the following basic information about you.

[Q1]

Variable	Response
Name	There are 6 response(s) to this question.
Position	There are 5 response(s) to this question.
Organization	There are 6 response(s) to this question.
Email	There are 6 response(s) to this question.

[Q1] | Name

#	Response
1.	Jeremy Shapiro
2.	Kathryn
3.	ALBERTO GUAJARDO
4.	patrick hoy
5.	Steve Lydenberg
6.	Sandor Schoichet

[Q1] | Position

#	Response
1.	ED
2.	DIRECTOS
3.	Associate Director
4.	Partner, Strategic Vision
5.	Director

[Q1] | Organization

#	Response
1.	Morgan Stanley
2.	GIIN
3.	EXCELENCIA GESTION
4.	Biogen Idec
5.	Domini Social Investments
6.	Meridian Management Consultants

[Q1] | Email

#	Response
1.	[REDACTED]
2.	[REDACTED]
3.	[REDACTED]

- 4. [REDACTED]
- 5. [REDACTED]
- 6. [REDACTED]

[Q2] Are you providing comments on behalf of your organization or as an individual?

Response	Chart	Percentage	Count
On behalf of my organization		17%	1
As an individual		83%	5
Total Responses			6

[Q3] What interest group do you represent?

Response	Chart	Percentage	Count
Market participant (e.g. asset owners, pension funds, asset manager, sell-side research analysts)		17%	1
Company or Industry Association in the Health Care sector		17%	1
Intermediary (e.g. NGO, academia, government)		33%	2
Other, please specify...		33%	2
Total Responses			6

[Q3] What interest group do you represent? (Other, please specify...)

#	Response
1.	Standards Council Member
2.	Biopharma industry consultant

[Q3A] If you are an investor, do you have a significant exposure to the US market?

Response	Chart	Percentage	Count
Yes		100%	1
No		0%	0
Total Responses			1

[Q3B] Does your organization file a Form 10-K or 20-F with the U.S. Securities and Exchange Commission (SEC)?

Response	Chart	Percentage	Count
Yes, 10K		100%	1
Yes, 20F		0%	0
No		0%	0
Does not apply		0%	0
Total Responses			1

Open Comments Form

In this section SASB is seeking your comments on the proposed set of material issues and associated KPIs described in the Exposure Draft for the Biotechnology industry. Specifically, SASB would like comments to address the following questions: Question 1: Are the sustainability issues material to a reasonable investor? Do the KPIs accurately represent performance with respect to the associated sustainability issue? How would metrics reported for the KPIs be used in making investment decisions? How would the metrics be useful for internal company management? Question 2: How costly would it be for companies to collect, analyze, and report information required for the proposed KPIs? Do you anticipate this cost to be a barrier to reporting, adoption, or usage of the proposed KPIs? What aspects of reporting would you foresee being most costly for reporting organizations? We strongly encourage participants to provide your comments on company/organization or individual letterhead signed by the authorized representative. Alternatively, comments can be made in a text box.

[Q5] How will you provide feedback?

Response	Chart	Percentage	Count
By uploading a PDF document with comments.		17%	1
By entering them on a text box in this survey		83%	5
Total Responses			6

[Q7] Enter your comments in the box below

#	Response
1.	<p>Jeremy Shapiro ED, Morgan Stanley Standards Board Member [REDACTED]</p> <p>Comment on SASB Exposure Draft for Biotech</p> <p>On my behalf:</p> <ol style="list-style-type: none">1. Employee Recruitment - should be moved to governance section.2. Same section - incomplete. Needs diversity, employee engagement, some indication of talent depth for scientists, and feel for headcount in the areas, and their talent strategy. For example - do they intend to buy small companies to innovate, or research on their own? One strategy needs a deep bench of scientists, the other does not. <p>(I can give specific KPIs if you'd like, but I think this is a meeting with others who have subject matter expertise)</p>
2.	<p>Test</p>
3.	<p>Alberto Guajardo Ingeniero Comercial Excelencia Gestión Santiago de Chile</p> <p>Re: Comment on SASB Exposure Draft for Biotechnology</p> <p>On behalf of my organization, I am providing comments on the SASB Exposure Draft for Biotechnology</p> <p>Sincerely,</p> <p>Name</p>
4.	<ol style="list-style-type: none">1. Compliance with SASB's Biotech accounting standards by Biogen would likely involve hundreds of staff hours per year A mix of 40 wide-ranging quantitative and qualitative metrics spanning impacts in three broad areas: environmental, social and governance.2. KPI's need to take foundational principle of sustainability context into account, which is otherwise well-established in non-financial measurement and reporting standards (GRI and GISR, in particular)3. Literally impossible to measure and report sustainability performance unless such context is taken into account. Examples include ecological limits and thresholds that must not be exceeded in order for organizational impacts to be sustainable4. KPIs specifically exclude context, and therefore do not constitute "sustainability" indicators at all.5. Other key standards in the field (including the world's leading corporate sustainability reporting standard GRI), correctly state that sustainability context must be included. Performance information should be placed in context per GRI 3.1. "The underlying question of sustainability reporting is how an organization contributes, or aims to contribute in the future, to the improvement or deterioration of economic, environmental, and social conditions, developments and trends at the local, regional, or global level. Reporting only on trends in individual performance (or the efficiency of the organization) will fail to respond to this underlying question".

6. GISR's position on context, too, is similar to GRI's. Context: "A ratings framework should assess performance within the wider context of the company's impacts at various geographic scales, referencing widely accepted thresholds, limits, targets or norms applicable to such impact...Companies operate in a local, national, regional, and global milieu, part of larger ecological and social systems delineated by biophysical limits and socially-defined thresholds. Without contextualization, the rigor of assessing the collective effect of individual companies on the preservation of vital capitals is compromised"

7. Best practices in sustainability measurement and reporting are also:

- Stakeholder-based (focused on the needs and interests of all stakeholders of an organization, not just its shareholders)
- Capital-based (focused on the sustainability of its impacts on all vital capitals, not just financial capital of importance to financial performance (i.e., natural, human, social and constructed capitals, too))

5. Sandor Schoichet
Director
Meridian Management Consultants



Re: Comment on SASB Exposure Draft for Biotechnology

On my own behalf, as a long-time biopharma industry manager and consultant, I am providing comments on the SASB Exposure Draft for Biotechnology.

Thank you for this important and difficult work ... my clients and I both see these standards as an important tool for engaging senior management on sustainability and materiality objectives, and moving our industry forward.

Sincerely,

Sandor

Social Capital

- The two categories "Access to Medicines" and "Affordability, Access, and Fair Pricing" are confusing. It would help if they were grouped together (positioned side-by-side), and the names clarified, e.g. "Global Access to Medicines" and "Fair Pricing".
- It would help to group "Ethical Marketing," "Employee Engagement," and "Counterfeit Drugs" together as well, as they're all concerned with management processes and engagement with stakeholder groups.
- "Disease Migration" should migrate from the Environmental Capital section, and be grouped with "Orphan Drugs" and "Chronic Diseases". Disease migration, while caused by environmental factors, is not an impact that a biopharma company can control ... rather it presents as context for business planning with social goods in mind, exactly like investing in orphan indications or high-impact chronic diseases.
 - For "Disease Migration" you should ask the same revenue questions as for "Orphan Drugs" and "Chronic Diseases"
 - For all three areas, there should be a question about investment as well as revenue ... as revenue alone isn't a good marker for commitment to social objectives

Environmental Capital

- The "Resource Efficiency" category lumps too many things together. It would be better to break out the three top ESG issues identified through the recent Biopharma Sustainability Roundtable that Meridian ran in collaboration with SASB:
 - Energy efficiency





- Waste reduction, which should be explicitly called out, not merely implied by the Process Mass Intensity (PMI) metric
- Water efficiency
- The new "Waste Reduction" topic should include better recycling and landfill avoidance, not only input materials efficiency (PMI).
- As mentioned above, "Disease Migration" should really be part of the Social Capital section.

Governance




- Need another ESG Issue to cover operational integration of materiality and sustainability concerns into corporate objectives, priorities, operational processes, and risk management analyses. This was one of the highest priority topics identified in the recent Biopharma Sustainability Roundtable.

Additional questions for Market Participants.





[MP1] How useful are the proposed set of sustainability issues and associated KPIs to investors when identifying material sustainability risks and opportunities within the industry?

Response	Chart	Percentage	Count
Very useful		0%	0
Somewhat useful		0%	0
Not useful		0%	0
Detrimental: Disclosure on these issues/ KPIs adds to the noise created by immaterial information		0%	0
Total Responses			0

[MP2] Would you use the information derived from the proposed material sustainability issues and associated KPIs in your investment process in the industry?

Response	Chart	Percentage	Count
Yes		0%	0
No		0%	0
I don't know		0%	0
Total Responses			0





[MP2y] How would you use this information?

Response	Chart	Percentage	Count
To help with fundamental valuation about individual companies		0%	0
To identify leading companies in the industry		0%	0
To assess risk exposure of your portfolio to ESG factors		0%	0
Other, please specify...		0%	0
Total Responses			0

[MP2y] How would you use this information? (Other, please specify...)

#	Response
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[MP2n] Why wouldn't you use this information?





Response	Chart	Percentage	Count
The issues covered in the 'exposure draft' are not material to this industry		0%	0
The issues covered in the 'exposure draft' are material to this industry but not in the time frame of our investment horizon		0%	0
The issues covered in the 'exposure draft' are material to this industry but the KPIs would not provide useful information for making an investment decision		0%	0
Other, please specify...		0%	0
Total Responses			0

[MP2n] Why wouldn't you use this information? (Other, please specify...)





#	Response
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Questions for companies, NGOs or intermediaries.




[Co1] How useful are the proposed set of material issues and associated KPIs to companies in the industry in managing material short, medium and long term risks and opportunities?

Response	Chart	Percentage	Count
Very useful		60%	3
Somewhat useful		40%	2
Not useful		0%	0
Detrimental: Disclosure on these issues/KPIs adds to the cost of reporting immaterial information		0%	0
Total Responses			5

[Co2] How costly do you think it will be to gather the information required to report on the proposed KPIs?

Response	Chart	Percentage	Count
Low cost – companies already collect most of this information		0%	0
Moderate cost – companies already collect some of this information; but will need to create processes to collect additional data		40%	2
High costs – companies do not collect most of this information and doing so will be a significant and costly burden.		20%	1
I don't know		40%	2
Total Responses			5

[Co3] Are there economic and/or business reasons that would impede a company in this industry from complying with disclosing on the proposed KPIs?

Response	Chart	Percentage	Count
Yes		20%	1
No		40%	2
I don't know		40%	2
Total Responses			5

[Co3y] Please elaborate

Still, compliance with SASB's Biotech accounting standards by Biogen Idec would likely involve hundreds of staff hours per year

- A mix of 40 wide-ranging quantitative and qualitative metrics
- Spanning impacts in three broad areas: environmental, social and governance

PCP Report - Medical Equipment Supplies

(Completion rate: 42.86%)

Public Comment on the proposed set of material sustainability issues and Key Performance Indicators for the Medical Equipment and Supplies Industry

The purpose of this survey is to obtain public feedback on the proposed set of material sustainability issues and associated key performance indicators (KPIs) for the Medical Equipment and Supplies Industry. Exposure Drafts of material sustainability issues and associated KPIs for each industry can be found here. These issues and KPIs were developed by SASB through a rigorous research and industry engagement process. If you wish to learn more about the process, please follow this link. The issues and KPIs form the basis for the recommended sustainability disclosures companies publicly listed in U.S. should include in their annual reports (Form 10-K or Form 20-F for foreign private issuers). This reporting framework will be supported by Technical Protocols to ensure proper and consistent accounting. SASB has developed Industry Briefs for all six industries in the Health Care sector. These documents provide background information on the industry and include evidence of materiality for each issue. Industry Briefs can be found here. Important note: SASB has identified a set of issues deemed material for an industry. Ultimately, determination of materiality is the responsibility of entities preparing annual reports and could differ from the set of material issues identified by SASB, given the specific circumstances of a company's operations. Please begin this survey only after you have thoroughly reviewed the Exposure Draft for the Medical Equipment and Supplies Industry. You may provide comments on as many industries as you would like by following the appropriate survey links found here. The results from the survey will be made publicly available once the public comment period ends. Should you have any technical difficulties with the survey, please contact Trent Boorman at: [REDACTED]

Basic information

Please provide the following basic information about you.

[Q1]

Variable	Response
Name	There are 5 response(s) to this question.
Position	There are 5 response(s) to this question.
Organization	There are 5 response(s) to this question.
Email	There are 5 response(s) to this question.

[Q1] | Name

#	Response
1.	Jeremy Shapiro
2.	Erol Odabasi
3.	William Blackburn
4.	Julie Brautigam
5.	Mark Miller

[Q1] | Position

#	Response
1.	ED
2.	Director, Sustainability
3.	President
4.	Director of Ethics Compliance/EHS
5.	Finance Director

[Q1] | Organization

#	Response
1.	Morgan Stanley
2.	Johnson Johnson
3.	William Blackburn Consulting, Ltd.
4.	██████
5.	Medtronic

[Q1] | Email

#	Response
1.	████████████████████
2.	████████████████
3.	████████████████████████████
4.	████████████████████
5.	████████████████████████████

[Q2] Are you providing comments on behalf of your organization or as an individual?

Response	Chart	Percentage	Count
On behalf of my organization		20%	1
As an individual		80%	4
Total Responses			5

[Q3] What interest group do you represent?

Response	Chart	Percentage	Count
Market participant (e.g. asset owners, pension funds, asset manager, sell-side research analysts)		0%	0
Company or Industry Association in the Health Care sector		40%	2
Intermediary (e.g. NGO, academia, government)		0%	0
Other, please specify...		60%	3
Total Responses			5

[Q3] What interest group do you represent? (Other, please specify...)

#	Response
1.	Standards Council Member
2.	Former vp EHS sustainability of a major medical products company
3.	Shareholder

[Q3A] If you are an investor, do you have a significant exposure to the US market?

Response	Chart	Percentage	Count
Yes		0%	0
No		0%	0
Total Responses			0

[Q3B] Does your organization file a Form 10-K or 20-F with the U.S. Securities and Exchange Commission (SEC)?

Response	Chart	Percentage	Count
Yes, 10K		100%	2
Yes, 20F		0%	0
No		0%	0
Does not apply		0%	0
Total Responses			2

Open Comments Form

In this section SASB is seeking your comments on the proposed set of material issues and associated KPIs described in the Exposure Draft for the Medical Equipment and Supplies industry. Specifically, SASB would like comments to address the following questions: Question 1: Are the sustainability issues material to a reasonable investor? Do the KPIs accurately represent performance with respect to the associated sustainability issue? How would metrics reported for the KPIs be used in making investment decisions? How would the metrics be useful for internal company management? Question 2: How costly would it be for companies to collect, analyze, and report information required for the proposed KPIs? Do you anticipate this cost to be a barrier to reporting, adoption, or usage of the proposed KPIs? What aspects of reporting would you foresee being most costly for reporting organizations? We strongly encourage participants to provide your comments on company/organization or individual letterhead signed by the authorized representative. Alternatively, comments can be made in a text box.

[Q5] How will you provide feedback?

Response	Chart	Percentage	Count
By uploading a PDF document with comments.		0%	0
By entering them on a text box in this survey		100%	4
Total Responses			4

[Q7] Enter your comments in the box below

#	Response
1.	<p>Jeremy Shapiro ED, Morgan Stanley Standards Board Member [REDACTED]</p> <p>Comment on SASB Exposure Draft for Medical Equipment and Supplies</p> <p>No talent measures at all. Are we saying that talent disclosures are not material to this industry?</p> <p>We should have a conversation about cross-cutting issues likes this.</p>
2.	<p>William Blackburn, President, William Blackburn Consulting, Ltd. (formerly vp chief counsel, Corp EHS sustainability leader, [REDACTED]) [REDACTED]</p> <p>Re: Comment on SASB Exposure Draft</p> <p>On my own behalf, I am providing comments on the SASB Exposure Draft for Medical Equipment Supplies, plus other drafts.</p> <p>Sincerely, William R. Blackburn</p> <p>These comments apply to all SASB standards:</p> <ol style="list-style-type: none">1. SASB should be using a definition of materiality that includes the interests of and impacts on the broad range of key stakeholders, not just investors. Because it doesn't do so, the importance of key issues like employee and community safety are not being properly valued and recognized. Moreover, SASB's focus on multiple capitals is too academic and confusing, which will impeded uptake of the standard. Better to view sustainability as a management approach framed around the values of the triple bottom line, including values associated with the key issues identified in GRI's indicator categories, which generally match the ISO 26000 Social Responsibility Core Subjects [governance, human rights, labor practices, environment, fair operating practices(--including anti-corruption, public policy, and anti-competitive behavior--), consumer issues/product responsibility, community involvement development, and financial/economic performance]. This change would make the standard more intuitive and reflect the combined consensus of the large multi-year, multi-stakeholder forums used to create GRI and ISO 26000.2. The indicators are not bad, but unfortunately do not address key information which experts use to determine how sound and effective a company's approach to managing the topic is, which in turn reflects the degree of risk the organization is assuming on the topic. GRI's latest draft of its Disclosure of Management Approach touches on some of this information. Not only would key stakeholders appreciate candid information about how the topic is being managed, but I'm sure many would appreciate information on how the organization addresses the topic through its enterprise risk management process, as well as information about what board of directors committee assumes responsibility for oversight of performance and management systems related to the key topics. (Note that South Africa's King III corporate governance standards underscore the importance of ERM and clear board committee accountability.)3. The standards do not emphasize transparency nor create any vehicle by which the degree of transparency is publicly confirmed by upper management. The lack of transparency about weaknesses, shortcomings, and failures is the biggest single gap in company communication with stakeholders and more than anything else, distorts the view about the risks being assumed by the organization.

3. Julie Brautigam

re: Comment on SASB Exposure Draft for Medical Equipment and Supplies

On my own behalf, I am providing confidential comments on the SASB Exposure Draft for Medical Equipment and Supplies. I would appreciate these comments not being attributed to [REDACTED] as well as any publication of actual comments redacting [REDACTED] from the text.

Many but not all of the sustainability issues may be deemed material by a reasonable investor. In fact, many of them are material issues already disclosed in a company's filings when an incident arises in those areas and when there is a material financial impact. However, there is an important distinction between material programs that a company manages and material issues that give rise to financial reporting obligations under SEC rules or for that matter voluntary standards. While the ESG issues identified may be very important, the manner in which they are described, discussed and intended to be measured (by the suggested KPIs in the exposure draft) are ultimately more problematic than the issue identification and reporting on the approach for managing that issue within the company itself. Moreover the SEC forms intended to be used for purposes of the ANSI standard and possible future regulation, coupled with the potential lack of globally consistent tracking systems for the items to be reported as well as robust independent verification and assurance schemes tied to those key performance indicators makes reporting to the SASB standard problematic from a corporate legal and individual liability standpoint. The company supports the opportunity to provide investors with meaningful context on how it manages the various material issues identified by SASB, and does so through various means, including importantly its annual sustainability report which discloses a number of indicators and our approaches to managing those items, periodic investor forums, and information contained in the company's regular SEC filings and annual financial report.

There are several KPI areas that are difficult to address in the exposure draft for medical equipment and supplies:

1. Product Safety –

- a. List of products recalled with associated revenue in preceding 12 month period before the recall. I do not believe that this provides context for product safety efforts, and does not address the complexity generated from a regulatory affairs standpoint in considering potentially multiple product codes that may exist within a product family and tying this to specific revenues generated in each country market. For various reasons, product components and families may have complexity due to regulatory filings in multiple country markets, and assimilating this information consistently with the related revenues for a time period may be difficult to track accurately and in a verifiable way. A product safety issue may be tied to a specific event, and it is difficult to see the meaning of the preceding 12-month period, especially if the product was deemed safe during the preceding 12 month period or a portion of the 12 month period. Therefore, it is hard to say how this KPI is meaningful to a reasonable investor. Alternatively, companies may measure the financial impact from revenue lost in future periods based on sales forecast/plan and remediation costs to address the issue, not specific to a time period.
- b. Fatalities related to products as reported in the FDA Adverse Event Reporting System – this is a publicly searchable database already available and reporting on this indicator on its own lacks context from a product safety standpoint. It is ultimately the role of the FDA and other regulatory authorities and medical experts in coordination with companies to determine if trends are apparent in adverse events that could be attributable to a product issue as opposed to other health circumstances of patients. More importantly the company has programs and functions in place to protect patient safety, and this metric alone does not provide a complete picture.

2. Affordability, Access and Fair Pricing –

- a. Ratio of weighted average rate of net price increases (for all products) to annual increase in U.S. Consumer Price Index – we understand the need for companies to provide healthcare products and services that are reflective of government budget pressures on healthcare spend. However, the systems to collect this data globally and compare to the U.S. CPI are a challenge. Additionally, the disclosure of price increases for products in markets

could potentially be seen to violate antitrust or competition law, and can be considered as competitively sensitive information, especially in lines of business where aggregate level reporting does not make sense. Also for companies with products that treat a range of diseases and care needs, the range of commodity-based products versus specialty items will not give a clear picture of the impact of such price increases in the aggregate.

b. Manufacturer discloses average and median price information for each product to customers or their agents (group purchasing organizations or consultants) – Price can vary by market depending on manufacturing costs in that market, distribution and supply chain channels to reach the end customer. Additionally, often governments use cost-based information and their healthcare budget-based information to set the maximum price at which they are willing to reimburse or pay companies for certain products. In this scenario, companies already share cost and pricing information with the government directly. Companies must then decide how they will supply products in that market and competitive forces drive down the overall price paid. Additionally, the disclosure of price increases for products in markets to consultants and others could potentially be seen to violate antitrust or competition law, and can be considered as competitively sensitive information, especially in lines of business where aggregate level reporting does not make sense. It is not clear what value this KPI will create and does not seem well suited for disclosure in a 10K.

3. Product Lifecycle Management –

a. Description and associated revenue of products with environmental considerations made at product lifecycle stages such as design, procurement, manufacturing, distribution, use and end of life, etc. – The indicator is relatively broad and hence difficult to measure. Without an appropriate technical standard for this area, many products and significant revenues will likely be able to be categorized as such. It is not clear if SASB is asking for how the environmental attributes drive sales value of products, which is also difficult to measure.

b. Original sales value of product taken back, reused, or donated through Extended Producer Responsibility initiatives – The company currently does not track or measure this or see a benefit to, other than where tax or other financial incentives would drive a need to report and measure such. Many durable medical equipment suppliers take back to equipment to service and repair and replace that unit on the market, and so it is not clear how the original sales value would actually be measured, and the value to measuring original sales value, which can be several years old for longer-lasting pieces of equipment.

4. Operational Standards and Supply Chain Management –

a. Number and type of FDA enforcement actions taken in response to violations of current good manufacturing practices (cGMP), etc. – the request for all sorts of regulatory notifications may diminish the actual materiality of the few that will actually have a material impact on the regulated activity. We urge SASB to discern which of those really matter to investors and further narrow the request.

b. Percent of facilities and suppliers (by tier) participating in third party audit programs for integrity of supply chain and products (materials, devices, packaging, etc.) – The company has a range of audit/monitoring activities, some internal and some third party. We think the other indicator asking for qualitative information on product traceability could be expanded to the supply chain rather than focusing on percentages of facilities and suppliers audited. Also, the range of auditing activity should be expanded to internal audit and control programs as well.

The other Key Performance Indicators identified are not as difficult to measure and many are ones the company is already measuring for other reasons, which further supports their incorporation as a potentially material indicator.

SASB asks specifically about the following questions, and I provide responses below for those KPIs that are the most difficult:

1. Do the KPIs accurately represent performance with respect to the associated sustainability issue?

a. No, not all of the KPIs accurately represent performance. See comments above.

2. How would metrics reported for the KPIs be used in making investment decisions?

a. If SASB is asking this from a company perspective, the questions do not prompt a company to make further investments in programs. Companies would require significant investment in systems to collect and report all such data, that currently do not have a business need or value.

3. How would the metrics be useful for internal company management?

a. Besides the comments provided above on the difficult to measure KPIs, other KPIs not specifically mentioned

above but included in the exposure draft have value in tracking progress toward sustainability goals and risk reduction activities.

Question 2: How costly would it be for companies to collect, analyze, and report information required for the proposed KPIs?

We estimate it would be moderately to prohibitively expensive to provide the manpower, resources, systems and external assurance to be able to report against the KPIs in an SEC filing.

1. Do you anticipate this cost to be a barrier to reporting, adoption, or usage of the proposed KPIs?
Yes.





2. What aspects of reporting would you foresee being most costly for reporting organizations?

Difficult to report indicators were already discussed above. Those would require significant resources to be able to report.




How would metrics reported for the KPIs be used in making investment decisions? How would the metrics be useful for internal company management?

Additional questions for Market Participants.





[MP1] How useful are the proposed set of sustainability issues and associated KPIs to investors when identifying material sustainability risks and opportunities within the industry?

Response	Chart	Percentage	Count
Very useful		0%	0
Somewhat useful		0%	0
Not useful		0%	0
Detrimental: Disclosure on these issues/ KPIs adds to the noise created by immaterial information		0%	0
Total Responses			0

[MP2] Would you use the information derived from the proposed material sustainability issues and associated KPIs in your investment process in the industry?

Response	Chart	Percentage	Count
Yes		0%	0
No		0%	0
I don't know		0%	0
Total Responses			0





[MP2y] How would you use this information?

Response	Chart	Percentage	Count
To help with fundamental valuation about individual companies		0%	0
To identify leading companies in the industry		0%	0
To assess risk exposure of your portfolio to ESG factors		0%	0
Other, please specify...		0%	0
Total Responses			0

[MP2y] How would you use this information? (Other, please specify...)

#	Response
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[MP2n] Why wouldn't you use this information?





Response	Chart	Percentage	Count
The issues covered in the 'exposure draft' are not material to this industry		0%	0
The issues covered in the 'exposure draft' are material to this industry but not in the time frame of our investment horizon		0%	0
The issues covered in the 'exposure draft' are material to this industry but the KPIs would not provide useful information for making an investment decision		0%	0
Other, please specify...		0%	0
Total Responses			0

[MP2n] Why wouldn't you use this information? (Other, please specify...)





#	Response
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Questions for companies, NGOs or intermediaries.




[Co1] How useful are the proposed set of material issues and associated KPIs to companies in the industry in managing material short, medium and long term risks and opportunities?

Response	Chart	Percentage	Count
Very useful		0%	0
Somewhat useful		67%	2
Not useful		33%	1
Detrimental: Disclosure on these issues/KPIs adds to the cost of reporting immaterial information		0%	0
Total Responses			3

[Co2] How costly do you think it will be to gather the information required to report on the proposed KPIs?

Response	Chart	Percentage	Count
Low cost – companies already collect most of this information		0%	0
Moderate cost – companies already collect some of this information; but will need to create processes to collect additional data		67%	2
High costs – companies do not collect most of this information and doing so will be a significant and costly burden.		0%	0
I don't know		33%	1
Total Responses			3

[Co3] Are there economic and/or business reasons that would impede a company in this industry from complying with disclosing on the proposed KPIs?

Response	Chart	Percentage	Count
Yes		67%	2
No		0%	0
I don't know		33%	1
Total Responses			3

[Co3y] Please elaborate

#	Response
1.	Concept of sustainability framed around multiple capitals is too academic, and therefore not so easy to sell to upper management. Also, some companies would be embarrassed to share candid information of this type or may not have it readily available and resources may be stretched thin for taking on added reporting burdens.
2.	We believe there may be legal ramifications for such reporting including possible antitrust and foreign competition law implications for cost and price sensitive KPIs, along with disclosure of competitively sensitive information that could be used by others in the sector. Additionally, in any business there are tradeoffs to investing in such reporting capabilities, systems and accuracy. Investments in this area take away from resources that could be spent on improving products and innovations that lead to meaningful patient outcomes. Lastly, we note that the form of reporting in the 10K places significant liability on executives for potentially inaccurate information. Where organizations are complex, the systems may not be mature enough to handle the degree of accuracy and verification required for 10K reporting and overall SEC disclosure. While we think the goals of SASB are laudable, we encourage reporting on material sustainability issues to be done in a form and way that encourages transparency and that does not have the same legal ramifications as 10K reporting.

PCP Report - Pharmaceuticals

(Completion rate: 35.0%)

Public Comment on the proposed set of material sustainability issues and Key Performance Indicators for the Pharmaceuticals Industry

The purpose of this survey is to obtain public feedback on the proposed set of material sustainability issues and associated key performance indicators (KPIs) for the Pharmaceuticals Industry. Exposure Drafts of material sustainability issues and associated KPIs for each industry can be found [here](#). These issues and KPIs were developed by SASB through a rigorous research and industry engagement process. If you wish to learn more about the process, please follow [this link](#). The issues and KPIs form the basis for the recommended sustainability disclosures companies publicly listed in U.S. should include in their annual reports (Form 10-K or Form 20-F for foreign private issuers). This reporting framework will be supported by Technical Protocols to ensure proper and consistent accounting. SASB has developed 'Industry Briefs' for all six industries in the Healthcare sector. These documents provide background information on the industry and include evidence of materiality for each issue. Industry Briefs can be found [here](#). Important note: SASB has identified a set of issues deemed material for an industry. Ultimately, determination of materiality is the responsibility of entities preparing annual reports and could differ from the set of material issues identified by SASB, given the specific circumstances of a company's operations. Please begin this survey only after you have thoroughly reviewed the Exposure Draft for the Pharmaceuticals Industry. You may provide comments on as many industries as you would like following the appropriate survey links found [here](#). The results from the survey will be made publicly available once the public comment period ends. Should you have any technical difficulties with the survey, please contact Trent Boorman at: [REDACTED]

Basic information

Please provide the following basic information about you.

[Q1]

Variable	Response
Name	There are 13 response(s) to this question.
Position	There are 13 response(s) to this question.
Organization	There are 13 response(s) to this question.
Email	There are 13 response(s) to this question.

[Q1] | Name

#	Response
1.	Bill Baue
2.	Yoshihiro Fujii
3.	Michael Sherber
4.	Jeremy Shapiro
5.	rita ogun
6.	Cora Olsen
7.	Madalina Dumitru
8.	Emmanuelle Probst
9.	Lauren Comperr
10.	Steve Lydenberg
11.	Meredith Miller
12.	Dinah Koehler
13.	Sandor Schoichet

[Q1] | Position

#	Response
1.	Corporate Sustainability Architect
2.	Professor
3.	VP of Engineering
4.	ED
5.	product manager
6.	ESG Data manager
7.	Associated Professor
8.	Group Sustainability Controller
9.	Managing Director
10.	Partner, Strategic Vision
11.	Chief Corporate Governance Officer

12. Sr Research Manager

13. Director



[Q1] | Organization

#	Response
1.	Independent
2.	Sophia University
3.	7AC Technologies, Inc.
4.	Morgan Stanley
5.	ifrs
6.	Novo Nordisk
7.	Bucharest Academy of Economic Studies
8.	Roche Holding
9.	Boston Common Asset Management
10.	Domini Social Investments
11.	UAW RMBT
12.	Deloitte
13.	Meridian Management Consultants





[Q1] | Email

#	Response
1.	[REDACTED]
2.	[REDACTED]
3.	[REDACTED]
4.	[REDACTED]
5.	[REDACTED]
6.	[REDACTED]
7.	[REDACTED]
8.	[REDACTED]
9.	[REDACTED]
10.	[REDACTED]
11.	[REDACTED]
12.	[REDACTED]
13.	[REDACTED]

[Q2] Are you providing comments on behalf of your organization or as an individual?

Response	Chart	Percentage	Count
On behalf of my organization		23%	3
As an individual		77%	10
Total Responses			13



[Q3] What interest group do you represent?

Response	Chart	Percentage	Count
Market participant (e.g. asset owners, pension funds, asset manager, sell-side research analysts)		23%	3
Company or Industry Association in the Health Care sector		15%	2
Intermediary (e.g. NGO, academia, government)		23%	3
Other, please specify...		38%	5
Total Responses			13





[Q3] What interest group do you represent? (Other, please specify...)

#	Response
1.	Manufacturer
2.	Standards Council Member
3.	accounting profession
4.	Biopharma industry consultant

[Q3A] If you are an investor, do you have a significant exposure to the US market?

Response	Chart	Percentage	Count
Yes		100%	3
No		0%	0
Total Responses			3



[Q3B] Does your organization file a Form 10-K or 20-F with the U.S. Securities and Exchange Commission (SEC)?

Response	Chart	Percentage	Count
Yes, 10K		20%	2
Yes, 20F		10%	1
No		30%	3
Does not apply		40%	4
Total Responses			10

Open Comments Form

In this section SASB is seeking your comments on the proposed set of material issues and associated KPIs described in the Exposure Draft for the Pharmaceuticals industry. Specifically, SASB would like comments to address the following questions: Question 1: Are the sustainability issues material to a reasonable investor? Do the KPIs accurately represent performance with respect to the associated sustainability issue? How would metrics reported for the KPIs be used in making investment decisions? How would the metrics be useful for internal company management? Question 2: How costly would it be for companies to collect, analyze, and report information required for the proposed KPIs? Do you anticipate this cost to be a barrier to reporting, adoption, or usage of the proposed KPIs? What aspects of reporting would you foresee being most costly for reporting organizations? We strongly encourage participants to provide your comments on company/organization or individual letterhead signed by the authorized representative. Alternatively, comments can be made in a text box.

[Q5] How will you provide feedback?

Response	Chart	Percentage	Count
By uploading a PDF document with comments.		11%	1
By entering them on a text box in this survey		89%	8
Total Responses			9

[Q7] Enter your comments in the box below

#	Response
1.	<p>Michael Sherber VP of Engineering 7AC Technologies, Inc. [REDACTED]</p> <p>My comment is to suggest that under the category of Resource Efficiency that "water" be replaced by "fresh water". In many instances fresh water use can be replaced by salt water or gray water use.</p>
2.	<p>Jeremy Shapiro ED, Morgan Stanley Standards Board Member [REDACTED]</p> <p>Comment on SASB Exposure Draft for Pharma</p> <p>On my behalf:</p> <ol style="list-style-type: none">1. Employee retention should move to governance.2. Same section - incomplete:<ol style="list-style-type: none">a. Inappropriate to lump employee safety with recruiting. Important on its own.b. Needs an employee engagement measure.c. Some disclosure on talent strategy (if they aren't a primary research shop than the scientist item is not material)d. Diversity measures <p>We should have a conversation about cross-cutting issues likes this.</p>
3.	<p>Cora Olsen ESG Data manager Novo Nordisk A/S [REDACTED] Denmark</p> <p>Comments on exposure draft regarding pharmaceutical sector:</p> <p>Question 1: Most of the disclosures in the exposure draft are very reactive - it should be considered if there are ways to cmbine it with more proactively measure performance. The 'damage' is done with the current focus of many of the KPIs. An example: The governance dimension could be expanded to cover more proactive measures. What is currently included is very reactive namely the law suits. Training of employees in business ethics could be a proactive measure as well as having policies and governance structures in place to drive this important aspect of business. Once the law suits are coming in it is too late. It would be of greater value to the investors to know more about what the companies are actually doing to prevent/mitigate risks instead of only getting info on the 'damage' once it has happened. It is important that SASB's contribution includes the whole management and strategic embeddedness of these issues, which comes before many of the measures. The purpose of the reporting is the show how well/poor these issues are managed within the company.</p>

Most but not all of the proposed KPIs is something we track to a certain extent, but our data is not 'cut' or calculated in the same way as defined in the exposure draft, which will pose a challenge for us if the expectation is full alignment when reporting in the 20F.

Question 2:

Collection all of this information and ensuring auditable data quality will pose a barrier as reaching this level for all of the KPIs in the exposure draft will require alot of work, as reporting externally comes with a greater pressure and expectation in terms of data quality and governance for these processes. I foresee a great barrier here, as this will be very time consuming.

-
4. Meredith Miller
Chief Corporate Governance Officer
UAW Retiree Medical Benefits Trust



I am providing comments on the Pharmaceutical Industry Draft. Thank you for your work on this impressive exposure draft. My comments focus more on governance risks and key metrics we use in evaluating this industry from an institutional investor perspective. My comments are overarching and apply to the other health care industry draft exposures as well.

First, it is unclear why corporate governance risks are missing from the key indicator list. It is hard to tell if this is because there is a view that governance is already disclosed in the proxy and/or that governance is baked into the stock price. Either way, it would be helpful to have a discussion about this since there are several governance risks which investors are asking to be disclosed which are not currently required under SEC rules. At a minimum, companies are not required to disclose corporate political contributions, compensation details below the top five highly compensated employees, whether or not they use (as opposed to have policy) or have used in any one year a clawback or recoupment policy, whether the board is operating under a corporate integrity agreement and/or independent reviewer and whether they have board members with compliance and regulatory healthcare experience, and finally whether the auditors investor may be voting on have paid fines are have served on boards that had financial restatements. The HHS OIG just released a video describing the roles and fiduciary duties that board of directors have when they serve on health care boards.

I was pleased to see the attention to detail on disclosure of settlements with the federal and/or state governments but I am unclear if such settlements have to trigger a financial restatement in order to be disclosed. How companies define significant financial harm varies.

Lastly, many investors are focusing in on safety, human and workplace rights and environmental compliance. There is good attention to supply chain standards in the drafts. This set of metrics can be strengthened by specifically asking whether suppliers monitor and report based on GRI or similar guidelines. Industry memberships or adoption of standards does not always give investors information they need to know about supply chain compliance.

Thank you for the opportunity to comment and for the larger effort here that will undoubtedly benefit investors on ESG issues. I would be happy to convene a group of investors to discuss concerns about the governance and workplace compliance issues.

Sincerely,

Meredith Miller

5. Dinah Koehler
Sr Research Manager, Sustainability
Deloitte
New York

Re: Comment on SASB Exposure Draft for pharmaceuticals/health care

On my own behalf, I am providing comments on the SASB Exposure Draft for pharmaceuticals/health care. Antibiotic resistance and incentives for doctors to prescribe antibiotics (via coupons) needs to be captured. This is a looming risk for human health (antibiotic resistance in humans and animals) and the eco-system (evidence of antibiotic resistance in aquatic environments. While new antibiotics need to be developed, use of existing antibiotics needs to be curtailed (in humans and animal husbandry).

Sincerely,

Dinah Koehler

6. Sandor Schoichet
Director
Meridian Management Consultants

Re: Comment on SASB Exposure Draft for Pharmaceuticals

On my own behalf, as a long-time biopharma industry manager and consultant, I am providing comments on the SASB Exposure Draft for Pharmaceuticals.

Thank you for this important and difficult work ... my clients and I both see these standards as an important tool for engaging senior management on sustainability and materiality objectives, and moving our industry forward.

Sincerely,

Sandor

My top-level comment - again - is that since there appears to be no meaningful difference between the Biotechnology and the Pharmaceuticals standards, would you please combine them into a single "Biopharma" industry standard? This will be simpler and less confusing ... and the industries are definitely overlapping to a greater and greater extent, both due to technology trends and ongoing M

Aside from that, I will repeat the same comments that I submitted for the Biotechnology survey:

Social Capital

- The two categories "Access to Medicines" and "Affordability, Access, and Fair Pricing" are confusing. It would help if they were grouped together (positioned side-by-side), and the names clarified, e.g. "Global Access to Medicines" and "Fair Pricing".
- It would help to group "Ethical Marketing," "Employee Engagement," and "Counterfeit Drugs" together as well, as they're all concerned with management processes and engagement with stakeholder groups.
- "Disease Migration" should migrate from the Environmental Capital section, and be grouped with "Orphan

Drugs" and "Chronic Diseases". Disease migration, while caused by environmental factors, is not an impact that a biopharma company can control ... rather it presents as context for business planning with social goods in mind, exactly like investing in orphan indications or high-impact chronic diseases.

For "Disease Migration" you should ask the same revenue questions as for "Orphan Drugs" and "Chronic Diseases"

For all three areas, there should be a question about investment as well as revenue ... as revenue alone isn't a good marker for commitment to social objectives

Environmental Capital

- The "Resource Efficiency" category lumps too many things together. It would be better to break out the three top ESG issues identified through the recent Biopharma Sustainability Roundtable that Meridian ran in collaboration with SASB:

Energy efficiency

Waste reduction, which should be explicitly called out, not merely implied by the Process Mass Intensity (PMI) metric

Water efficiency

- The new "Waste Reduction" topic should include better recycling and landfill avoidance, not only input materials efficiency (PMI).

- As mentioned above, "Disease Migration" should really be part of the Social Capital section.

Governance

- Need another ESG Issue to cover operational integration of materiality and sustainability concerns into corporate objectives, priorities, operational processes, and risk management analyses. This was one of the highest priority topics identified in the recent Biopharma Sustainability Roundtable.

Additional questions for Market Participants.

[MP1] How useful are the proposed set of sustainability issues and associated KPIs to investors when identifying material sustainability risks and opportunities within the industry?

Response	Chart	Percentage	Count
Very useful		50%	1
Somewhat useful		50%	1
Not useful		0%	0
Detrimental: Disclosure on these issues/ KPIs adds to the noise created by immaterial information		0%	0
Total Responses			2

[MP2] Would you use the information derived from the proposed material sustainability issues and associated KPIs in your investment process in the industry?

Response	Chart	Percentage	Count
Yes		50%	1
No		0%	0
I don't know		50%	1
Total Responses			2

[MP2y] How would you use this information?

Response	Chart	Percentage	Count
To help with fundamental valuation about individual companies		0%	0
To identify leading companies in the industry		100%	1
To assess risk exposure of your portfolio to ESG factors		0%	0
Other, please specify...		0%	0
Total Responses			1

[MP2y] How would you use this information? (Other, please specify...)

#	Response
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[MP2n] Why wouldn't you use this information?





Response	Chart	Percentage	Count
The issues covered in the 'exposure draft' are not material to this industry		0%	0
The issues covered in the 'exposure draft' are material to this industry but not in the time frame of our investment horizon		0%	0
The issues covered in the 'exposure draft' are material to this industry but the KPIs would not provide useful information for making an investment decision		0%	0
Other, please specify...		0%	0
Total Responses			0

[MP2n] Why wouldn't you use this information? (Other, please specify...)





#	Response
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Questions for companies, NGOs or intermediaries.




[Co1] How useful are the proposed set of material issues and associated KPIs to companies in the industry in managing material short, medium and long term risks and opportunities?

Response	Chart	Percentage	Count
Very useful		60%	3
Somewhat useful		40%	2
Not useful		0%	0
Detrimental: Disclosure on these issues/KPIs adds to the cost of reporting immaterial information		0%	0
Total Responses			5

[Co2] How costly do you think it will be to gather the information required to report on the proposed KPIs?

Response	Chart	Percentage	Count
Low cost – companies already collect most of this information		0%	0
Moderate cost – companies already collect some of this information; but will need to create processes to collect additional data		80%	4
High costs – companies do not collect most of this information and doing so will be a significant and costly burden.		0%	0
I don't know		20%	1
Total Responses			5

[Co3] Are there economic and/or business reasons that would impede a company in this industry from complying with disclosing on the proposed KPIs?

Response	Chart	Percentage	Count
Yes		0%	0
No		20%	1
I don't know		80%	4
Total Responses			5

[Co3y] Please elaborate

There are no responses to this question.