Additional sector guidance
Biotechnology and pharmaceuticals

June 2024
Version 1.0

SICS® industry:
Biotechnology and pharmaceuticals (HC-BP)

tnfd.global

Taskforce on Nature-related Financial Disclosures

Contents

1. Introduction

1.1. The purpose of this guidance

In September 2023, the TNFD published its recommendations for disclosure of nature-related issues and supporting implementation guidance. This document provides sector-specific additional guidance for the biotechnology and pharmaceuticals sector, covering:

- The assessment of nature-related issues using the TNFD's LEAP approach (Section 2); and
- The disclosure of sector-specific metrics in line with the TNFD's recommended approach to metrics (Section 3).

The TNFD's Guidance on the identification and assessment of nature-related issues: The LEAP approach is designed as an iterative process – across business locations and business lines – in line with established risk management processes and corporate reporting cycles. Organisations may choose to start with a narrow scope for a LEAP assessment, and gradually expand the scope of the assessment as they gain experience and insight.

The TNFD recognises that there can be significant differences across sectors for corporates applying the LEAP approach. It has published this additional guidance with significant input from a range of knowledge partners and market participants, to help biotechnology and pharmaceuticals sector participants apply the LEAP approach to their context. The overall structure of the LEAP approach is set out in Figure 1. This guidance follows that structure and Table 1 sets out the elements of LEAP for which this document provides additional guidance.

The Taskforce also recognises that investors and other stakeholders require quantitative information to compare performance and nature-related issues within sectors. To facilitate that sector-level analysis, this guidance also includes:

- Guidance on the application of the core global disclosure indicators and metrics to the biotechnology and pharmaceuticals sector (Section 3.1); and
- Core and additional sector disclosure indicators and metrics (Sections 3.2 and 3.3).

Figure 2 provides an overview of the TNFD disclosure measurement architecture and where indicators and metrics are listed in the TNFD recommendations and relevant sector guidance.

Figure 1: The TNFD approach for identification and assessment of nature-related issues – LEAP

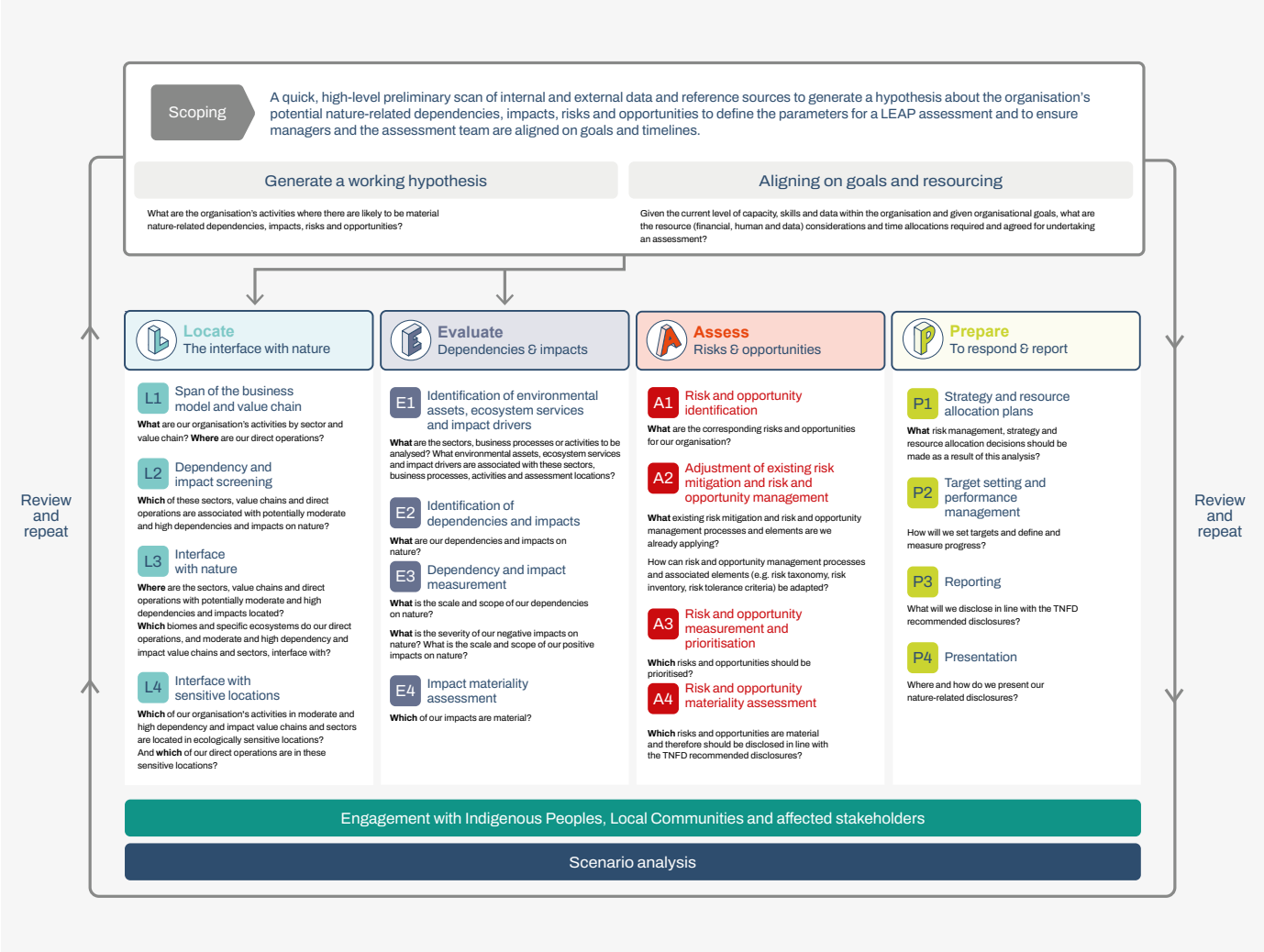
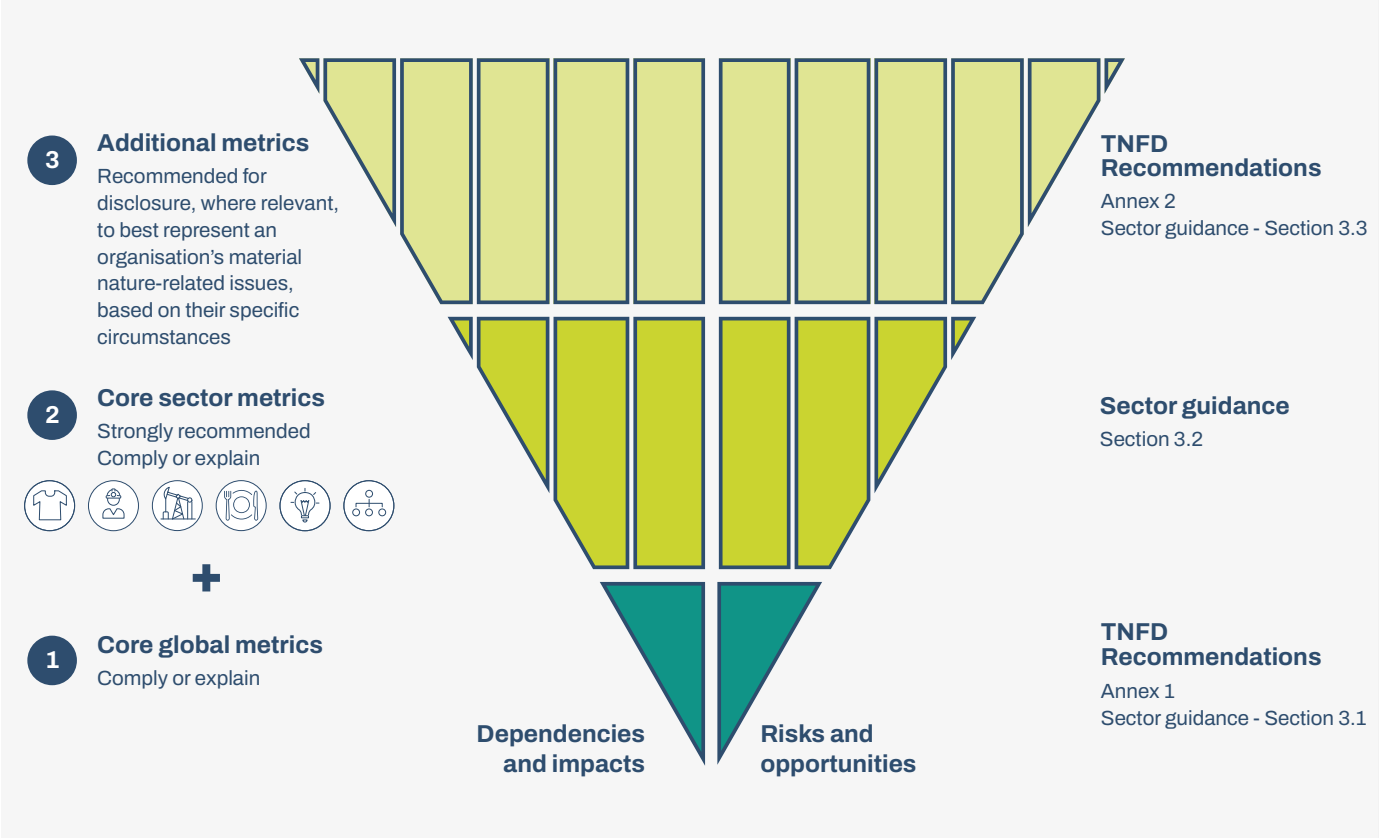


Figure 2: TNFD disclosure metrics architecture signposted to metrics lists



The guidance in Section 3 on the application of the TNFD core global metrics for this sector, as well as the core and additional sector metrics outlined, expand on the disclosure indicators and metrics outlined in Annexes 1 and 2 of the TNFD recommendations. The TNFD has incorporated and sought to build on existing industry standards and disclosure metrics wherever possible to build on current data collection and reporting practices and minimise additional assessment and reporting costs.

1.2. Audience for this guidance

This guidance covers those organisations with business models or value chains in the Biotechnology & Pharmaceuticals industry, as defined in the Sustainable Industry Classification System® (SICS®) developed by the Sustainability Accounting Standards Board (SASB) (Box 1).[1] These are referred to as 'biotechnology and pharmaceuticals sector organisations' in this guidance.

1 SASB (2018) SASB's Sustainable Industry Classification System (SICS).

Box 1: SICS® industry in the scope of this guidance document

Biotechnology and pharmaceuticals (HC-BP)

The Biotechnology & Pharmaceuticals industry develops, manufactures and markets a range of brand-name and generic medications. Research and development propels a significant portion of the industry and involves a high risk of product failure during clinical trials and the need to obtain regulatory approval. Concerns regarding sector pricing practices and consolidation have created downward pricing pressures. Primarily, demographics, insurance coverage rates, disease profiles and economic conditions drive consumer demand for the industry's products.[2]

The biotechnology and pharmaceutical sector is diverse and has complex processes along its value chain. How biotechnology and pharmaceuticals industry organisations consider their nature-related dependencies, impacts, risks and opportunities differs based on their types of activities, products, assets, the location of their operations and the regulatory regimes in which they are operating. This guidance provides additional considerations for organisations operating in this sector when applying the LEAP approach.

The examples provided in this guidance for the biotechnology and pharmaceuticals sector are intended to be illustrative. They are not exhaustive, universally applicable or recommended by the TNFD as examples of measures for all entities within the industry. Each company's context, location and nature-related interactions are unique. The TNFD encourages all companies to consult additional relevant sources and conduct thorough assessments to identify and assess nature-related dependencies, impacts, risks, and opportunities specific to their direct operations and value chains. This guidance aims to support, not replace, a tailored assessment, which will be necessary for each entity.

This guidance is a supplement to the TNFD's Guidance on the identification and assessment of nature-related issues: The LEAP approach and should be read in conjunction with that guidance.

Table 1: Areas of LEAP with additional guidance for the biotechnology and pharmaceuticals sector in this guidance document

Scoping	✓

L1	✓	E1	✓	A1	✓	P1	✓
L2	✓	E2	✓	A2		P2	✓
L3	✓	E3	✓	A3		P3	✓
L4	✓	E4		A4		P4	

2 SASB Standards (2023) Biotechnology & Pharmaceuticals.

2. Sector-specific LEAP assessment guidance

2.1. Scoping a LEAP assessment

Working hypothesis generation:

What are the organisation's activities where there are likely to be material nature-related dependencies, impacts, risks and opportunities?

Goals and resourcing alignment:

Given the current level of capacity, skills and data within the organisation and given the organisational goals, what are the resource (financial, human and data) considerations and time allocations required and agreed for undertaking an assessment?

The activities and processes in the biotechnology and pharmaceuticals value chain that typically have interfaces with nature are presented in Figure 3.[3] The process and product research and development (R&D) components refer to the 'safe and sustainable by design' approach, whereby the products are manufactured and processed in a way that maximises their contribution to society while enabling safety, fostering reuse and recycling of materials in a circular economy, and lowering the environmental impact.[4] Land use is relevant to organic feedstock sourcing, building facilities, circularity loops and waste treatment across the value chain, including the end of life of biotechnology and pharmaceuticals products.

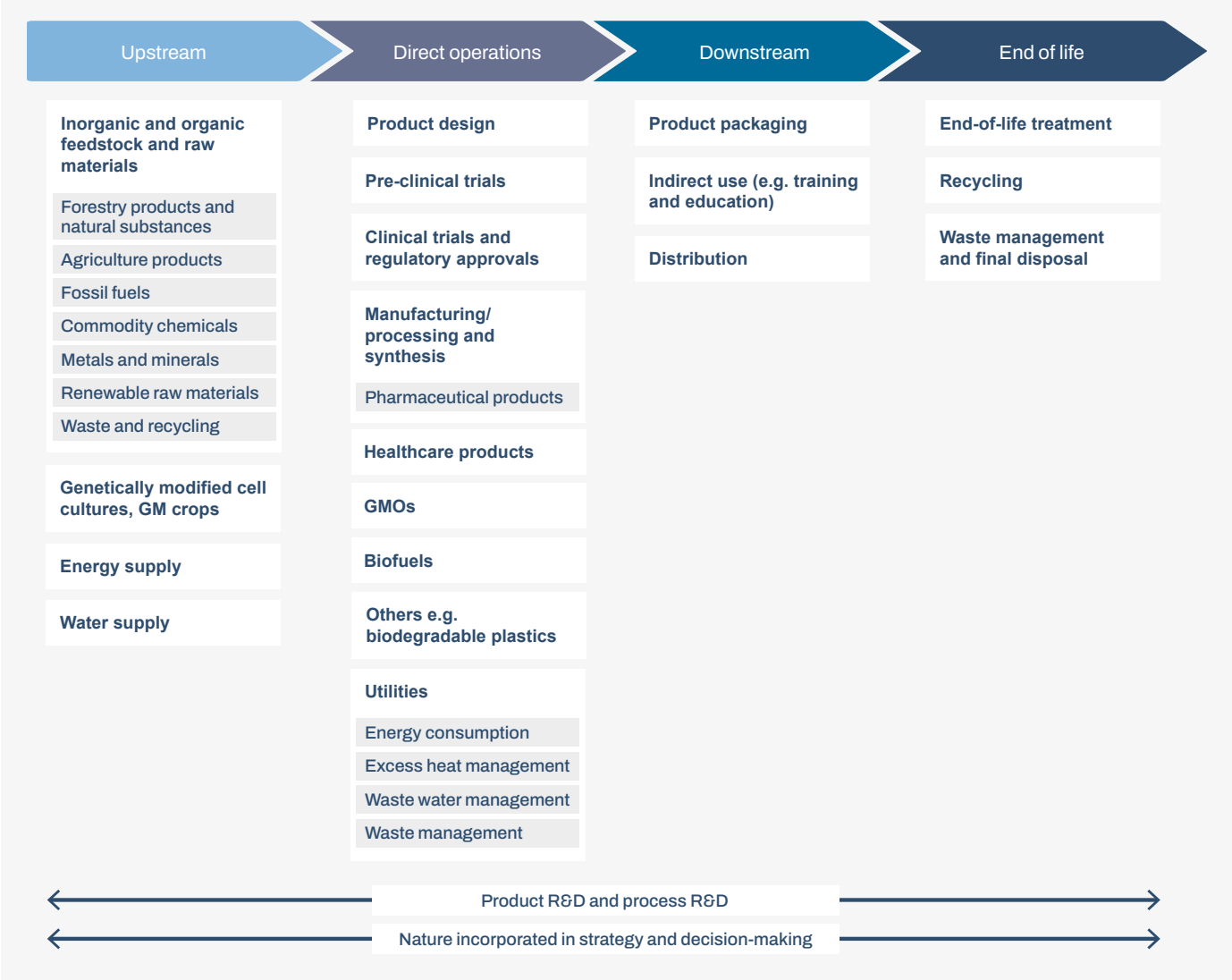
Where activities across the value chain overlap with other sectors, organisations are recommended to refer to the relevant TNFD sector guidance, where available.

Table 2 contains questions that could be used by biotechnology and pharmaceuticals sector organisations to help scope the boundaries for their nature-related assessments.

3 Depending on the level of vertical integration of their business activities, organisations may have different components of the value chain from those represented.

4 European Environment Agency (2021) Designing safe and sustainable products requires a new approach for chemicals.

Figure 3: Typical business activities in the value chain of biotechnology and pharmaceuticals sector organisations



The value chain shown in Figure 3 provides an overview of typical activities and processes of biotechnology and pharmaceuticals value chains. The TNFD recognises that organisations within the biotechnology and pharmaceuticals sectors may have varying focuses in their direct operations, as well as different suppliers and customers, based on their specific business model. Consequently, each reporting organisation is encouraged to conduct a tailored assessment of its activities across the full value chain.

Value chain considerations when scoping

Table 2: Questions for the biotechnology and pharmaceuticals sector to help scope a LEAP assessment

Area of the value chain	Questions
Direct operations	1. Which are the stakeholders to engage with in your direct operations?
Upstream	2. What is your organisation's sphere of control and influence for engagement across your value chain? 3. What inorganic and organic feedstock is sourced from areas where there are potentially material nature-related dependencies, impacts, risks and opportunities? 4. Which suppliers and other stakeholders should you engage with in your upstream operations?
Downstream/End of life	5. What are the potentially material nature-related impacts associated with downstream use of the products your organisation produces, sells or finances? What is the geographic scope and what are the likely locations of those potentially material impacts? 6. Which stakeholders should you engage with in your downstream and end-of-life operations?

Biotechnology and pharmaceuticals sector organisations may operate across many different sites and have many different suppliers and consumers across their value chains with significant potential nature-related dependencies and impacts. Biotechnology and pharmaceuticals organisations may therefore choose to start with a narrow scope to create a manageable starting point, such as a small number of high priority sites and areas of the value chain where material nature-related dependencies, impacts, risks and opportunities are most likely to arise. The LEAP approach is designed as an iterative process in line with established risk management processes and corporate reporting cycles, and organisations should look to expand the breadth and depth of the assessment over time as they gain experience and maturity in applying the process. Further guidance is available in the TNFD guidance on value chains.

2.2. Locate the organisation's interface with nature

This section provides additional guidance to help biotechnology and pharmaceuticals sector organisations with the Locate phase of the LEAP approach.

L1 L1: Span of the business model and value chain

Guiding questions:

What are our organisation's activities by sector, value chain and geography? Where are our direct operations?

Biotechnology and pharmaceuticals sector organisations should map their value chains and consider that their nature-related dependencies and impacts could be material at the following stages of the value chain, as well as direct operations:

- Upstream, due to extraction of fossil fuels, mining of metals, production of bio-based feedstock and chemical transformation;
- Downstream, due to use of products by consumers and end consumers; and
- End of life, due to toxicity of product, persistent residues and unintended releases of substances, if appropriate measures are not taken.

L2 L2: Dependency and impact screening

Guiding question:

Which of the sectors, value chains and direct operations are associated with potentially moderate and high dependencies and impacts on nature?

Upstream traceability is critical for biotechnology and pharmaceutical sector organisations to enable insight and transparency at the source of supply, particularly for nature-based commodities linked to land, freshwater and ocean use.

Downstream and end-of-life traceability should consider the potential material nature-related dependencies, impacts, risks and opportunities of the biotechnology and pharmaceutical sector organisation as well as the regulatory requirements applicable to the organisation's activities.

Tables 3a, 3b, 4a, and 4b present impact drivers and ecosystem services that may be relevant to the biotechnology and pharmaceuticals sector. These tables can be used to help screen an organisation's value chain activities for potentially moderate and high impacts and dependencies on nature.

Table 3a: Materiality ratings of ecosystem services the biotechnology and pharmaceuticals sector typically depends on (based on ENCORE 2018-2023 data)

Ecosystem services category	Ecosystem services	Inorganic & organic feedstock	Energy supply	Water supply	Manufacturing & production	Packaging	Distribution	End use (incl. end of life treat., recycle, waste)
Provisioning services	Biomass provisioning	Medium						
	Genetic material	Medium			Medium			
	Groundwater	Very High	Medium		Medium			Very Low
	Surface water	High	Very High		High			Very Low
Regulating services Resource use/ replenishment	Bioremediation	Medium	Very Low	Medium		Very Low		
	Global climate regulation	High	Very Low				High	
	Air filtration		Low		Very Low			Low
	Flood mitigation	Very High	Medium				Medium	
	Nursery population and habitat maintenance							
	Soil and sediment retention	Very High	Low		Low	Low	Medium	

Ecosystem services category	Ecosystem services	Inorganic & organic feedstock	Energy supply	Water supply	Manufacturing & production	Packaging	Distribution	End use (incl. end of life treat., recycle, waste)
Regulating Services Resource use/ replenishment	Noise attenuation							
	Biological control	High						
	Pollination	High						
	Soil quality regulation	High						
	Water flow regulation	High	Medium		Medium			
	Water purification	High	Low		Low			

Source: 2018-2023 version of the ENCORE knowledge base.

Table 3b: Materiality ratings of ecosystem services the biotechnology and pharmaceuticals sector typically depends on (based on ENCORE 2024 data)

	ISIC class/group	Manufacture of basic chemicals	Silviculture and other forestry activities	Growing of cereals (except rice), leguminous crops and oil seeds	Manufacture of refined petroleum products	Fossil fuels energy production	Research and experimental development on natural sciences and engineering	Manufacture of pharmaceuticals, medicinal chemical and botanical products
Provisioning services	Other provisioning services – Animal-based energy	N/A	Low	Medium	N/A	N/A	N/A	N/A
	Biomass provisioning	N/A	Very high	Very high	N/A	N/A	Low	N/A
	Genetic material	N/A	Very high	Very high	N/A	N/A	Medium	High
	Water supply	Medium	High	High	Low	High	Low	High
Regulating & maintenance services	Solid waste remediation	Low	Medium	Medium	Low	Medium	Low	Low
	Soil and sediment retention	Medium	Very high	Very high	Medium	Medium	Very low	Medium
	Water purification	Medium	Very high	Very high	High	Medium	Medium	Very high
	Soil quality regulation	N/A	Very high	Very high	N/A	N/A	N/A	N/A
	Other regulating and maintenance service	Low	ND	Medium	Low	N/A	Very low	Low
	Biological control	N/A	High	High	N/A	N/A	Very low	N/A
	Air filtration	Very low	Medium	Medium	Very low	Very low	Very low	Very low

	ISIC class/group	Manufacture of basic chemicals	Silviculture and other forestry activities	Growing of cereals (except rice), leguminous crops and oil seeds	Manufacture of refined petroleum products	Fossil fuels energy production	Research and experimental development on natural sciences and engineering	Manufacture of pharmaceuticals, medicinal chemical and botanical products
Regulating & maintenance services continued	Flood control	Medium	High	High	Medium	Medium	Very low	Medium
	Global climate regulation	Very low	Very high	Very high	Very low	Medium	Low	Very low
	Nursery population and habitat maintenance	N/A	High	Very low	N/A	N/A	N/A	N/A
	Noise attenuation	Very low	N/A	N/A	Very low	Very low	Very low	N/A
	Other regulating and maintenance service	Very low	N/A	N/A	N/A	N/A	Very low	N/A
	Local (micro and meso) climate regulation	Low	Very high	Very high	Low	Low	Low	Low
	Pollination	N/A	Medium	High	N/A	N/A	Low	N/A
	Storm mitigation	Medium	Medium	High	Medium	Low	Low	Medium
	Water flow regulation	Medium	Medium	High	Medium	High	Low	High
	Rainfall pattern regulation	Very low	Very high	Very high	N/A	N/A	N/A	N/A

	ISIC class/group	Manufacture of basic chemicals	Silviculture and other forestry activities	Growing of cereals (except rice), leguminous crops and oil seeds	Manufacture of refined petroleum products	Fossil fuels energy production	Research and experimental development on natural sciences and engineering	Manufacture of pharmaceuticals, medicinal chemical and botanical products
Cultural services	Recreation related services	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Visual amenity services	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Education, scientific and research services	N/A	N/A	N/A	N/A	N/A	Very high	Very high
	Spiritual, artistic and symbolic services	N/A	ND	N/A	N/A	N/A	N/A	N/A

N/A = Non-applicable

ND = No data

Source: ENCORE Partners (Global Canopy, UNEP FI, and UNEP-WCMC) (Unpublished, Expected 2024). ENCORE: Exploring Natural Capital Opportunities, Risks and Exposure. Cambridge, UK: the ENCORE Partners. Available at: https://encorenature.org. *DOI:* https://doi.org/10.34892/dz3x-y059.

Table 4a: Materiality ratings for impact drivers typically relevant for the biotechnology and pharmaceuticals sector (based on 2018-2023 version of ENCORE)

Drivers of nature change	Impact drivers	Inorganic & organic feedstock	Energy Supply	Water supply	Manufacturing & production	Packaging	Distribution	End use (incl. end of life treat., recycle, waste)
Land, freshwater and ocean-use change	Land-use change	Very High		High				
	Freshwater-use change	Very High	High	High				
	Ocean-use change						Medium	
Climate change	GHG emissions	High	High	High	High		High	
Pollution/ pollution removal	Non-GHG air pollutants	High	High	Medium	Medium	Medium	High	
	Water pollutants	High	Medium	Low	High	High	Low	
	Soil pollutants	High	Medium	Low	High	High	Low	
	Solid waste	Low	High	Medium	High	Medium		Medium
	Disturbances		High				High	
Resource use/ replenishment	Water use	Very High	Very High	High	High	High		

Drivers of nature change	Impact drivers	Inorganic & organic feedstock	Energy Supply	Water supply	Manufacturing & production	Packaging	Distribution	End use (incl. end of life treat., recycle, waste)
Invasive alien species introduction/ removal	Biological alterations	High					High	

Source: 2018-2023 version of the ENCORE knowledge base.

Table 4b: Materiality ratings for impact drivers typically relevant for the biotechnology and pharmaceuticals sector (based on 2024 version of ENCORE)

	ISIC Class/Group	Manufacture of basic chemicals	Growing of cereals (except rice), leguminous crops and oil seeds	Manufacture of refined petroleum products	Fossil fuels energy production	Research and experimental development on natural sciences and engineering	Silviculture and other forestry activities	Manufacture of pharmaceuticals, medicinal chemical and botanical products
Land, freshwater and ocean use change	Area of land use	Low	High	Low	Medium	Low	Very high	Low
	Area of freshwater use	N/A	Medium	N/A	Medium	ND	N/A	N/A
	Area of seabed use	N/A	N/A	N/A	ND	ND	N/A	N/A
Climate change	Emissions of GHG	Medium	Medium	Medium	Very high	Low	ND	Medium
Pollution/ pollution removal	Emissions of non-GHG air pollutants	Medium	High	High	Very high	Low	Very high	Medium
	Disturbances (e.g noise, light)	Very high	Medium	Very high	Very high	Low	High	Medium
	Emissions of toxic soil and water pollutants	Very high	High	Very high	Very high	Low	High	Medium
	Emissions of nutrient soil and water pollutants	N/A	Very high	N/A	N/A	ND	High	Medium
	Generation and release of solid waste	Medium	High	Medium	High	Medium	Low	Medium

	ISIC Class/Group	Manufacture of basic chemicals	Growing of cereals (except rice), leguminous crops and oil seeds	Manufacture of refined petroleum products	Fossil fuels energy production	Research and experimental development on natural sciences and engineering	Silviculture and other forestry activities	Manufacture of pharmaceuticals, medicinal chemical and botanical products
Resource use/ replenishment	Other biotic resource extraction (e.g. fish, timber)	N/A	ND	N/A	N/A	Very low	ND	N/A
	Other abiotic resource extraction	N/A	N/A	N/A	N/A	ND	N/A	N/A
	Volume of water use	Medium	Very high	Low	Medium	Medium	Medium	Medium
Invasive alien species introduction/ removal	Introduction of invasive species	N/A	Very high	N/A	N/A	Low	High	ND

N/A = Non-applicable

ND = No data

Source: ENCORE Partners (Global Canopy, UNEP FI, and UNEP-WCMC) (Unpublished, Expected 2024). ENCORE: Exploring Natural Capital Opportunities, Risks and Exposure. Cambridge, UK: the ENCORE Partners. Available at: https://encorenature.org. *DOI:* https://doi.org/10.34892/dz3x-y059.

L3

L3: Interface with nature

Guiding questions:

Where are the sectors, value chains and direct operations with potentially moderate and high dependencies and impacts located?

Which biomes and specific ecosystems do our direct operations, and moderate and high dependency and impact value chain and sectors, interface with?

As a general guide and starting point for this analysis, organisations in the biotechnology and pharmaceuticals sector typically interface with the following biomes in their direct operations and upstream or downstream value chains:

- Tropical-subtropical forests (T1);
- Temperate-boreal forests and woodlands (T2);
- Shrublands and shrubby woodlands (T3);
- Savannas and grasslands (T4);
- Intensive land-use systems (T7);
- Shoreline systems (MT1);
- Maritime vegetation (MT2);
- Vegetated wetlands (TF1);
- Rivers and streams (F1);
- Lakes (F2);
- Artificial wetlands (F3);
- Subterranean freshwaters (SF1);
- Artificial subterranean freshwaters (SF2);
- Coastal inlets and lagoons (FM1);
- Marine shelfs (M1);
- Open ocean waters (M2); and
- Artificial marine systems (M4).

This list can be considered as a reference. However, organisation should review all applicable biomes across their value chains and associated activities where significant dependencies and impacts in those biomes exist.

Organisations should refer to the TNFD biome guidance for further guidance on analysing interfaces with these biomes.

L4 L4: Interface with sensitive locations

Guiding questions:

For our organisation's activities in moderate and high dependency and impact value chains and sectors, which of these are in ecologically sensitive locations? Which of our direct operations are in sensitive locations?

When biotechnology and pharmaceutical sector organisations do not know specific locations – for example, for natural commodities that are sourced on the open market or from commodity traders where the location of the original source of the product is not known or available – organisations should consider the criteria for ecologically sensitive locations for the relevant broader region. Organisations can also consider using the supply shed approach outlined in the TNFD food and agriculture sector guidance, where appropriate for the commodity in question.

In addition to tools to address sensitive location criteria suggested in section L4 of the Guidance on the identification and assessment of nature-related issues: The LEAP approach, organisations can refer to additional credible sources as identified in their own assessments. For example, the Information Platform for Chemical Monitoring (IPCHEM)) is a tool that can be used to identify and interface with areas characterised by high levels of chemicals present in the environment.

Organisations are also strongly recommended to complement these suggested tools with region-specific databases, where available and relevant.

2.3. Evaluate dependencies and impacts on nature

This section provides additional guidance to help biotechnology and pharmaceuticals industry organisations with the Evaluate phase of the LEAP approach.

E1 E1: Identification of environmental assets, ecosystem services and impact drivers

Guiding questions:

What are the sectors, business processes or activities to be analysed?

What environmental assets, ecosystem services and impact drivers are associated with these sectors, business processes, activities and assessment locations?

For a list of the environmental assets and ecosystem services likely to be most relevant to the dependency and impact analysis of biotechnology and pharmaceuticals sector organisations, refer to Table 5 below. For a list of impact drivers, refer to Table 6.

The definitions and criteria used in impact assessment methodologies, such as eco-toxicity or the extent of the producer's responsibility to consider the use and disposal of the biotechnology and pharmaceutical products at their end of life, may vary depending on regional and/or regulatory specificities.

E2 E2: Identification of dependencies and impacts

Guiding question:

What are our dependencies and impacts on nature?

Table 5 and Table 6 present an illustrative (non-exhaustive) list of potential dependencies and impacts that biotechnology and pharmaceutical sector organisations can consider in their evaluation. Organisations are encouraged to draw from this non-exhaustive list, along with other sources and internal assessments to understand their dependencies and impacts on nature.

Table 5: Examples of dependency pathways for the biotechnology and pharmaceuticals sector

Environmental assets	Ecosystem services	Value chain and activities	Dependency description, examples and considerations
Land Terrestrial (land based) ecosystems Marine (ocean) ecosystems	Biomass provisioning; Genetic material	Upstream: Organic feedstock and raw materials	Land biomass provides essential organic feedstock, used as starting material for pharma production. If land and/or genetic diversity is degraded, this could impact raw material quality and availability. Horseshoe crabs play a relevant role in the sector due to their unique blood properties, containing a substance called LAL, which is sensitive to bacterial endotoxins. The use of LAL tests is, for example, a regulatory requirement for the Food and Drug Administration (FDA) and other health regulation agencies to ensure products are safe and free from harmful bacteria. While crabs are typically returned to the environment, the process can result in their mortality.
Water resources	Water supply	Upstream, direct operations: organic feedstock and raw materials, water supply, manufacturing	Water can be essential in some biotechnology and pharmaceutical sector organisations for its role as a solvent in drug production, for ensuring cleanliness and sterilisation to meet regulatory standards, and as an ingredient in drug formulations.
Water resources	Water flow regulation; water purification	Upstream, direct operations, downstream: water supply, manufacturing, waste management	Water is used for temperature control during manufacturing and for the safe disposal of waste. Its purity and availability are critical for maintaining product quality and production efficiency.
Land Terrestrial (land based) ecosystems	Soil quality regulation; soil and sediment retention	Upstream, direct operations, downstream, end of life: organic feedstock and raw materials; manufacturing; product packaging; waste management	Soil quality regulation is essential to ensure the sustainable production of botanical raw materials used in drug manufacturing. Soil and sediment retention prevent soil erosion and maintain land fertility, which is crucial for consistent crop yield and quality.

Environmental assets	Ecosystem services	Value chain and activities	Dependency description, examples and considerations
Land	Biomass provisioning services	Upstream, inorganic feedstock and raw material	Mining and quarrying of metals and other materials is relevant for the biotechnology and pharmaceuticals sectors as they provide the basis for some chemical compounds and instruments used across the sector.
Terrestrial (land based) ecosystems	Pollination; biological control	Upstream: organic feedstock and raw materials (e.g. forestry, agriculture products)	Pollination and biological control can be relevant for the sector due to their role in maintaining the health of plant species that are sources of medicinal compounds. Pollination is critical for plant reproduction, while biological control supports the natural regulation of pests and diseases.
Marine (ocean) ecosystems	Biomass provisioning; Genetic material	Upstream, direct operations: organic feedstock and raw materials manufacturing	Marine organisms, such as cone snails, bacteria, cyanobacteria, fungi, and halophytes, can yield valuable compounds for drug development. These organisms contribute over 90% of the oceanic biomass, offering unique chemical properties with great potential, particularly in the field of anti-cancer research. Enzymes derived from marine systems are ideal for processes in the biotechnology and pharmaceuticals sector. Squalane, a compound derived from shark liver oil, can be relevant to some organisations due to its stability and moisturising properties.

Table 6: Examples of impact pathways for the biotechnology and pharmaceuticals sector

Value chain and activities (illustrative)	Drivers of nature change	Impact drivers	Impact description and considerations
Upstream: inorganic and organic feedstock, water supply	Land/ freshwater/ ocean ecosystem use change	Land/ecosystem use change	Bio-based feedstock requires land for production and – if not sustainably produced – can drive soil degradation, land conversion and deforestation.
Upstream, direct operations: inorganic and organic feedstock, energy supply, R&D, manufacturing, packaging	Resource use/ replenishment	Water use Other resource use	Production processes are water-intensive and extensive withdrawal of freshwater contributes to water scarcity and water stress, affecting water quantity, quality and access. The sector may have impacts on some threatened wild species, such as horseshoe crabs, sharks and species listed on CITES Appendix I, II or II.

Value chain and activities (illustrative)	Drivers of nature change	Impact drivers	Impact description and considerations
Direct operations, downstream, end of life: manufacturing, final disposal, end-of-life treatment	Pollution/ pollution removal	Water pollutants Soil pollutants Solid waste	Pharmaceuticals designed to be slowly degradable or even non-degradable to resist chemical degradation during passage through a human or animal body present a special risk when they enter, persist or disseminate in the environment. Such substances are referred to as environmentally persistent pharmaceutical pollutants (EPPPs). When released into the environment, the biological activity of EPPPs may directly adversely affect non-target organisms, and cause long-term impacts on ecosystem health and resilience. The concept of 'Pharmaceuticals in the Environment' (PiE) refers to the presence and impact of pharmaceutical substances in ecosystems. These can result from veterinary medicines, from patient use and other pathways, such as improper disposal of unused medication, agricultural runoff and improper discharges from pharmaceutical manufacturing processes, including the discharge of API (Active Pharmaceuticals Ingredients). Once in the environment, these substances can have a range of adverse effects on wildlife and ecosystems. For example, these can affect non-target species (e.g. estrogenic compounds from contraceptives can disrupt the reproductive systems of fish) but can also cause AMR (antimicrobial resistance). AMR occurs when microorganisms such as bacteria, viruses, fungi and parasites evolve to resist the effects of antimicrobial drugs—like antibiotics, antivirals, antifungals and antiparasitic—that once killed or inhibited their growth. This resistance might make standard treatments ineffective, leading to persistent infections, increased spread of disease and greater risk of severe illness and death. AMR is primarily driven by the misuse and overuse of antimicrobials in human medicine, agriculture and animal husbandry, among others.

Value chain and activities (illustrative)	Drivers of nature change	Impact drivers	Impact description and considerations
Direct operations, downstream, end of life: manufacturing, final disposal, end-of-life treatment	Pollution/ pollution removal Land/ freshwater/ ocean-use change	Water (ocean) pollutants Ocean-use change	When improperly discharged in ocean environments, pharmaceuticals and their by products can accumulate in the marine food web. Smaller organisms may absorb these chemicals, which are then ingested by larger predators, leading to increased concentrations higher up the food chain. This process, known as biomagnification, can have severe health impacts on top predators, including marine mammals, and also humans.

E3

E3: Dependency and impact measurement

Guiding questions:

What is the scale and scope of our dependencies on nature?

What is the severity of our negative impacts on nature? What is the scale and scope of our positive impacts on nature?

Table 7 and Table 8 provide additional considerations and examples of assessment metrics to help evaluate the scale and scope of dependencies and positive and negative impacts on nature in the biotechnology and pharmaceuticals sector.

Table 7: Typical considerations for the biotechnology and pharmaceuticals sector regarding the scale and scope of potential dependencies on nature

Value chain	Ecosystem services	Additional considerations	Examples of assessment metrics
Upstream Direct operations	Provisioning; regulating and maintenance	Consider high water consumption and water diversion from critical habitats and reduction in ecosystem services to the organisation and affected stakeholders.	Change in the distribution and quantity of wild species. Capacity of reservoirs or alternative forms of storage (m^3) otherwise needed to provide same surface volume (m^3) of diverted water flow.
Upstream	Biomass provisioning	Consider biomass availability and sourcing from the agricultural sector and forestry as residues and/or on purpose, as well as bio-waste and/or sustainably sourced feedstock.	Gross tonnes of biomass by type of biomass (e.g. cultivated plants, residues, bio-waste, sustainably sourced). Area and yield of area providing crops, by crop type.

Table 8: Typical considerations for the biotechnology and pharmaceuticals sector regarding the scale, scope and severity of potential impacts on nature

Value chain	Impact drivers	Additional considerations	Examples of assessment metrics
Upstream Direct operations	Greenhouse gas (GHG) emissions	Consider energy efficiency and increased electricity and bioenergy use compared with coal and fossil fuel use to produce energy.	Refer to IFRS S2 Climate-related Disclosures.
Upstream	Land/ ecosystem use change	Consider evaluating deforestation/ forest conversion, habitat loss, fragmentation and biodiversity loss at the landscape level.	Mean Species Abundance; Forest Structural Condition/ Forest Structural Integrity Index; Accounting for Nature Econd®.
Upstream Direct operations	Water use	Consider availability of water flow with involvement of local communities and affected stakeholders. Analysis should cover the water needs of the ecosystem. Organisations should also look to align with UN SDG6 (Clean Water and Sanitation for All), and efforts to protect local water sources and to improve access to clean water for drinking, sanitation and hygiene (WASH).	Water withdrawal and consumption (m^3) from areas of water scarcity, including identification of water source. Total volume of water withdrawal and consumption (m^3). Volume of water replenished to the environment through replenishment programmes (split into total and to areas of water scarcity).
Direct operations Downstream end of life	Non-GHG air pollutants Water pollutants Soil pollutants Solid waste	Consider relevant regional and national regulations (see Annex 1 for examples), including existing international conventions, conventions for emerging pollutants, as well "new substances" and substances possibly already present in the environment-food-human continuum, but "causing a new concern" for water and soil pollution.[5]	Pollutants released to soil (tonnes) by types. Concentration of key pollutants in the wastewater discharged, by type of pollutant.

5 See HBM4EU Substances.

E4

E4: Impact materiality assessment

Guiding question:

Which of the identified impacts are material?

As for all components, refer to the Guidance on the identification and assessment of nature-related issues: The LEAP approach.

List of datasets and tools

Table 9 provides a list of tools that biotechnology and pharmaceuticals industry organisations may find useful for the Evaluate phase of LEAP, in addition to those listed in the cross-sector LEAP guidance. Organisations should also reference tools in the LEAP guidance and TNFD Tools Catalogue.

Table 9: Additional tools for organisations in the Evaluate phase of LEAP

Tool name	Use in this LEAP phase	Link to tool
SimaPro	Life Cycle Analysis (LCA) software tool	SimaPro
ReCiPe	Method for the impact assessment in an LCA	ReCiPe

2.4. Assess nature-related risks and opportunities

How biotechnology and pharmaceuticals companies consider their nature-related risks and opportunities will differ based on their activities, products, assets, the geographical reach of their operations and the regulatory regimes in which they are operating.

Organisations are recommended to refer to the TNFD Nature-related Risk and Opportunity Registers as a general guide to frame their material nature-related risks and opportunities in relation to the dependencies and impacts assessed in the Evaluate phase.

A1

A1: Risk and opportunity identification

Guiding question:

What are the corresponding risks and opportunities for our organisation?

Table 10 and Table 11 provide illustrative examples of nature-related risks and opportunities for the biotechnology and pharmaceuticals sector.

Table 10: Illustrative nature-related risks for the biotechnology and pharmaceuticals sector

Risk category	Examples for biotechnology and pharmaceuticals	Impact driver/ ecosystem service associated (illustrative)
Physical		
Acute	Delay in production and operations from affected delivery of raw materials/ finished products due to disruption of transportation routes. Increase in repair costs from site-specific weather events possibly leading to damage to biotech labs or pharmaceutical production facilities due to localised storms, affecting sensitive equipment and precision manufacturing processes.	Global climate regulation Storm/flood protection
Chronic	Increased costs of supplies due to scarcity of material sourcing (e.g. plant-based compounds, minerals) due to shifts in climate patterns, over exploitation and habitat degradation. For example, deforestation can lead to infectious diseases that may affect raw materials (e.g. natural vanilla used in flavouring of some solutions) used within the industry, or reduce the availability of freshwater for use to manufacture sterile products. Pharmaceuticals entering ecosystems can be toxic to aquatic life, disrupt habitats, and cause bioaccumulation and biomagnification, affecting food chain dynamics and ecosystem health. These can also cause AMR, which fosters the spread of resistant bacteria, reducing the efficacy of drugs, increasing healthcare costs and potentially leading to more widespread disease outbreaks.	Provisioning services Pest control Water pollution Water use
Transition		
Policy	The concern about Pharmaceuticals in the Environment has led to several regulatory measures and guidelines being implemented globally. The EU UWWTD (Urban Waste Water Treatment Directive) imposes significant requirements on the sector, such as investing in the upgrade of urban and municipal wastewater treatment plants, to facilitate the treatment of wastewater to remove harmful substances like APIs before discharge. The directive also mandates regular monitoring and reporting of pollutant levels. Another relevant example is the United Nations Biodiversity of Areas Beyond National Jurisdiction Treaty (also referred to as the High Seas Treaty). It is an international agreement designed to protect and sustainably manage marine biodiversity in areas beyond national borders, which cover nearly half the planet's surface. For pharmaceutical companies, the treaty could introduce new regulations on access to genetic resources and stricter requirements for environmental impact assessments, potentially affecting how marine-derived substances are sourced for drug development and production.	Water pollution Water use Ocean-use change

Risk category	Examples for biotechnology and pharmaceuticals	Impact driver/ ecosystem service associated (illustrative)
Liability	Pharmaceutical companies are exposed to liability risks for legal responsibilities arising from actions or inactions resulting in the harm or damage of nature. Liability risks in the pharmaceutical industry could be caused by: environmental contamination (pollution from manufacturing or improper disposal of hazardous waste); biodiversity impact (overharvesting of natural resources used in production processes); regulatory compliance (non-compliance with existing laws); community and stakeholder actions (if operations are perceived as harmful to local environment or public health).	Soil pollution Water pollution GHG emissions Biomass provisioning Water use
Technological	Companies slow to adopt technologies that reduce impacts on nature may find their products less competitive in markets that value environmental sustainability. For example, traditional chemical synthesis used in drug production often involves solvents and reagents that can be harmful to the ecosystems. As regulatory and societal pressures increase for cleaner processes, these traditional methods risk becoming obsolete.	Non-GHG air pollution Soil pollution Water pollution
Market	Increase of bio-feedstock prices/competition due to supply scarcity. Increased cost and reduced productivity to address requests from consumers and regulators for eco-friendly production processes (e.g. packaging, sustainability considerations in healthcare tender processes). This shift could pose risks, for example, to companies that rely on conventional plastic packaging and energy-intensive manufacturing processes. For example, a biotech company producing drugs using traditional chemical synthesis might face market pushback unless it adopts less harmful synthesis methods, such as biocatalysis, and moves away from single-use plastic blisters to biodegradable packaging options.	Biomass provisioning Soil pollution Water pollution GHG emissions
Reputation	Growing demand for transparency in supply chains regarding sustainability of sourced materials. For example, there is ongoing scrutiny over the sourcing of palm oil or other plant-derived materials used in drug formulations, which if sourced from deforested areas, could lead to negative publicity and consumer boycotts. Companies that fail to engage with and respect the rights of Indigenous Peoples, Local Communities and affected stakeholders, especially when sourcing biological materials or conducting clinical trials, can face significant reputational risks. For instance, if a pharmaceutical company is perceived to be extracting local resources, like plant-based compounds or genetic material, without fair compensation or acknowledgment of Indigenous rights, it can lead to protests and negative press.	Provisioning services Soil pollution Land-use change Genetic materials

Table 11: Illustrative nature-related opportunities for the biotechnology and pharmaceuticals sector

Opportunity type	Examples for biotech and pharma	Impact driver/ecosystem service associated (illustrative)
Business performance		
Resource efficiency	Increased productivity from switch to more efficient manufacturing systems (e.g. green chemistry). Reduced costs from consumption of physical inputs (e.g. freshwater-saving technologies).	GHG emissions Non-GHG air pollution Water use Water supply
Products and services	Increased revenues due to R&D and new materials/product innovation and discovery (e.g. pioneering the development of solvents derived from plant-based or microbial sources).	Soil/water pollution
Market	Increased revenues coming from access to new markets (e.g. new disease response in different parts of the world) and from process innovation. For example, the development of biodegradable packaging materials derived from marine-based biopolymers, reducing environmental impact and appealing to eco-conscious consumers.	Water pollution Ocean-use change
Capital flow	Increased financial flows through agreements with banks and debt capital markets on sustainable finance frameworks to access new sources of green finance.	All
Reputational capital	Increase of talent attraction and retention, and increase of revenue/brand value thanks to high nature-related reputation.	All
Sustainability performance		
Sustainable use of natural resources	Increased credibility from market and reputational status through use of certification schemes to ensure raw materials are sustainably harvested and medicinal plants are sustainably cultivated.	Land-use change Genetic materials
Ecosystem protection, restoration regeneration	Positioning as sustainability leader by investing in initiatives to conserve and restore high biodiversity areas (rich in medicinal plants and animals).	Land-use change

A2

A2: Adjustment of existing risk mitigation and risk and opportunity management

Guiding questions:

What existing risk and opportunity management processes and elements are we already applying?

How can risk and opportunity management processes and associated elements (e.g. risk taxonomy, risk inventory and risk tolerance criteria) be adapted?

As for all components, refer to the Guidance on the identification and assessment of nature-related issues: The LEAP approach.

A3

A3: Risk and opportunity measurement and prioritisation

Guiding question:

Which risks and opportunities should be prioritised?

As for all components, refer to the Guidance on the identification and assessment of nature-related issues: The LEAP approach.

A4

A4: Risk and opportunity materiality assessment

Guiding question:

Which risks and opportunities are material and therefore should be disclosed in line with the TNFD recommended disclosures?

As for all components, refer to the Guidance on the identification and assessment of nature-related issues: The LEAP approach.

Locate | Evaluate | Assess | Prepare

2.5. Prepare to respond and report

This section provides additional guidance to help biotechnology and pharmaceuticals sector organisations with the Prepare phase of the LEAP approach.

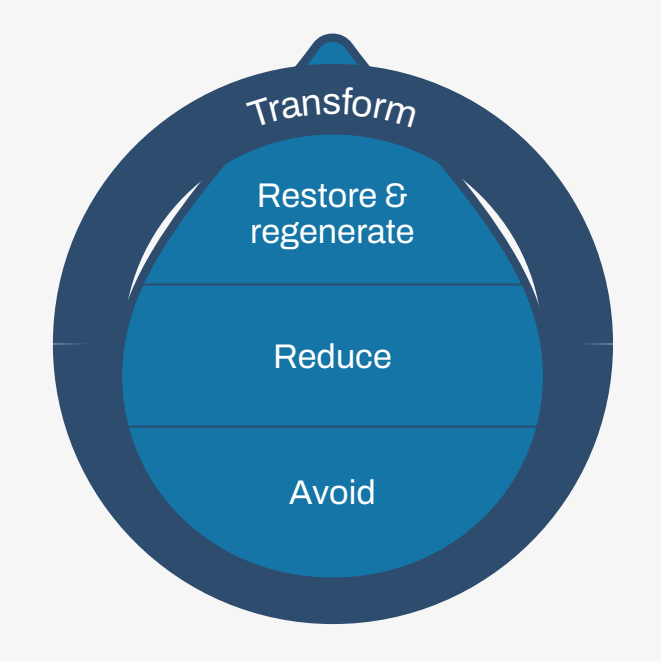
P1: Strategy and resource allocation plans

Guiding question:

What risk management, strategy and resource allocation decisions should be made as a result of this analysis?

Table 12 maps a non-exhaustive list of actions in the biotechnology and pharmaceuticals sector based on TNFD's interpretation of SBTN's AR3T framework (and pending alignment with future development of SBTN's Step 4 guidance), which covers mitigation hierarchy principles when determining responses to identified nature-related issues, and against the same potential risk for different phases of the value chain.[6]

Figure 4: The SBTN AR3T framework



6 In alignment with Business for Nature, World Economic Forum and World Business Council on Sustainable Development sector actions for a nature-positive future series.

Table 12: Illustrative priority and transformative actions for the biotechnology and pharmaceuticals sector mapped to the AR3T Framework

Impact driver/ ecosystem service associated	Value chain (illustrative)	Addressed risk	Examples of actions	SBTN Action Framework (A3RT)				
				Avoid	Reduce	Regenerate	Restore	Transform
Land-use change	Upstream	Deforestation to access plant-based compounds exposes company to reputational risk	Natural ecosystem restoration through nature-based solutions (e.g. invest in the reforestation of the Amazon rainforest where cinchona tree is harvested for quinine used in malaria treatment)					
Freshwater-use change	Upstream	Required operating changes due to reduced availability and access to freshwater	Improve water stewardship through engagement strategies with sustainable suppliers					
	Direct operations		Increase water use efficiency and implement sustainable water management strategies (e.g. upgrade to closed loop systems)					

Impact driver/ ecosystem service associated	Value chain (illustrative)	Addressed risk	Examples of actions	SBTN Action Framework (A3RT)				
				Avoid	Reduce	Regenerate	Restore	Transform
Non-GHG air pollution, solid waste, soil pollution, water pollution	Direct operations	Increased operational costs/taxation from stricter environmental regulations related to waste and emissions	Elimination, remediation and minimisation of pollution at molecular level (e.g. design controlled-release drug formulations)					
			Waste minimisation and recycling (e.g. invest in green chemistry for drug design and manufacturing)					
			Use of renewable raw materials and energy (e.g. install solar PV to support ancillary production activities, such as packing and storage)					
Resource use, biomass provisioning	Upstream	Scarcity of material sourcing (e.g. plant-based compounds, mineral) due to over exploitation	Use of sustainable biobased feedstock (e.g. use algae as a microbial source of feedstock, once their research use has been fulfilled)					
			Use of regenerative agriculture to produce bio-based feedstock (e.g. maintain habitats beneficial to biodiversity enhancement while growing crops for feedstock)					

Impact driver/ ecosystem service associated	Value chain (illustrative)	Addressed risk	Examples of actions	SBTN Action Framework (A3RT)				
				Avoid	Reduce	Regenerate	Restore	Transform
Water pollution and soil pollution	Downstream	Patient use of medication has potential to affect the environment after consumption or due to improper disposal	Develop and design environmentally benign pharmaceuticals, which can degrade more easily					
			Invest and support the development and implementation of technologies to enhance the removal of pharmaceutical residues from wastewater (e.g. oxidation processes)					
			Implement take-back programmes allowing patients to return unused or expired medication for proper disposal					

P2 P2: Target setting and performance management

Guiding question:

How will we set targets and define and measure progress?

As for all components, refer to the Guidance on the identification and assessment of nature-related issues: The LEAP approach, which includes additional guidance on target setting in this component P2.

Organisations may wish to refer to the target-setting methods developed by the Science Based Targets Network and the summary guidance on SBTN's methods for setting science-based targets for nature, which the TNFD has co-developed with the Science Based Targets Network (SBTN).

P3 P3: Reporting

Guiding question:

What will we disclose in line with the TNFD recommended disclosures?

Organisations are recommended to prepare to disclose their strategy and management plans to:

- Manage substances of concern including production, sales and waste handling; and
- Develop alternatives with reduced human and/or environmental impact across their value chains.[7]

P4 P4: Presentation

Guiding question:

Where and how do we present our nature-related disclosures?

As for all components, refer to the Guidance on the identification and assessment of nature-related issues: The LEAP approach.

7 SASB Standards (2023) SASB RT-CH-10b.2.

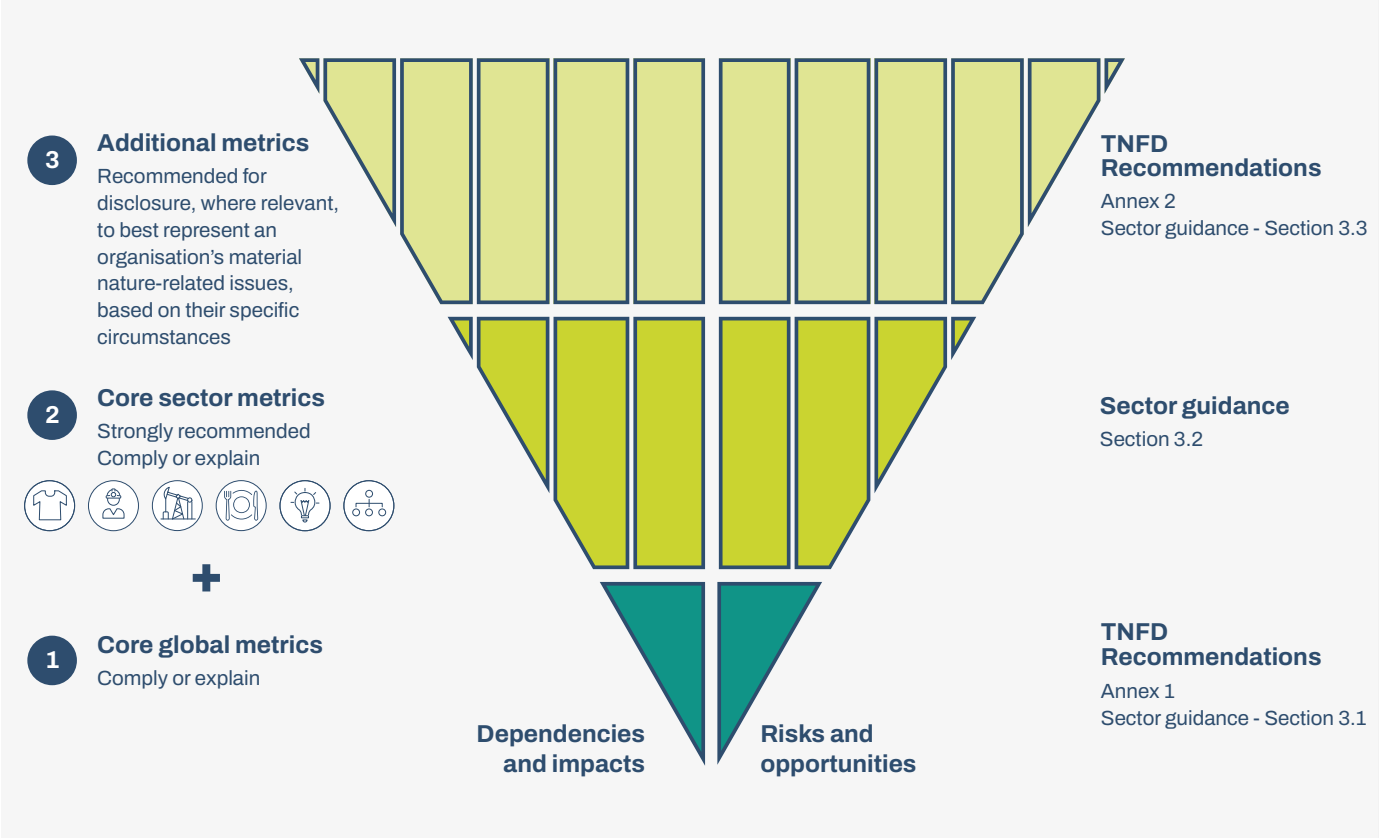
3. Sector-specific disclosure metrics and related guidance – biotechnology and pharmaceuticals

Sector-specific metrics form an important part of the TNFD's measurement architecture (see Figure 5). This reflects the diversity of business models across value chains and their interface with nature across and within sectors. Sector-specific metrics help financial institutions to compare organisations within the same sector, which often face similar nature-related issues.

This section provides the TNFD sector-specific metrics for the biotechnology and pharmaceuticals sector. It includes:

- Guidance on the application of the core global disclosure indicators and metrics to the biotechnology and pharmaceuticals sector (Section 3.1); and
- Core and additional disclosure indicators and metrics for the biotechnology and pharmaceuticals sector (Sections 3.2 and 3.3).

Figure 5: TNFD disclosure measurement architecture



Where available, the TNFD's recommended metrics for disclosure draw from a range of existing standards and frameworks including the IFRS Sustainability Disclosure Standards, Sustainability Accounting Standards Board (SASB) Standards, GRI Standards, the CDP disclosure platform, the Kunming-Montreal Global Biodiversity Framework and other relevant UN frameworks, ESRS and others. A number of organisations, including standard-setting organisations, continue to work on identifying relevant sector-level assessment and reporting metrics. The Taskforce recommends that report preparers stay engaged with year-on-year progress on these developments and implement the latest definitions within their risk management processes and disclosures. The TNFD is working closely with standard-setting organisations and others and will periodically update this guidance on recommended sector metrics for disclosure in line with these ongoing initiatives.

Organisations in the biotechnology and pharmaceuticals sector should refer to Annex 1 of the TNFD Recommendations for further information on the core global disclosure metrics. As outlined in the TNFD Recommendations, core global disclosure metrics should be reported on a comply or explain basis, with the exception of the placeholder metrics.

Where organisations are unable to report against any of the core global metrics, they should provide a short explanatory statement as to why they have not reported those metrics. An organisation should report on the core global disclosure metrics unless:

- It has not been identified as relevant and material to the organisation, e.g. not relevant to business activities or the location the organisation is operating in, or not found to be a material issue for the organisation; or
- It has been identified as relevant and material, but the organisation is unable to measure it due to limitations with methodologies, access to data or because the information is commercially sensitive. In this case, organisations should explain how they plan to address this in future reporting periods.

Companies should report on the same basis for the core sector disclosure metrics outlined in Section 3.2.

Organisations are also encouraged to draw on the TNFD additional sector disclosure indicators and metrics outlined in Section 3.3 and any other relevant metrics to represent most accurately the organisation's nature-related dependencies, impacts, risks and opportunities.

1 Core global metrics

3.1. Guidance on the application of the core global disclosure metrics

This section provides guidance, where relevant, on how to apply the TNFD core global disclosure metrics in the biotechnology and pharmaceuticals sector. If no further sector specific guidance is provided, organisations should refer to the core global disclosure metrics.

As outlined above, core global disclosure metrics should be reported on a comply or explain basis following the guidance for the biotechnology and pharmaceuticals sector where provided.

For the placeholder indicators on invasive alien species and the state of nature, the TNFD encourages organisations to consider and report against these indicators where possible, but are not expected a comply or explain bases. There are not yet widely accepted metrics for these indicators, but the Taskforce recognises their importance, and will continue to work with knowledge partners to develop further guidance on these metrics.

Table 13: Guidance on the application of the core global disclosure metrics

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Land/freshwater/ ocean-use change	C1.0	Total spatial footprint	Total spatial footprint (km^2) (sum of): • Total surface area controlled/ managed by the organisation, where the organisation has control (km^2); • Total disturbed area (km^2); and • Total rehabilitated/restored area (km^2).	No further sector specific guidance; refer to the core global disclosure metric.	TNFD
Land/freshwater/ ocean-use change	C1.1	Extent of land/ freshwater/ ocean-use change	Extent of land/freshwater/ ocean ecosystem use change (km^2) by: • Type of ecosystem;[8] and • Type of business activity.	An organisation may provide information additional to the IUCN Global Ecosystem Typology (GET) to define the type of ecosystem they refer to, such as regional or local classifications.	TNFD
Land/freshwater/ ocean-use change	C1.1	Extent of land/ freshwater/ ocean-use change	Extent of land/freshwater/ ocean ecosystem conserved or restored (km^2), split into: • Voluntary; and • Required by statutes or regulations.	An organisation should report area conserved and restored separately, if data is available.	TNFD

8 When disclosing on ecosystem types, refer to the International Union for Conservation of Nature Global Ecosystem Typology

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Land/freshwater/ ocean-use change	C1.1	Extent of land/ freshwater/ ocean-use change	Extent of land/freshwater/ ocean ecosystem that is sustainably managed (km^2) by: • Type of ecosystem;[9] and • Type of business activity.	No further sector specific guidance; refer to the core global disclosure metric.	TNFD
Pollution/pollution removal	C2.0	Pollutants released to soil split by type	Pollutants released to soil (tonnes) by type, referring to sector-specific guidance on types of pollutants.	**Direct operations, downstream and end of life** In reporting this core global disclosure metric, pollutants should be identified referring to the environmental quality standards in Annex 1. An organisation should also: • Consider API and AMR safe discharge definitions, e.g. safe discharge limits for live viruses or other vaccine-related discharges, primarily for direct operations; • Refer to standard measurement methodologies, e.g. mass balance at receiving water; and • Refer to TNFD food and agriculture sector guidance for nitrogen, phosphorus and potassium-based pollutants relevant for fermentation and biopharma manufacturing.	AMR Industry Alliance, TNFD Food and Agriculture sector guidance

9 When disclosing on ecosystem types, refer to the International Union for Conservation of Nature Global Ecosystem Typology

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Pollution/pollution removal	C2.1	Wastewater discharged	Volume of water discharged (m^3), split into: • Total; • Freshwater; and • Other.[10] Including: • Concentrations of key pollutants in the wastewater discharged, by type of pollutant, referring to sector-specific guidance for types of pollutants; and • Temperature of water discharged, where relevant.	**Direct operations, downstream and end of life** In reporting this core global disclosure metric, pollutants should be identified referring to the environmental quality standards in Annex 1. An organisation should also: • Consider API and AMR safe discharge definitions, e.g. safe discharge limits for live viruses or other vaccine related discharges, primarily for direct operations; • Refer to standard measurement methodologies, e.g. mass balance at receiving water; and • Refer to TNFD food and agriculture sector guidance for nitrogen, phosphorus and potassium-based pollutants relevant for fermentation and biopharma manufacturing.	AMR Industry Alliance, TNFD Food and Agriculture sector guidance

10 Freshwater: (≤1,000 mg/L Total Dissolved Solids). Other: (>1,000 mg/L Total Dissolved Solids). Reference: GRI (2018) GRI 303-4 Water discharge

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Pollution/pollution removal	C2.2	Waste generation and disposal	Weight of hazardous and non-hazardous waste generated by type (tonnes), referring to sector-specific guidance for types of waste. Weight of hazardous and non-hazardous waste (tonnes) disposed of, split into: • Waste incinerated (with and without energy recovery); • Waste sent to landfill; and • Other disposal methods. Weight of hazardous and non-hazardous waste (tonnes) diverted from landfill, split into waste: • Reused; • Recycled; and • Other recovery operations.	No further sector specific guidance; refer to the core global disclosure metric.	TNFD

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Pollution/pollution removal	C2.3	Plastic pollution	Plastic footprint as measured by total weight (tonnes) of plastics (polymers, durable goods and packaging) used or sold broken down into the raw material content.[11] For plastic packaging, percentage of plastics that is: • Re-usable; • Compostable; • Technically recyclable; and • Recyclable in practice and at scale.	No further sector specific guidance; refer to the core global disclosure metric.	TNFD
Pollution/pollution removal	C2.4	Non-GHG air pollutants	Non-GHG air pollutants (tonnes) by type: • Particulate matter ($PM_{2.5}$ and/or PM_{10}); • Nitrogen oxides (NO_2, NO and NO_3); • Volatile organic compounds (VOC or NMVOC); • Sulphur oxides (SO_2, SO, SO_3, SO_x); and • Ammonia (NH_3).	No further sector specific guidance; refer to the core global disclosure metric.	TNFD

11 Raw material content: % of virgin fossil-fuel feedstock; % of post-consumer recycled feedstock; % of post-industrial recycled feedstock; % of virgin renewable feedstock.

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Resource use/ replenishment	C3.0	Water withdrawal and consumption from areas of water scarcity	Water withdrawal and consumption[12] (m^3) from areas of water scarcity, including identification of water source.[13]	No further sector specific guidance; refer to the core global disclosure metric.	TNFD

12 Water consumption is equal to water withdrawal less water discharge. Reference: GRI (2018) GRI 303-5

13 Surface water; groundwater; seawater; produced water; third-party water. Reference: GRI (2018) GRI 303-3

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Resource use/ replenishment	C3.1	Quantity of high-risk natural commodities sourced from land/ ocean/ freshwater	Quantity of high-risk natural commodities[14] (tonnes) sourced from land/ocean/ freshwater, split into types, including proportion of total natural commodities.	**Upstream** In reporting this core global disclosure metric, the organisation should: • Include all feedstock and raw materials covered by the SBTN High Impact Commodity List and IUCN Red List of threatened species, and wild threatened species used in biotechnology and/or pharmaceutical discovery and product development; • Differentiate between dependency on the natural material versus scarcity/ management of the resource; • Take into consideration if the resource is a main product or by-product of another industry and whether the dependency is linked to the future of the main product and its degradation. In addition to commodities on the SBTN High Impact Commodity List, organisations should refer to threatened species on the IUCN Red List.	SBTN High Impact Commodity list, IUCN Red List, CITES (2024) Appendix I, II or II

14 Users should refer to the Science Based Targets Network (SBTN) High Impact Commodity List (HICL), species listed as vulnerable, endangered or critically endangered on the IUCN red list, and species listed in appendix I, II and III of CITES

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Resource use/ replenishment	C3.1	Quantity of high-risk natural commodities sourced from land/ ocean/ freshwater	Quantity of high-risk natural commodities[15] (tonnes) sourced under a sustainable management plan or certification programme, including proportion of total high-risk natural commodities.	**Upstream** In reporting this core global disclosure metric, the organisation should: • Include all feedstock and raw materials covered by the SBTN High Impact Commodity List and IUCN Red List of threatened species, and wild threatened species used in biotechnology and/or pharmaceutical discovery and product development; • Under sustainable management programme, include production using regenerative practices, including any standard adhered to and the definition used for regenerative; • Differentiate between dependency on the natural material versus scarcity/ management of the resource; and • Take into consideration if the resource is a main product or by-product of another industry and whether the dependency is linked to the future of the main product and its degradation. In addition to commodities on the SBTN High Impact Commodity List, organisations should refer to threatened species on the IUCN Red List.	SBTN High Impact Commodity list, IUCN Red List, CITES (2024) Appendix I, II or II

15 Users should refer to the Science Based Targets Network (SBTN) High Impact Commodity List (HICL), species listed as vulnerable, endangered or critically endangered on the IUCN red list, and species listed in appendix I, II and III of CITES

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
Invasive alien species and other	C4.0	Placeholder indicator: Measures against unintentional introduction of invasive alien species (IAS)[16]	Proportion of high-risk activities operated under appropriate measures to prevent unintentional introduction of IAS, or low-risk designed activities.	No further sector specific guidance; refer to the core global disclosure metric.	TNFD

16 Due to the measurement of levels of invasive species for organisations being a developing area, the chosen indicator focuses on whether an appropriate management response is in place for the organisation. The additional sets of metrics contain measurement of the level of invasive species within an area. The TNFD intends to do further work with experts to define 'high-risk activities' and 'low-risk designed activities'.

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
State of nature	C5.0	Placeholder indicator: Ecosystem condition	For those organisations that choose to report on state of nature metrics, the TNFD encourages them to report the following indicators, and to refer to the TNFD additional guidance on measurement of the state of nature in Annex 2 of the LEAP approach: • Level of ecosystem condition by type of ecosystem and business activity; • Species extinction risk. There are a number of different measurement options for these indicators. The TNFD does not currently specify one metric as there is no single metric that will capture all relevant dimensions of changes to the state of nature and a consensus is still developing. The TNFD will continue to work with knowledge partners to increase alignment.	No further sector specific guidance; refer to the core global disclosure metric.	TNFD

Driver of nature change/Other metric category	Metric no.	Core global indicator	Core global metric	Guidance for sector	Source
State of nature	C5.0	Placeholder indicator: Species extinction risk	For those organisations that choose to report on state of nature metrics, the TNFD encourages them to report the following indicators, and to refer to the TNFD additional guidance on measurement of the state of nature in Annex 2 of the LEAP approach: • Level of ecosystem condition by type of ecosystem and business activity; • Species extinction risk. There are a number of different measurement options for these indicators. The TNFD does not currently specify one metric as there is no single metric that will capture all relevant dimensions of changes to the state of nature and a consensus is still developing. The TNFD will continue to work with knowledge partners to increase alignment.	No further sector specific guidance; refer to the core global disclosure metric.	TNFD
Climate change		GHG emissions	Refer to IFRS S2 Climate-related Disclosure Standard	No further sector specific guidance; refer to the core global disclosure metric.	TNFD

3.2. Core sector disclosure indicators and metrics

The TNFD core sector disclosure metrics for the biotechnology and pharmaceuticals sector are outlined below. These metrics are recommended by the TNFD to be disclosed by all report preparers in the sector on a comply or explain basis.

Table 14: Core sector disclosure indicators and metrics

Metric category	Metric subcategory	Metric number	Indicator	Core sector metric	Source
Impact driver	Pollution/ pollution removal	BP.C2.0	Hazardous waste recycling at end of life	**Direct operations, downstream, and end-of-life** Proportion (%) of hazardous waste recycled at end-of-product life for reuse (circularity), defined as total weight of hazardous waste recycled from end-of-life or final disposal for reuse, divided by the weight of total input (e.g. same substance from new and recycled sources) used in production.	GRI 306: Waste 2020: SASB RT-CH-150a.1
Impact driver	Pollution/ pollution removal	BP.C2.1	Hazardous waste recycling during production	**Direct operations, downstream, and end-of-life** Proportion (%) of hazardous waste recycled for reuse, defined as total weight of hazardous waste generated during production that was recycled (circularity), divided by the total weight of hazardous waste generated.	GRI 306: Waste 2020: SASB RT-CH-150a.1
Impact driver	Pollution/ pollution removal	BP.C2.2	Non-compliance incidents	**Direct operations, downstream, and end-of-life** Number of incidents of non-compliance associated with soil quality permits, standards and regulations. Number of incidents of non-compliance associated with water quality permits, standards and regulations.	TNFD; WHO

Metric category	Metric subcategory	Metric number	Indicator	Core sector metric	Source
Impact driver	Pollution/ pollution removal	BP.C2.3	Persistent ingredients	**Direct operations, downstream, and end-of-life** Weight (tonnes) of active pharmaceutical ingredients manufactured or used that are suspected of AMR by type (tonnes).[17]	WHO
Impact driver	Pollution/ pollution removal	BP.C2.4	Pesticides manufactured by toxicity level	**Direct operations, downstream, and end-of-life** Proportion (%) of total revenue generated from pesticides manufactured by toxicity hazard level (Ia extremely hazardous, Ib highly hazardous, II moderately hazardous, III slightly hazardous, or U unlikely to present an acute hazard) according to the WHO classification.[18] An organisation should also refer to Annex 2 of the biotechnology and pharmaceuticals guidance for EU definitions of hazardous pesticides.	TNFD; WHO

17 AMRIA (2023) AMR Alliance Science-Based PNEC Targets for Risk Assessments.

18 WHO (2019) The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2019.

3 Additional metrics

3.3. Additional sector disclosure indicators and metrics

The TNFD additional sector disclosure metrics for the biotechnology and pharmaceuticals sector are outlined below. The TNFD encourages all report preparers in the sector to draw on these and any other relevant metrics where relevant to best represent an organisation's material nature-related dependencies, impacts, risks and opportunities.

Table 15: Additional sector disclosure indicators and metrics

Metric category	Metric subcategory	Metric number	Indicator	Additional sector metric	Source
Impact driver	Resource use/replenishment	BP.A3.0	Water replenished	**Direct operations** Volume of water (m^3) replenished in the basin where extraction has occurred or is occurring through replenishment programmes.	TNFD; ESRS E3 Water and marine resources
Response	Dependency, impact, risk and opportunity management: Changes to nature (dependency and impact): mitigation hierarchy steps	BP.A23.0	Products under LCA assessment	**Upstream, direct operations, downstream, and end-of-life** Proportion (%) of products that undergo a full or simplified Life Cycle Assessment (LCA), calculated using revenues as the denominator.	TNFD

4. References

AMRIA (2023) AMR Alliance Science-Based PNEC Targets for Risk Assessments.

AMRIA (2022) Antibiotic manufacturing standard: Minimizing risk of developing antibiotic resistance and aquatic ecotoxicity in the environment resulting from the manufacturing of human antibiotics.

Business for Nature, WEF and the WBCSD (2023) Sector actions towards a nature positive future series.

CEN (2014) Bio-based products – Vocabulary, as cited in European Commission (2021) bio-based product.

European Commission (n.d.) Single-use plastics.

Economic Co-operation and Development (2018) Due diligence guidance for responsible business conduct.

EU (n.d.) European Platform on LCA.

EU (n.d.) European Chemicals Agency (ECHA).

EU (n.d.) Water Framework directive.

EU (n.d.) Pesticides data base.

EU (n.d.) HBM4EU substances.

EU (2021) Pathway to a Healthy Planet for All EU Action Plan: Towards zero pollution for air, water and soil, EUR-Lex – 52021DC0400.

European Environment Agency (2021) Designing safe and sustainable products requires a new approach for chemicals.

GRI (2020) GRI 306: Topic standard for waste.

IEA (2023) Tracking clean energy progress 2023.

ISO (2016) ISO 14021:2016, 3.1.1 as cited in ISO (2023) ISO/DIS 59004(en) Circular economy – terminology, principles and guidance for implementation.

ECDC, EFSA and EMA (2018) Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/ EEA, JIACRA III. 2016–2018JIACRA III 2016-2018.

UNICEF (n.d.) Water, Sanitation and Hygiene (WASH) | UNICEF.

SASB Standards (2023) Biotechnology & Pharmaceuticals.

SASB Standards (2018) SASB's Sustainable Industry Classification System (SICS).

SBTN (n.d.) The first science-based targets for nature.

WHO (2019) The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2019.

Annex 1: List of environmental quality standards for pollutants

Biotechnology and pharmaceuticals sector organisations should refer to the list of standards below that are contained in relevant regional and national regulations, including existing international conventions, conventions for emerging pollutants (e.g. PFAS[19] family), as well as new substances and substances possibly already present in the environment-food-human continuum, but causing a new concern for water and soil pollution.[20]

Table 16: Selected examples of environmental regulations for pollutants

List	Number of substances	Link to resource
EU REACH Annex XIV Authorisation list	59 substances	Authorisation List – ECHA
REACH SVHCs	476 substances	Candidate list of substances of very high concern for authorisation
EU POP Regulation (EU) 2019/2021	31 unique substances/entries 10 unique new proposed substances	POPs Regulation – ECHA The new POPs
EU PIC Regulation (EU) No 649/2012	287 substances	Chemicals subject to PIC – ECHA
EU Water Framework Directive, Annex X	Priority substances	Pollutants in EU waters: Update of chemical substances listed for control
Annex to Sustainable Use of Pesticides Directive 1107/2009	Approval criteria for active substances by specifying the approval procedure	Regulation (EC) No 1107/2009 EU Pesticides Database
MRL residues lists 396/2005	29 449 unique substances/entries	EUCLEF Annexes II, III, IV, VII
SVHC Intentions List (to be used as a proxy)	269 substances	Registry of SVHC intentions until outcome

19 OECD, Environment Directorate Chemicals and Biotechnology Committee defines PFASs as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–).

20 HBM4EU Substances.

Table 17: Selected examples of environmental quality standards for pollutants

List	Number of substances	Link to resource
Emerging chemicals – HBM4EU – science and policy for a healthy future	The first round of HBM4EU priority substances in 2016 (and family of substances) and the second round of prioritisation between 2017 and 2018	HBM4EU substances
For AMR classifications and indicators, refer to JIACRA III Report	Refer to antimicrobial classes identified	JIACRA III – Antimicrobial consumption and resistance in bacteria from humans and animals
PFAS	PFAS TRI disclosures Entities should stay abreast of further development on PFAS, such as the OECD PFAS definition in Europe, grounded in ECHA and EPA methodologies List of applicable disclosures should adhere to relevant regional and national chemicals regulations	Toxics Release Inventory (TRI) Program – United States Environment Program

Annex 2: List of hazardous pesticides

The list of hazardous pesticides in Table 18 can be referenced in addition to the requirements in Annex 1 Table 16 and Table 17.

Table 18: Hazardous pesticides in the European Union

List	Number of pesticides	Link to resource
Annex to Sustainable Use of Pesticides Directive 1107/2009	Approval criteria for active substances by specifying the approval procedure	Regulation (EC) No 1107/2009 EU Pesticides Database
MRL residues lists 396/2005	29 449 unique substances/entries	EUCLEF Annexes II, III, IV, VII

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