Draft sector guidance
Biotechnology and pharmaceuticals

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For market consultation and feedback

SASB sectors:
Biotechnology and pharmaceuticals (HC-BP)

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Taskforce on Nature-related Financial Disclosures

Contents

Draft for consultation

This sector guidance is a draft for consultation with market participants and other interested stakeholders. The Taskforce welcomes feedback via the TNFD website by 29 March 2024.

Feedback will be reviewed by the Taskforce and final sector guidance issued by the TNFD by 30 June 2024.

Introduction

The purpose of this guidance

In September 2023, the TNFD published its recommendations for disclosure of nature-related issues. Accompanying those recommendations is a set of additional guidance, including Guidance on the identification and assessment of nature-related issues: The LEAP approach. The TNFD recognises that there can be significant differences across sectors for corporates applying the LEAP approach. It has published this additional guidance to help biotechnology and pharmaceuticals industry 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 recommended sector disclosure metrics for the biotechnology and pharmaceuticals industry, including: 1) guidance on the application of the core global disclosure indicators and 2) recommended core sector disclosure metrics. These complement the disclosure metrics outlined in Annexes 1 and 2 of the TNFD recommendations.

What this guidance covers

This guidance covers those organisations with business models or value chains in the SASB biotechnology and pharmaceuticals industry.[1] These are referred to as 'biotechnology and pharmaceuticals industry organisations' in this guidance.

Box 1: Industry in scope of this guidance

Biotechnology and pharmaceuticals

The biotechnology and pharmaceuticals industry develops, manufactures and markets a range of brand-name and generic medications. A significant portion of the industry is driven by research and development, a high risk of product failure during clinical trials, and the need to obtain regulatory approval. Demand for the industry's products is largely driving by population demographics, rates of insurance coverage, disease profiles and economic conditions.[2]

The industry also develops, manufactures and markets healthcare products, genetically modified organisms, biofuels and other products such as biodegradable plastics.

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 geographical scope 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. It does not provide guidance on specific examples of nature-related dependencies, impacts, risks and opportunities as these should be based on the organisation's individual operational and organisational requirements. Organisations are recommended to perform all other necessary risk and opportunity assessments not covered in this guidance.

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.

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

2 SASB (2023) Biotechnology & Pharmaceuticals: Sustainability Accounting Standard.

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

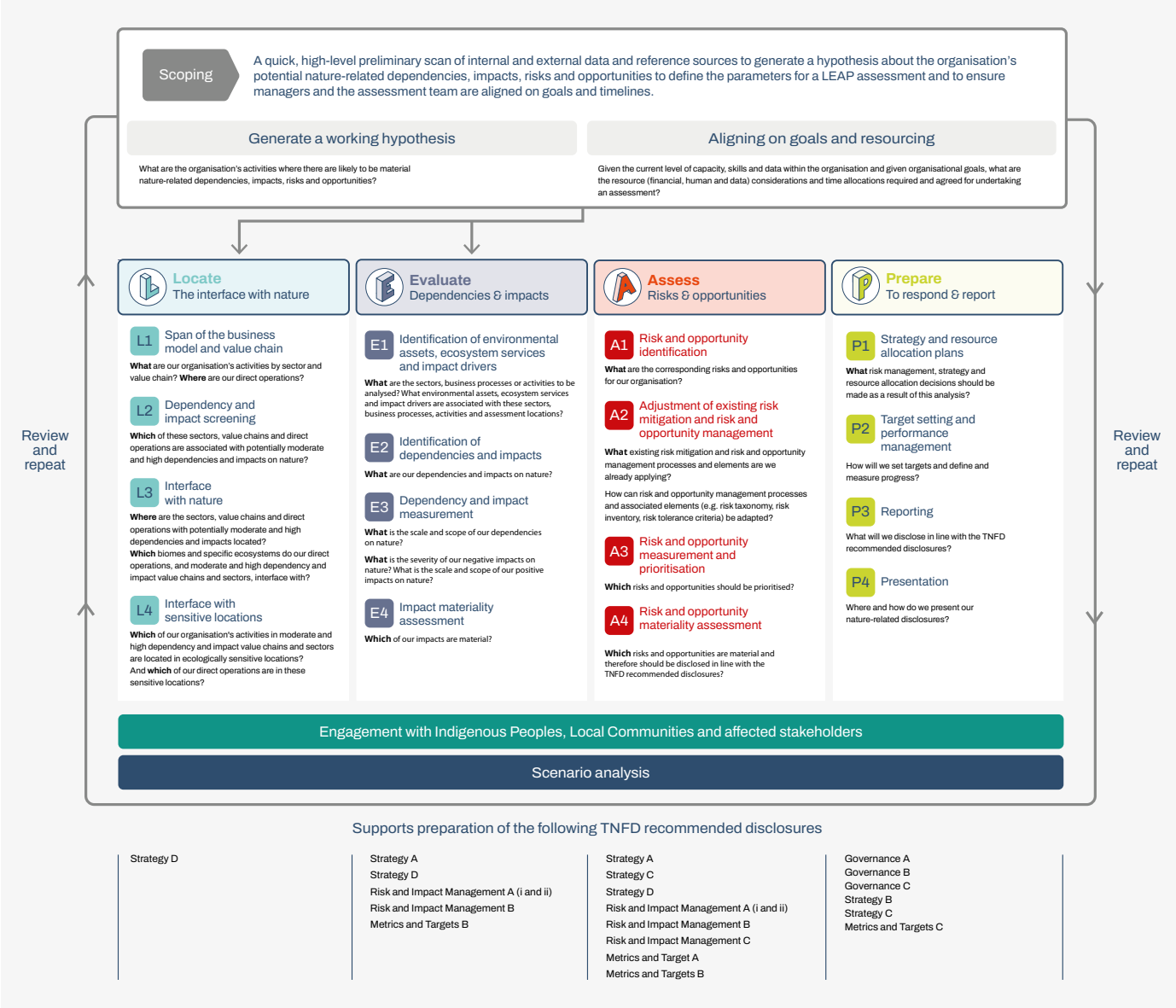

Table 1: Areas of LEAP with additional guidance for the biotechnology and pharmaceuticals industry

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

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 resource 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 2 and 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.

Organisations should choose the widest possible approach when screening areas of potentially material nature-related issues across their value chain. Organisations may want to take account of the system boundaries of their Life Cycle Assessment (LCA) methodologies[5] as determined by regulatory requirements for their operations and/or internal risk management processes. However, organisations should include any elements of the value chain that might produce material dependencies, impacts, risks and opportunities, regardless of whether they sit in or outside LCA system boundaries.

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 industry 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.

5 Life Cycle Assessments (LCA) under the standard ISO 14040:2006 and common methods to measure the life cycle environmental performances of Product Environmental Footprint (PEF) and Organisation Environmental Footprint (OEF).

Figure 2: Typical activities and processes of the pharmaceuticals industry value chain

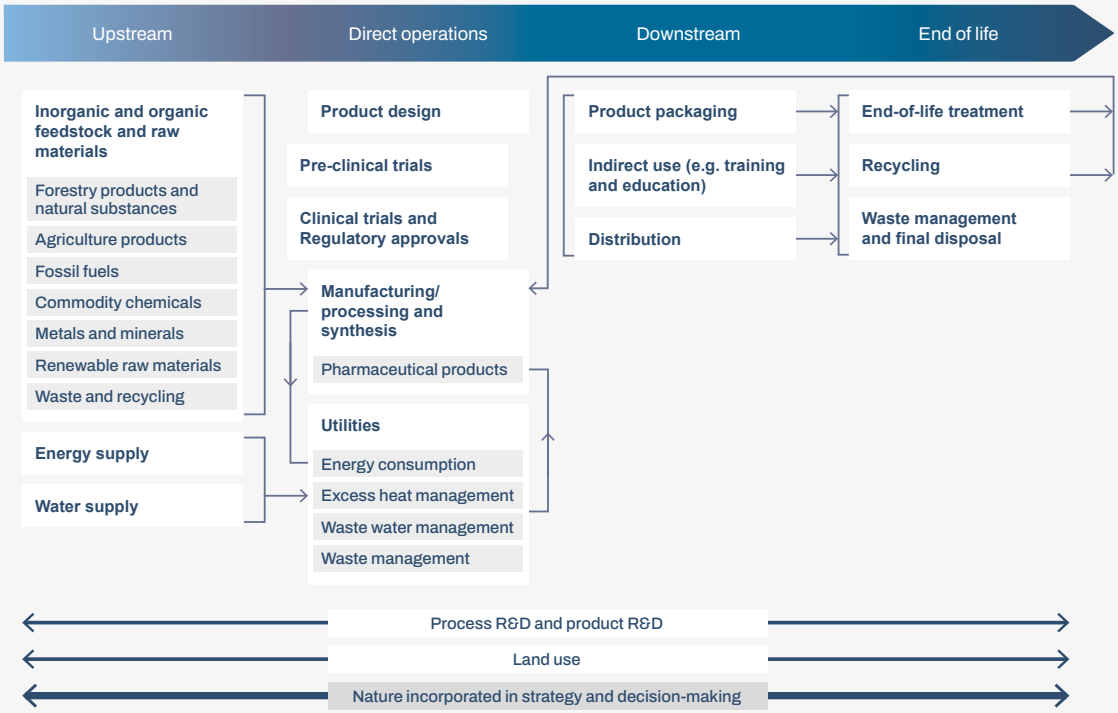

Figure 3: Typical activities and processes of the biotechnology industry value chain

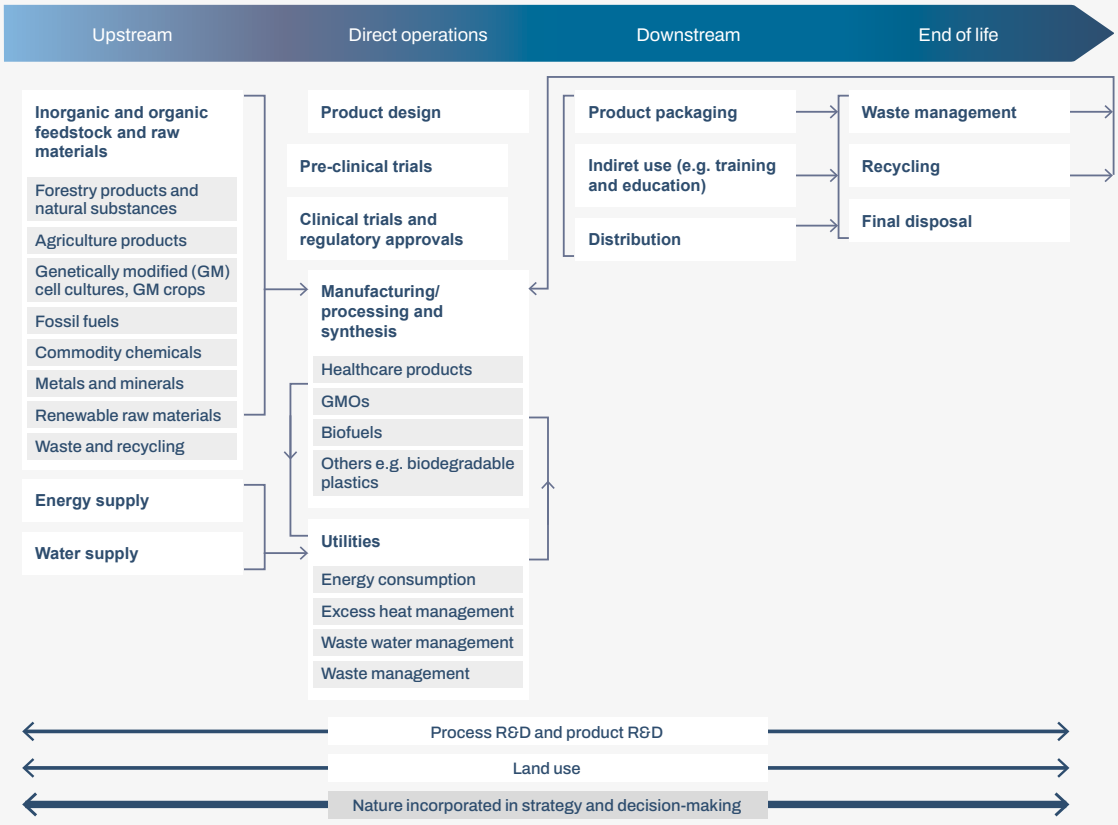

Table 2: Questions for biotechnology and pharmaceuticals industry to help scope a LEAP assessment

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 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?

Locate the organisation's interface with nature

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

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 industry 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;
- Downstream, due to use of products by consumers and end consumers; and
- End of life, due to persistent residues and leaks, if appropriate measures are not taken.

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 geographical traceability is a critical activity for biotechnology and pharmaceutical industry organisations that enables better 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 dependencies, impacts, risks and opportunities of the biotechnology and pharmaceutical industry organisation as well as the regulatory requirements applicable to the organisation's activities.

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 industry 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 is to be considered as a reference, but organisations 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: 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? And which of our direct operations are in sensitive locations?

When biotechnology and pharmaceutical industry 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 guidance, where appropriate for the commodity in question.

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: Identification of environmental assets, ecosystem services and impact drivers

Guiding questions:

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

What are the 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 industry organisations, refer to Table 3 below. For a list of impact drivers, refer to Table 4.

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: Identification of dependencies and impacts

Guiding question:

What are our dependencies and impacts on nature?

Table 3 and Table 4 present an illustrative (non-exhaustive) list of significant dependencies and impacts that biotechnology and pharmaceutical sector organisations can consider in their evaluation.

Table 3: Significant dependencies on nature of the biotechnology and pharmaceuticals industry

Environmental assets	Ecosystem services	Assessment metrics
Land Terrestrial (land based) ecosystems	Biomass provisioning Genetic material	**Upstream** • Weight of provisioned assets (tonnes) • Weight of cultivated plants, woods, aquatic products (tonnes)
Water resources	Water supply	**Upstream, Direct operations** • Volume of water by quality type (m^3)

Environmental assets	Ecosystem services	Assessment metrics
Water resources	Water flow regulation Water purification	**Upstream, Direct operations, Downstream, End of life** • Weight of pollutants remediated by type of pollutants, e.g. nutrients and other pollutants (tonnes) • Volume of water regulated (m^3)
Land Terrestrial (land based) ecosystems	Soil quality regulation Soil and sediment retention Solid waste remediation	**Upstream, Direct operations, Downstream, End of life** • Weight of solid waste remediated (tonnes)
Terrestrial (land based) ecosystems	Pollination Biological control Nursery population and habitat maintenance	**Upstream** • Areas of crop pollinated per type of crop (m^2) • Area of habitat providing services (m^2)

Table 4: Significant impacts on nature from the biotechnology and pharmaceuticals industry

Value chain	Drivers of nature change	Impact drivers	Activities
Upstream	Land/freshwater/ocean ecosystem use change	Land ecosystem use	Bio-based feedstock requires land for production and – if not sustainably produced – can drive soil degradation, land conversion and deforestation.
Upstream Direct operations	Resource use/replenishment	Water use	Production processes are water-intensive and extensive withdrawal of freshwater contribute to water scarcity and water stress, affecting water quantity, quality and access.
Direct operations Downstream End of life	Pollution/pollution removal	Water pollutants Soil pollutants Solid waste	The growing occurrence of biotechnology and pharmaceutical substances released to soil and water is a growing concern, especially through wastewater discharge, which includes antimicrobial resistance (AMR) and active pharmaceutical ingredients (API), with negative impacts on the health of humans and ecosystems.

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 5 and Table 6 provide additional considerations and examples of assessment metrics to help evaluate the scale and scope of dependencies and positive impacts on nature and the severity of negative impacts on nature.

Table 5: Typical considerations for the biotechnology and pharmaceuticals industry 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.	For ecosystem services (provisioning, regulating, maintenance and cultural) measure change in the availability and quality of the ecosystem services; 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 6: Typical considerations for the biotechnology and pharmaceuticals industry regarding the scale, scope and severity of potential impacts on nature

Value chain	Impact drivers	Additional considerations	Example 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 ISSB S2 climate-related disclosure standard.
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®.

Value chain	Impact drivers	Additional considerations	Example of assessment metrics
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.[6]	Pollutants released to soil (tonnes) by types. Concentration of key pollutants in the wastewater discharged, by type of pollutant.

E4: Impact materiality assessment

Guiding question:

Which of the identified impacts are material?

No additional sector-specific guidance identified for E4.

List of datasets and tools

Table 7 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 7: Additional tools for forestry and paper sector 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

6 HBM4EU Substances.

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. This guidance therefore does not provide specific examples of nature-related risks and opportunities as these should be assessed based on the organisation's individual operational and organisational context.

Organisations are recommended to refer to 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: Risk and opportunity identification

Guiding question:

What are the corresponding risks and opportunities for our organisation?

No additional sector-specific guidance identified for A1.

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?

No additional sector-specific guidance identified for A2.

A3: Risk and opportunity measurement and prioritisation

Guiding question:

Which risks and opportunities should be prioritised?

No additional sector-specific guidance identified for A3.

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?

No additional sector-specific guidance identified for A4.

Prepare to respond and report

This section provides additional information to help biotechnology and pharmaceuticals industry 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 8 maps priority initiatives in the biotechnology and pharmaceuticals industry against the SBTN AR3T framework, which covers mitigation hierarchy principles when determining responses to identified nature-related issues.[7]

Table 8: Typical sector initiatives mapped against AR3T Framework

	Upstream	Direct operations	Downstream/End of life
Avoid and reduce negative impacts	• Use of renewable raw materials and energy • Water stewardship • Responsible sourcing	• Process energy efficiency • Creation of energy saving products • Elimination, remediation and minimisation of pollution of water and soil[8] • Waste water reduction • Waste minimisation • Waste recycling • Freshwater management	• Elimination, remediation and minimisation of pollution at molecular level • Educate/or incentivise end users for ultimate disposal and/or to prevent waste

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

8 EU (2021) Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil', EUR-Lex – 52021DC0400.

	Upstream	Direct operations	Downstream/End of life
Regenerate and restore	• Use of sustainable bio-based feedstock • Use of regenerative agriculture to produce bio-based feedstock	• Ecosystem services quantification used to develop opportunities associated with land-use change in direct operations (e.g. nature-based solutions)	• Waste recycling and upcycling
Transform ecosystems	• Circular business model along product total life cycle • Service shed level restoration in both direct and indirect operation (e.g. nature-based solutions) • Consideration of nature-climate related trade-offs in relation to the organisation's energy management		

Source: Science Based Targets Network (2023) Step 4: Act.

P2: Target setting and performance management

Guiding question:

How will we set targets and define and measure progress?

No additional sector-specific guidance identified for P2.

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.[9]

P4: Presentation

Guiding question:

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

No additional sector-specific guidance identified for P4.

9 SASB (2018) SASB RT-CH-10b.2.

Glossary

Sector specific concepts and definitions are defined in this section. The TNFD glossary will be updated to include these concepts once the biotechnology and pharmaceuticals industry guidance is finalised, based on market consultation and feedback. The user is recommended to visit the TNFD glossary for other terms used throughout the document.

Concept	Definition
Bio-based	A product wholly or partly derived from biomass. Notes: 1. Bio-based products are normally characterised by the bio-based carbon content or the bio-based content. For the determination and declaration of the bio-based content and the bio-based carbon content, see the relevant standards developed by CEN/TC 411. 2. Product can be an intermediate, material, semi-finished or final product. 3. The term 'bio-based product' is often also used to refer to a product that is only partly bio-based. In those cases, the claim should be accompanied by a quantification of the bio-based content. CEN (2014) Bio-based products – Vocabulary, as cited in European Commission (2021) Bio-based product.
Biomass	Material of biological origin, excluding material embedded in geological formations and material transformed to fossilised material. Biomass includes organic material (both living and dead), such as trees, crops, grasses, tree litter, algae, animals, manure and waste of biological origin. In this guidance, biomass excludes peat. 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.
Single-use plastic (SUP)	Single-use plastic products (SUPs) are used once, or for a short period of time, before being thrown away. Refer to EU's Directive on Single-use plastics for additional details such as the products included and the measures being applied. European Commission (n.d.) Single-use plastics.

Annex 1: Sector-specific metrics – Biotechnology and pharmaceuticals

The TNFD's recommended core global and core sector metrics for disclosure draw from, and are aligned with, a range of existing standards such as the IFRS's ISSB standards, SASB, GRI, CDP, UN frameworks, ESRS and others. Where the Taskforce believes it is important to do so, it has also proposed additional metrics below. 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 will periodically update its recommended core sector metrics for disclosure in line with these ongoing initiatives.

Proposed guidance on the application of the core global disclosure metrics

Biotechnology and pharmaceuticals organisations should refer to Annex 1 of the TNFD recommendations for further information on the core global disclosure metrics.

Table 10: Proposed guidance on the application of the core global disclosure metrics

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
Driver of nature change: Climate change				
	GHG emissions	Refer to IFRS S2 Climate-related Disclosure Standard.	No further guidance.	
Driver of nature change: 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 guidance.	

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
C1.1	Extent of land/ freshwater/ocean-use change	Extent of land/freshwater/ocean ecosystem use change (km^2) by: • Type of ecosystem;[10] and • Type of business activity.	No further guidance.	
		Extent of land/freshwater/ocean ecosystem conserved or restored (km^2), split into: • Voluntary; and • Required by statues or regulations.	No further guidance.	
		Extent of land/freshwater/ocean ecosystem that is sustainably managed (km^2) by: • Type of ecosystem;[11] and • Type of business activity.	No further guidance.	

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

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

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
Driver of nature change: 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** Pollutants to report under the core global disclosure metric should be identified referring to the environmental quality standards indicated in Annex 1. An organisation should also: • Consider API and AMR safe discharge definitions,[12] 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

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

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
C2.1	Wastewater discharged	Volume of water discharged (m^3), split into: • Total; • Freshwater; and • Other.[13] Including: • Concentration of key pollutants in the waste water 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** Pollutants to report under the core global disclosure metric should be identified referring to the environmental quality standards in Annex 1. An organisation should: • Consider API and AMR safe discharge definitions, e.g. safe discharge limits[14] 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, phosphate and potassium-based pollutants relevant for fermentation/ biopharma manufacturing.	AMR Industry Alliance

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

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

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
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 into 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.	**Upstream, Direct operations; Downstream; End of life** In reporting the core global disclosure metric, the organisation should define hazardous wastes in line with the Basel Convention; if the legal or regulatory framework(s) applicable to the jurisdiction(s) where the waste is generated impose greater or more stringent requirements, then those frameworks should prevail.	TNFD
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.[15] For plastic packaging, percentage of plastics that is: • Reusable; • Compostable; • Technically recyclable; and • Recyclable in practice and at scale.	No further guidance.	

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

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
C2.4	Non-GHG air pollution	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 guidance.	
Driver of nature change: Resource use/replenishment				
C3.0	Water withdrawal and consumption from areas of water scarcity	Water withdrawal and consumption[16] (m^3) from areas of water scarcity, including identification of water source.[17]	No further guidance.	

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

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

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
C3.1	Quantity of high-risk natural commodities sourced from land/ocean/ freshwater	Quantity of high-risk natural commodities[18] (tonnes) sourced from land/ocean/freshwater, split into types, including proportion of total natural commodities. Quantity of high-risk natural commodities[19] (tonnes) sourced under a sustainable management plan or certification programme, including proportion of total high-risk natural commodities.	**Upstream** In reporting the core global disclosure metric, the organisation should • 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 HICL, organisations should refer to threatened species on the IUCN Red List.	SBTN HICL, as well as species classified by the IUCN Red List as threatened (vulnerable: VU; endangered: EN; or critically endangered: CE), and species listed on CITES Appendix I, II or II
Driver of nature change: Invasive alien species and other				
C4.0	Placeholder indicator: Measures against unintentional introduction of invasive alien species (IAS[20])	Proportion of high-risk activities operated under appropriate measures to prevent unintentional introduction of IAS, or low-risk designated activities.	No further guidance.	

18 Users should refer to the Science Based Targets Network (SBTN) High Impact Commodity List (HICL) and indicate what proportion of these commodities represent threatened and CITES listed species.

19 Users should refer to the Science Based Targets Network (SBTN) High Impact Commodity List (HICL) and indicate what proportion of these commodities represent threatened and CITES listed species.

20 Due to the measurement of levels of invasive species for organisations being a developing area, the chose 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 designated activities".

Metric no.	Core global indicator	Core global metric	Proposed guidance for the sector	Sources
State of nature				
C5.0	Placeholder indicator: Ecosystem condition 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; and • 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 of state of nature and consensus is still developing. The TNFD will continue to work with knowledge partners to increase alignment.	No further guidance.	

Proposed core sector disclosure indicators and metrics

In addition to the core global disclosure metrics outlined in the TNFD Recommendations document and restated above, the Taskforce recommends that biotechnology and pharmaceuticals organisations also disclose the following sector-specific metrics.

Table 11: Proposed core sector disclosure indicators and metrics

Metric category	Metric subcategory	Indicator	Proposed core sector disclosure indicator or metric	Sources
Impact driver	Pollution/ pollution removal	Persistent ingredients	**Direct operations, Downstream and End of Life** List and quantity of active pharmaceutical ingredients by type, suspected of AMR manufactured or used (tonnes).[21]	WHO
Impact driver	Pollution/ pollution removal	Pesticides manufactured by toxicity level	**Direct operations, Downstream and End of life** Percentage 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.[22] An organisation should also refer to Annex 3 of this document for EU definitions of hazardous pesticides.	TNFD

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

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

Metric category	Metric subcategory	Indicator	Proposed core sector disclosure indicator or metric	Sources
Impact driver	Pollution/ pollution removal	Pollutants released to soil during agricultural production	**Upstream** Pesticides used, by toxicity hazard level (Ia extremely hazardous, Ib highly hazardous, II moderately hazardous, III slightly hazardous, or U unlikely to present an acute hazard) against baseline.[23] Nitrogen balance: • Nitrogen input from livestock manure and fertilisers; and • Nitrogen output. Phosphorus balance: • Phosphorus input; and • Phosphorus output. If relevant, balances for potassium and other nutrients (e.g. micronutrients).	TNFD Food and Agriculture guidance
Impact driver	Pollution/ pollution removal	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
Impact driver	Pollution/ pollution removal	Hazardous waste recycling during production	**Direct operations, Downstream, End of life** Percentage 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: SASB RT-CH-150a.1

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

Metric category	Metric subcategory	Indicator	Proposed core sector disclosure indicator or metric	Sources
Impact driver	Pollution/ pollution removal	Hazardous waste recycling at end-of-life	**Direct operations, Downstream, End of life** Percentage 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: SASB RT-CH-150a.1
Impact driver	Pollution/ pollution removal	Plastic pollution	**Direct operations, Downstream, End of life** Percentage of plastic resin volume attributed to single-use plastic.	Directive (EU) 2019/904 Doc. 32019L0904, Reduction of the impact of certain plastic products on the environment
Impact driver	Resource use/ replenishment	Water replenished	**Direct operations** Volume of water (m^3) replenished to the environment through replenishment programmes (split into total and to areas of water scarcity).	TNFD
Impact driver	Resource use/ replenishment	Bio-based feedstock	**Upstream** Percentage of total feedstock/raw materials that are sustainably sourced (by weight/mass) by material, and whether that material is typically associated with high impacts on nature, referring to the SBTN HICL and IUCN Red List of threatened species.	SBTN HICL, as well as species classified by the IUCN Red List as threatened (vulnerable: VU; endangered: EN; or critically endangered: CE), and species listed on CITES Appendix I, II or II

Metric category	Metric subcategory	Indicator	Proposed core sector disclosure indicator or metric	Sources
Impact driver	Resource use/ replenishment	Bio-based feedstock sourced from regenerative practices	**Upstream** Percentage of bio-based feedstock produced under regenerative practices by weight/mass and material, and whether that material is typically associated with high impacts on nature, referring to the SBTN HICL and IUCN Red List of threatened species.	SBTN HICL, as well as species classified by the IUCN Red List as threatened (vulnerable: VU; endangered: EN; or critically endangered: CE), and species listed on CITES Appendix I, II or II
Impact driver	Resource use/ replenishment	Products under LCA assessment	**Upstream, Direct operations, Downstream and End of life** Percentage of products that undergo a full or simplified Life Cycle Assessment (LCA).	TNFD
State of nature	Species extinction risk	Species used in production	**Upstream and Direct operations** List of species at risk used in biotechnology and/ or pharmaceutical product development. Rate/percentage of substitution of species at risk used in biotechnology and/or pharmaceutical product development to synthetic substances over the reporting period.	Species classified by the IUCN Red List as threatened (vulnerable: VU; endangered: EN; or critically endangered: CE) and species listed on CITES Appendix I, II or II
Other	Access and benefits sharing	Permits and agreements	Report the number of access and benefit sharing permits obtained and the country where they have been obtained. Report the number of access and benefit sharing agreements established and the country where they have been established.	GRI 304-7

Proposed additional sector disclosure indicators and metrics

There are no proposed additional sector disclosure indicators and metrics for the biotechnology and pharmaceutical industry.

Annex 2: List of environmental quality standards for pollutants

Biotechnology and pharmaceuticals industry organisations should refer to the lists of standards below that are contained in relevant regional and national regulations, including existing international conventions, conventions for emerging pollutants (e.g. PFAS[24] 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.[25]

Table A1: List of environmental quality standards 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	POPs Regulation – ECHA
	10 unique new proposed substances	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

24 OECD, Environment Directorate Chemicals and Biotechnology Committee defines PFASs are defined 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–).

25 HBM4EU Substances.

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 3: List of hazardous pesticides

The list of hazardous pesticides in Table A2 can be referenced in addition to the requirements in Annex 2 Table A1.

Table A2: 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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European Commission (n.d.) Single-use plastics.

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

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EU (n.d.) Water Framework directive.

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Taskforce on Nature-related Financial Disclosures

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