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Growing International Focus on the Importance of Nature, Biodiversity and Sustainability in the Life Science Sector

KPMG Life Science Regulatory Solutions Practice

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Introduction

The natural environment supports a diverse range of habitats, species and ecosystem services which humanity relies upon every day for food, medicine, and the air we breathe.

Pharmaceutical companies benefit from nature and biodiversity in terms of raw (genetic) material for drug discovery, and inspiration for research and development.

However, climate change, pollution, deforestation, overfishing and other human activities have unfortunately contributed towards the rapid decline in biodiversity over recent years.

The loss of nature and global biodiversity presents financial risks (deemed material today) that can affect life science businesses and investors, but also longer term risks linked to their impacts (e.g. biodiversity loss, pollution, climate change, antimicrobial resistance, ocean acidification) and dependencies (e.g. drug discovery, supply chains, livelihoods, carbon sequestration, food security) on nature.

As such, corporate focus and regulatory attention linked to nature and biodiversity is growing, not only from a risk management perspective but also in terms of broader strategic opportunities.

Consumers are becoming more conscious of the environmental and social impacts that their choices make. Businesses that demonstrate their commitment to sustainability in clear reports may benefit from new opportunities.

This article provides an overview of the recent and emerging regulations linked to nature and biodiversity which will help life science businesses to define their associated ambition and approach.

Nature, Biodiversity and Ecosystem Services

Biodiversity

Within nature, biodiversity is the diversity of life on Earth, including the diversity of ecosystems species and genes. Biodiversity is a **key indicator** to understand the status and intactness of nature.

Ecosystems Species Genes

Nature

Nature considers both the **living (biodiversity) and non-living components** (water, soil, air) of a well-functioning ecosystem. Nature can be understood through a construct of four realms: ocean, land, freshwater and atmosphere. Society both impacts and depends on each of these four realms of nature.

Land Ocean Water Atmosphere

Source: KPMG adapted from IPBES Global Assessment, 2019

Ecosystem services to humans

Nature and biodiversity create ecosystems which provide services that are fundamental to human well-being. These services can be grouped into different categories:

Provision of services

Material benefits, such as energy, food, energy and raw materials.

Regulating services

Benefits obtained from the regulation of ecosystem processes, such as carbon sequestration, moderation of extreme weather events.

Cultural services

Non-material benefits people gain from ecosystems that enhance mental and physical health, such as spiritual and cultural benefits, a sense of place and belonging.

Supporting service

Necessary for the production of all other ecosystem services, such as nutrient cycling, soil formation and pollination.

Human activities driving nature and biodiversity loss

Our society depends on, as well as impacts nature and biodiversity — affecting the services ecosystems can provide.

Drivers of biodiversity loss

Land, freshwater and sea use change

E.g. Land use change impacting habitats, erosion and flood risk

Direct exploitation

E.g. Resource exploitation affecting water availability and river quality.

Climate change

E.g. Increase in ocean temperatures impacting habitats of fish

Pollution

E.g. Acid rain causes damage to aquatic ecosystems, soil and vegetation

Introduction of invasive species

E.g. Introduction of invasive species impacting security of resources

Emerging Nature and Biodiversity Regulations (1/3)

The Convention on Biological Diversity (CBD) COP15 and the Global Biodiversity Framework

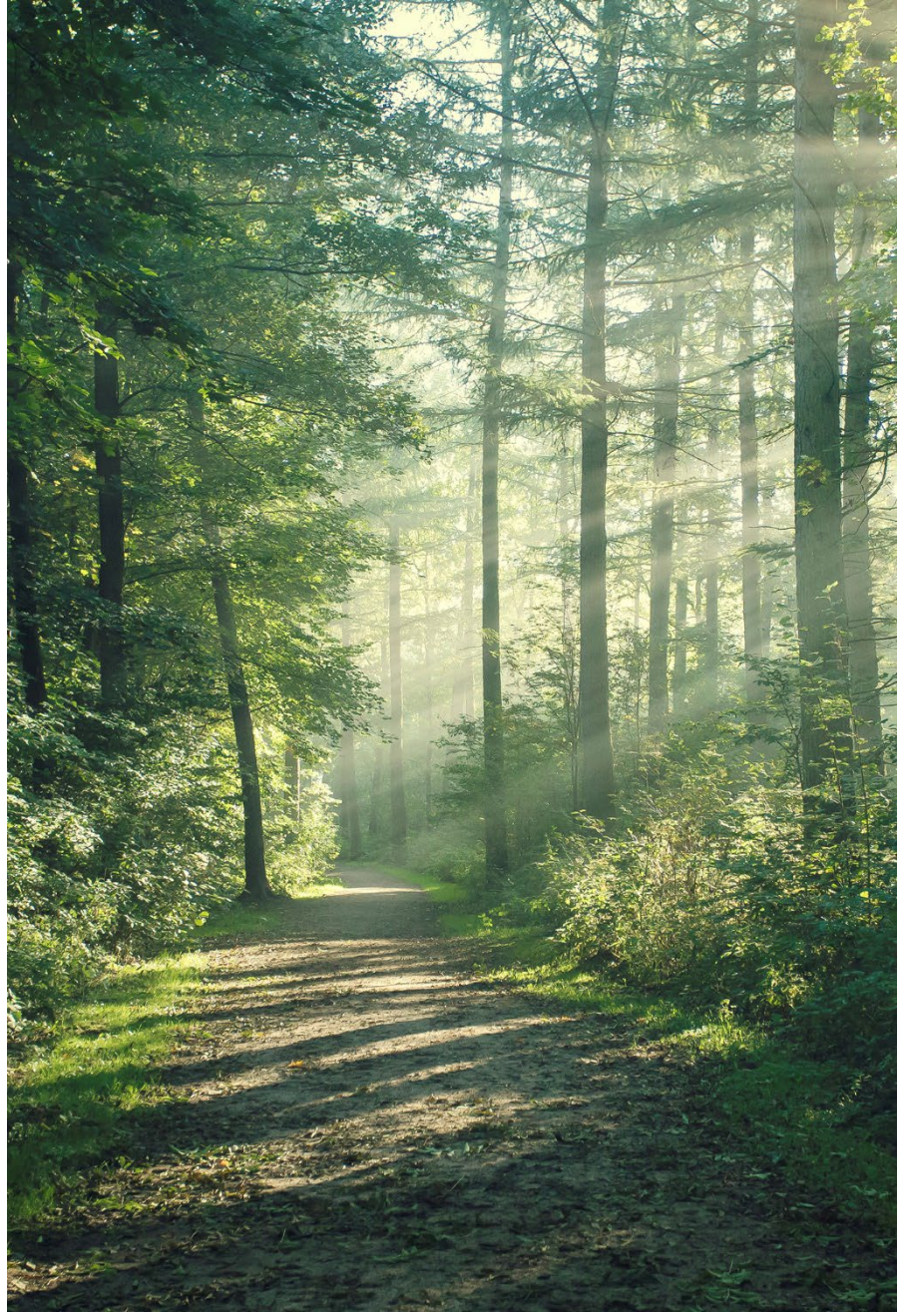
- The Convention on Biological Diversity (CBD) COP15 and the Global Biodiversity Framework
- The Convention on Biological Diversity (CBD, 1992) is a global multilateral environmental agreement which provides for global governance of biodiversity. The Conference of the Parties to the CBD adopted the Kunming-Montreal Global Biodiversity Framework (GBF) in December 2022 which includes four goals and 23 targets for achievement by 2030.
- As such, the GBF sets out a framework through which countries can help to promote nature-positive outcomes.

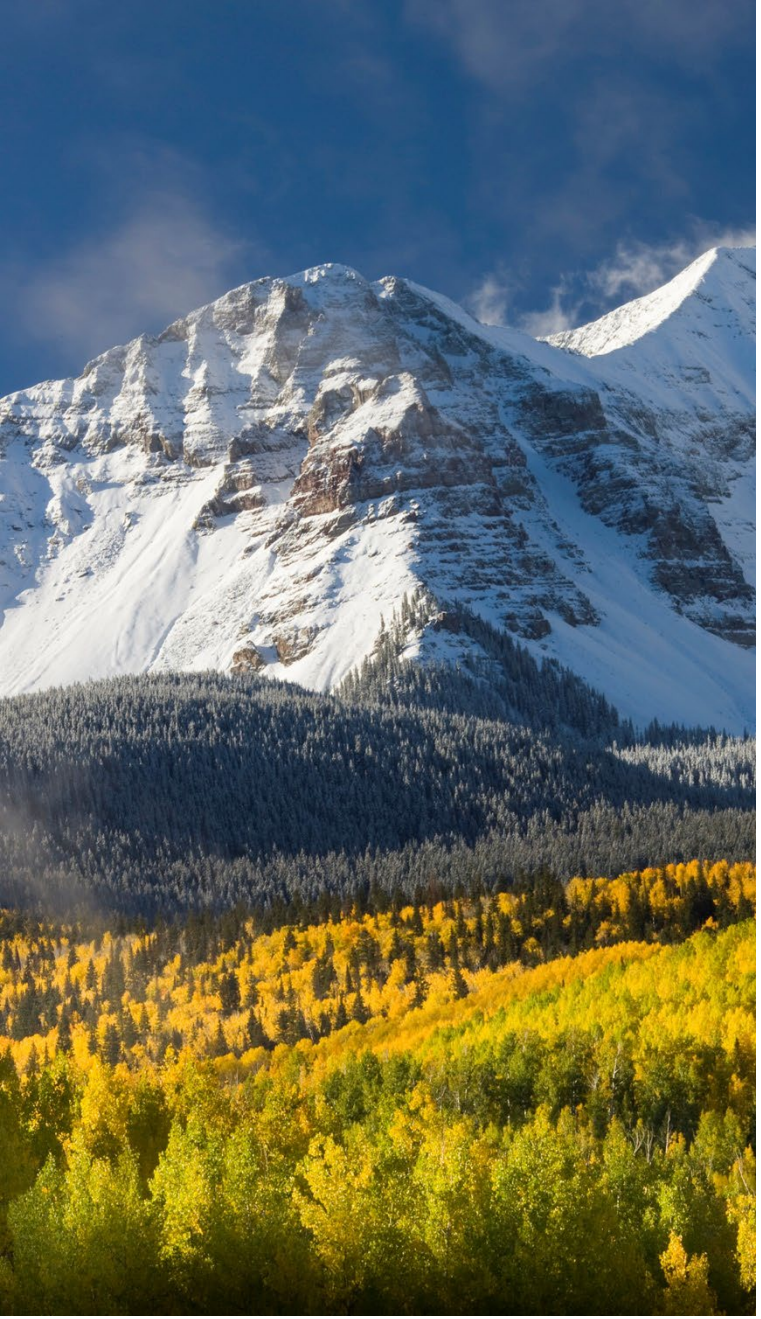
EU Taxonomy

- EU taxonomy (EUT) (i.e. "green taxonomy") is a classification system established to clarify which investments are environmentally sustainable, in the context of the European Green Deal.
- In 2022 two environmental objectives were released: climate change mitigation and climate change adaptation
- Most recently, four additional new environmental objectives have been proposed to be added to the taxonomy:
  - Sustainable use and protection of water and marine resources
  - Transition to a circular economy
  - Pollution prevention and control
  - Protection and restoration of biodiversity and ecosystems

All four objectives directly or indirectly promote economic activities that reduce the loss of biodiversity and biodiversity loss drivers and promote regeneration (e.g. via circular economy models).

EUT is closely interlinked with other regulations taking nature into considerations in the financial sector, such as the Sustainable Finance Disclosure Regulation (SFDR).





Emerging Nature and Biodiversity Regulations (2/3)

The International Sustainability Standards Board (ISSB)

- The International Sustainability Standards Board (ISSB) which was formed in Glasgow in 2021 at COP26 was established to develop a universal set of sustainability reporting standards. It has become a central part of the global sustainability landscape in the past two years. In a world facing the triple planetary crises of climate change, biodiversity loss, and pollution, sustainability has never been more critical for firms and communities.
- The ISSB aims to ensure that businesses, regardless of their geographical location or sector, communicate their sustainability impacts transparently. This consistency enables stakeholders (both internal and external) to better manage sustainability-related risks and opportunities.
- The ISSB standards were designed for compatibility with existing global frameworks such as the Taskforce on Climate-related Financial Disclosures (TCFD) and the European Sustainability Reporting Standards (ESRS). When the ISSB standards officially come into effect at the start of 2024, they will provide the basis of mandatory reporting standards in multiple jurisdictions. Harmonising these expectations will provide businesses with a clear roadmap for their sustainability efforts and disclosures'
- Read more here - Get ready for ISSB sustainability disclosures - June 2023 (kpmg.com)

EU Sustainability Reporting Standards (ESRS) – Biodiversity and ecosystems (ESRS E-4)

- EU ESRS are the new EU mandatory sustainability reporting standards. The aim of the standards is to ensure companies in scope report comparable, transparent and reliable sustainability information The ESRSs are composed of two cross-cutting standards and 10 topic-specific (5 environmental, 4 social and 1 governance) standards.
- ESRS includes a standards specifically addressing biodiversity and ecosystems (ESRS E4), where companies, subject to materiality, are required to disclose, amongst others, impacts and dependencies on nature, targets & KPIs, a biodiversity transition plan and actions to address the identified issues.
- In addition to ESRS E4., three other environmental standards have nature-related disclosures that promote transparent reporting on biodiversity loss and biodiversity loss drivers: E1 Climate Change, E2 Pollution, E3 Water and Marine Resources, and E5 Resource Use and Circular Economy
- Read more here - Navigating CSRD Reporting in Life Sciences - KPMG Belgium

Emerging Nature and Biodiversity Regulations (3/3)

The Taskforce on Nature-related Financial Disclosures (TNFD)

- Nature loss represents a major risk to businesses. However, moving towards nature-positive investments presents business opportunities.
- To address this issue and to enable companies and financial institutions to integrate nature into their decision-making processes, a market-led, science-based and government-supported taskforce was launched in 2021. The overarching objective is to support a shift in global financial flows towards nature-positive outcomes. The TNFD has embraced an iterative, 'open innovation' approach towards development of the framework, with pilot-testing and incorporation of feedback from businesses, financial institutions, governments, regulatory and standards setting bodies, civil society organizations and Indigenous Peoples and local communities from around the world.
- The TNFD is a risk management and disclosure framework for organisations to report and act on evolving nature-related risks (https://tnfd.global/).
- The final version (V0.4) of the framework was published in September 2023.
- Read more here: https://kpmg.com/xx/en/home/insights/2022/11/developing-and-delivering-a-risk-management-and-disclosure-framework-for-organizations.html

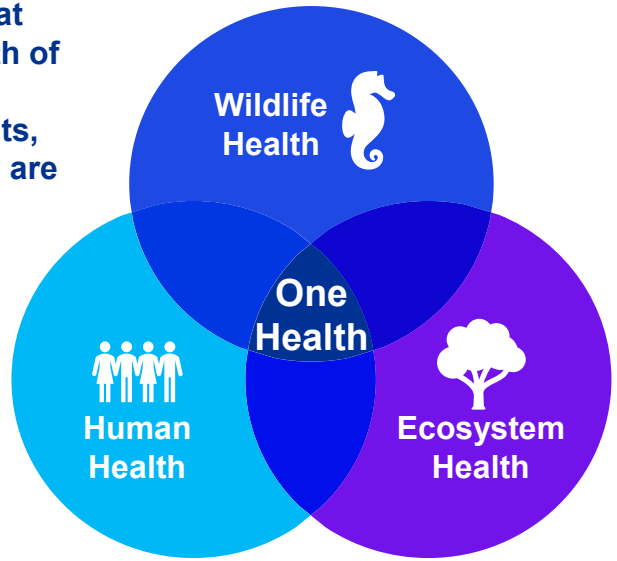
The UN Ocean Biodiversity Beyond National Jurisdiction (BBNJ) Agreement

- An international agreement under the UN Convention of the Law of the Sea, for the **conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction** was reached in March 2023.
- The new agreement provides an international legal framework that governs human activities within or linked to these massive ocean areas. For example, it includes provisions pertaining to the creation of marine protected areas as well as access to and benefit sharing associated with marine genetic resources. The agreement covers a 'package' of four key elements plus cross-cutting issues:
  - Marine genetic resources, including questions on the sharing of benefits;
  - Measures such as area-based management tools, including marine protected areas;
  - Environmental impact assessments, and;
  - Capacity-building and the transfer of marine technology
- States will take steps over the coming months to implement the BBNJ Agreement by transposing it into their national legislation. At that stage the agreement will become fully binding on companies and organizations or entities who conduct activities that fall within the scope of the agreement.
- The agreement has significant implications for businesses with operations or supply chains that rely on activities in the ocean, with the imposition of new regulations and potentially penalties for compliance failure. As the focus on protection and responsible, sustainable management of natural resources continues to gain momentum, understanding the BBNJ Agreement and impact on activities linked to the ocean is expected to be crucial.
- Read more here: The blue economy - KPMG Global

One Health Approach: Beyond the Regulatory Landscape

'One Health' is an integrated, unifying approach that aims to sustainably balance and optimise the health of people, animals and ecosystems. It recognises the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent.

The pharmaceutical industry is well positioned to champion the 'One Health' approach and to build a healthier and more environmentally sustainable future. This can be achieved by driving an agile, innovative, evidence-based sustainability strategy, enabling the pharmaceutical industry to embrace advances in science, technology and society and to integrate sustainability across entire value chains. This will help to deliver quality-based, healthy and green outcomes while positively impacting patient lives.



Key areas the life science sector can focus on to promote sustainability include:

- Transitioning to a circular economic model
- Aiming to mitigate climate change
- Safe use of chemicals
- Reducing water consumption and minimising the impact of pharmaceuticals on water quality

Source: How embracing the One Health approach can create a more sustainable planet (unep.org); https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-environmental-risk-assessment-medicinal-products-human-use-first-version_en.pdf; Improving the regulatory environmental risk assessment of human pharmaceuticals: Required changes in the new legislation - ScienceDirect

Active Pharmaceutical Ingredients (APIs) in Surface Waters

When pharmaceuticals are used by patients, residues may travel through the sewage system and enter surface waters and soils. This leads to concentrations of pharmaceuticals in the environment that may pose a risk to ecosystems, contribute to the spread of antimicrobial resistance (AMR) and contaminate drinking water sources.

To address this risk, the European Medicines Agency (EMA) guideline on the environmental risk of medicinal products for human use (2006) indicates the rules to which new chemical entities should adhere. The first mandatory step in completing an Environmental Risk Assessment (ERA) include the requirement for companies to calculate the Predicted Environmental Concentration (PEC) of API in surface water. PEC results indicate the potential for negative environmental impact and determine whether further testing is required to more clearly determine risk to the environment. At present, unfavourable ERA results cannot be a reason to deny market authorisation applications. However, there is speculation and pressure on the European Parliament to change this decision and allow ERAs to form the basis for refusal of a licence. This change will be an important next step in terms of progressing a 'One Health' approach to pharmaceutical product development.

How We Can Help

KPMG is already supporting clients with identifying their nature-related impacts, dependencies, risks and opportunities and setting ambitious nature strategies and targets in line with their broader ESG strategies. Our end-to-end approach allows you to locate and understand your touchpoints with nature and prepare you for voluntary disclosures and emerging regulations. KPMG can bring the experience, skills and expertise to assist you throughout your journey, helping you to embed nature in your future business strategy.

Examples of areas of support include:

Regulatory Diagnostic

Benchmarking progress relative to peers and policy and regulatory drivers, and supporting you with shaping your nature ambition and target setting, in line with incoming regulatory requirements.

TNFD LEAP Pilot

Undertaking a TNFD-aligned[1] pilot assessment focussed on priority commodities and/or locations within your value chain, including risk heatmapping to prioritise and respond to hotspots.

Nature Vision Setting

Upskill senior leadership and establish a shared understanding of your corporate vision and headline target(s) for nature through a KPMG-facilitated workshop, with clarity around next steps.

Source: (1) Based on the Taskforce on Nature-related Financial Disclosures' (TNFD's) Locate-Evaluate-Assess-Prepare (LEAP) approach.

Nature & Biodiversity Strategies in Life Science

As a result of the recent shift in the regulatory and market landscape, as well as growing appreciation of the value of our natural environment, organisations worldwide are increasingly striving to put nature at the heart of decision making.

The KPMG Life Science Regulatory Solutions team has expertise in the field of nature and biodiversity frameworks and can provide advice in terms of understanding the requirements and implications for the pharmaceutical and medical device sectors. In addition, the team offer strategic regulatory advice to life science organisations throughout key product development stages, from early phase planning to launch and compliance for approved products across critical markets internationally.

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