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Protocol for a scoping review of research on environmental effects of biodegradable plastics relevant for Norwegian conditions

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Siamak Yazdankhah

Protocol from the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment

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Protocol for a scoping review of research on environmental effects of biodegradable plastics (relevant for Norwegian conditions)

Preparation of the protocol

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed a project group to draft the protocol. The project group consisted of VKM members, one external expert and VKM staff. The Committee, by the Panel on Microbial Ecology has assessed and approved the final protocol.

Authors of the opinion

The authors have contributed to the opinion in a way that fulfils the authorship principles of VKM (VKM, 2019). The principles reflect the collaborative nature of the work, and the authors have contributed as members of the project group and/or the VKM Panel on Microbial Ecology as approval group, appointed specifically for the assignment.

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Acknowledgment
The project group extend our appreciation to research librarian Astrid Merete Nøstberg for developing the literature search strategy together with the project group and for conduction the database searches together with peer review librarian Trude Anine Muggerud.

Competence of VKM experts

Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third-party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Summary

In this self-tasking scoping review, VKM will map research about the environmental impacts of biodegradable plastics, including biodegradation rates and material persistence in different environments and geographical regions, the influence on microbial ecology and activity, and ecotoxicological effects of materials and associated chemical substances. Related to this is also research associated with the development of methodology, standards, environmental risk assessment, life cycle impact analyses, material sources and properties of biodegradable plastics and products.

The aim is to 1) determine the extent of evidence summarised in reviews and original research papers within this emerging research area and 2) map the evidence according to the materials and chemicals studied, types of environments and geographical regions covered, the hypotheses addressed, the type of endpoints assessed and the reported key findings.

Systematic literature searches will be performed to identify the summarised evidence, applying APRIO to develop a tailored search protocol that addresses the multi- and cross-disciplinary nature of the research area. We will select and map the identified publications applying Rayyan and sort them into three categories based on their main scientific focus and aim of study: 1) material properties and application, 2) biodegradation and microbial ecology, and 3) ecotoxicology.

There will be no geographical restrictions on the search and study selection, but in the data charting process we will highlight findings relevant to Norway and other Nordic countries.

The current project adheres to the “Preferred Reporting Items for Systematic Reviews and MetaAnalyses extension for Scoping Reviews (PRISMA-ScR) Checklist” for protocol development and reporting. We will address uncertainties associated with research studies applying EFSA guidelines and their generic list of common types of uncertainty affecting scientific studies and assessments.

Key words: VKM, Protocol, scoping review, knowledge summary, biodegradable plastic, applications, regulation, biodegradability, environmental biodegradation rate, environmental effects, microbial ecotoxicology, ecotoxicology, environmental/ecological risk assessment, Norwegian Scientific Committee for Food and Environment.

Sammendrag

I denne selv-initierte kunnskapsoppsummeringen skal vi kartlegge forskning om miljøpåvirkninger av bionedbrytbar plast. Sentrale tema er nedbrytningshastighet og materialbestandighet i ulike typer miljø og geografiske regioner, virkninger på mikrobiell økologi og aktivitet, og økotoksikologiske effekter av materialer og assosierte kjemiske stoffer. Her er også forskning knyttet til utvikling av metoder, standarder, miljørisikovurdering, livsløpskonsekvensanalyser relevant, samt kilder til råstoff og egenskaper til bionedbrytbare plastpolymerer og plastprodukter.

Formålet er å 1) bestemme omfanget av vitenskapelig basert kunnskap beskrevet i oversiktsartikler og originale forskningsartikler innenfor dette nye forskningsområdet og 2) kartlegge kunnskapen med referanse til materialer og kjemiske stoffer studert, miljøtyper og geografiske regioner inkludert i studier, arbeidshypoteser, målepunkter og rapporterte hovedfunn.

Systematiske litteratursøk vil bli gjennomført for å identifisere relevant litteratur, der vi bruker APRIO metoden til å utvikle en skreddersydd søkeprotokoll som hensyntar forskningsområdets fler- og tverrfaglige natur. Vi vil gjennomføre utvelgelse og kartlegging av litteratur ved hjelp av Rayyan og sortere funnene i tre kategorier basert på vitenskapelig hovedfokus og formål: 1) materialegenskaper og bruk, 2) bionedbrytning og mikrobiell økologi, og 3) økotoksikologi.

Det vil ikke bli satt geografiske begrensninger på søke- og studieutvalget, men i datakartleggingen vil vi fremheve funn som er relevante for Norge og andre nordiske land.

Prosjektet følger "Preferred Reporting Items for Systematic Review and MetaAnalyses extension for Scoping Review (PRISMA-ScR) Checklist" som grunnlag for protokollutvikling og rapportering, og vi vil vurdere usikkerheter knyttet til forskningen med utgangspunkt i EFSA-retningslinjer og generiske liste over vanlige typer usikkerhet forbundet med vitenskapelige studier og vurderinger.

Abbreviations and glossary

Abbreviations

APRIO	Agent, Pathway, Receptor, Intervention, and Output
EFSA	European Food Safety Authority
PA	Polyamides
PBAT	Polybutylene adipate terephthalate
PBS	Polybutylene succinate
PCL	Polycaprolactone
PE	Polyethylene
PET	Polyethylene terephthalate
PHA	Polyhydroxyalkanoate
PLA	Polylactic acid
PP	Polypropylene
PS	Polystyrene
PTT	Polytrimethylene terephthalate
PVA	Polyvinyl acetate
TPS	Thermoplastic starch
VKM	Vitenskapskomiteen for mat og miljø (Norwegian Scientific Committee for Food and Environment)

Glossary

Additives are chemicals added to plastic products during manufacturing to enhance or modify their properties.

Biodegradable plastics are bio-based or fossil-based polymeric materials that are designed to be converted to CO_2 (and methane at anoxic conditions), mineral salts and biomass through the action of microorganisms.

Biodegradable plastic products are certified to biodegrade in specific types of environments (e.g., soil or marine environment) within a given temperature range and time span. Like conventional plastic products, biodegradable plastic products contain various additives for desired performance, functionality and appearance.

Compostable plastics is a subset of biodegradable plastics that requires industrial composting at high temperature (~58°C) for efficient biodegradation to occur.

Bio-based plastics are obtained from renewable resources such as alga, bacteria and plants. They may be biodegradable or not.

Ecotoxicology concerns the study of the harmful effects caused by natural and synthetic pollutants to biota in aquatic and terrestrial ecosystems.

Ecosystem services are benefits that the ecosystems provide to humans in terms of outputs, conditions, or processes of natural systems (i.e., **ecosystem functioning**) that directly or indirectly benefits humans.

Environmental effects are the result of the impacts left on organisms, their habitats and ecosystems, and the environment as a biogeochemical entity, from actions of anthropogenic or natural origin. The effects may be beneficial or adverse.

Fossil-based plastics are polymeric materials derived from petrochemicals.

Mesocosms are any simulated outdoor experimental system that examines the natural environment under controlled conditions.

Microplastics are particles of synthetic or semi-synthetic organic polymer or rubber between 1 µm and 5 mm in size along their largest dimension (NAMC North Atlantic Microplastic Centre)[1]. Particles between 1 nm and 1 µm are considered **nanoplastics** (Gigault et al., 2018)

Microorganisms are micro-sized living organisms that are not visible to the naked eye when in unicellular form but may form visible biofilms when growing in arranged multicellular form. The definition technically includes bacteria, archaea, fungi, microalgae (single-celled plants) and protists. Although incapable of reproducing outside a host, viruses and prions are often included in the term.

Microbial ecotoxicology is a multidisciplinary scientific research area including microbial ecology, microbial toxicology, physics and chemistry (Ghiglione et al., 2016). This new branch of science responds to an increasing demand by politics and society because of the threats on environmental and human health caused by intense anthropogenic activities and impacts.

Outdoor environments are all natural ecosystems including terrestrial environments, riverine and lacustrine environments, and marine environments. Also included are human-impacted ecosystems, such as agro-environments and recreational areas.

Plastics are synthetic or semi-synthetic materials made of one or more organic polymeric substances as the main ingredient.

Polymers/polymeric materials are natural or synthetic macromolecules that consist of repeated units (building blocks) called monomers. All plastics are polymers, but not all polymers are plastics.

[1] Definition developed by NAMC North Atlantic Microplastic Centre.

1 Introduction

Plastic pollution and the release and spreading of micro- and nano plastics and plastic additives is a serious and growing global environmental challenge that affects wildlife, humans and ecosystems (Agamunthu et al., 2019). Plastics that can degrade in the environment through natural microbial processes have been developed with the aim to reduce persistent plastic pollution.

Biodegradable plastics are generally considered environmentally friendly, and many stakeholders are looking at this diverse group of polymers as part of the solution to reduce the accumulation of plastic in the environment. There are currently numerous plastic products on the market that claim to be biodegradable in the environment. At the same time, there is a lack of knowledge about the polymer characteristics and additive compositions of plastics products marketed as biodegradable, their biodegradation timespan in the environment, and the environmental consequences associated with their intended use.

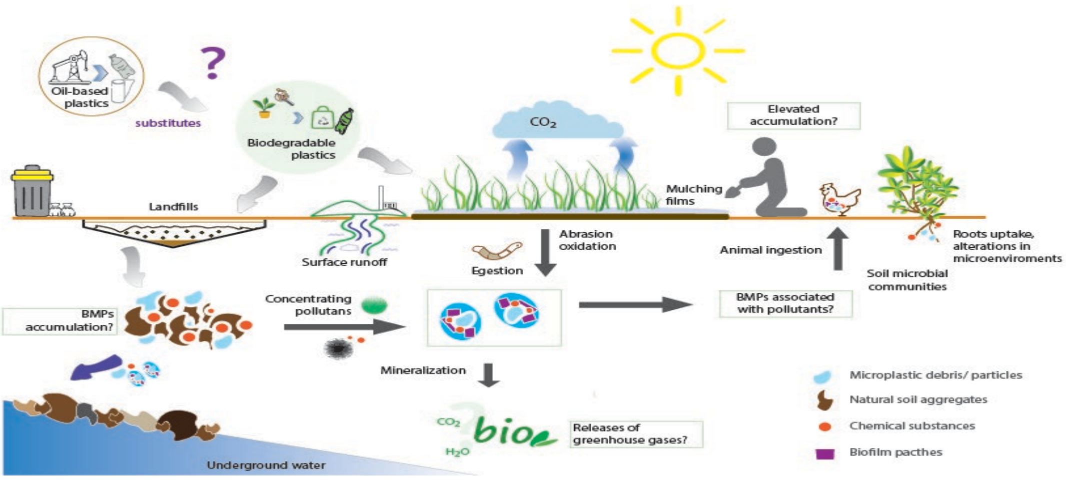

Figure 1. Examples of sources and routes of transformation and translocation of biodegradable plastics and associated environmental risks.BMP stands for biodegradable microplastics.

1.1 Biodegradable plastics

Biodegradable plastics may be part of the solution to reduce persistent plastic pollution if appropriately regulated, tested, labelled and managed (Yu & Flury, 2024). Biodegradable plastics are polymers that can be converted to CO_2, biomass and mineral salts through the action of microorganisms such as bacteria, fungi and algae (SAPEA, 2020). Under anoxic conditions, methane (CH_4) may also be formed through the activity of methanogenic archaea.

There are concerns about the biodegradation timespan of biodegradable plastic products in the open environment, considering the different types of natural environments (soil, marine and freshwater) and the wide range of environmental factors that influence and regulate the biodegradation process and rates. The potential ecotoxicological impacts from microplastics deriving from biodegradable plastics and the release of additives and other chemical substances during the (bio)degradation process is another environmental concern (Mut et al., 2024; Qin et al., 2021).

There is widespread confusion about the characteristics of the new generation of plastics, including biodegradable, compostable and biobased varieties, often collectively referred to as bioplastics. While biobased plastics are made fully or partly from biological resources, they are not necessarily biodegradable (Figure 2). Similarly, some fossil-based plastics are biodegradable and are therefore also included under the term bioplastics, as are non-biodegradable conventional plastics made from renewable biobased sources (e.g. Bio-PE). Hence, the term bioplastic does not provide any information about the material source or biodegradability but is generally perceived by the public as environmentally friendly and sustainable (SAPEA, 2020).

The global production of biobased plastics reached 2 million tonnes in 2023, and according to the forecast by European Bioplastics, the market shares are estimated to triple by 2029 (Market – European Bioplastics e.V. https://www.european-bioplastics.org/market/). Biodegradable plastics accounted for 50% of the production in 2023 and are estimated to increase to 66% in 2029 (Figure 3). While specific data on the annual consumption of biodegradable plastics in Norway could not be obtained, it is assumed that the usage will continue to increase also in Norway in line with global trends. The United Nations´ goal to reduce the production and use of fossil-based plastics in the frame of a legally binding global plastics treaty is likely to boost the market for alternative materials with properties like conventional plastics.

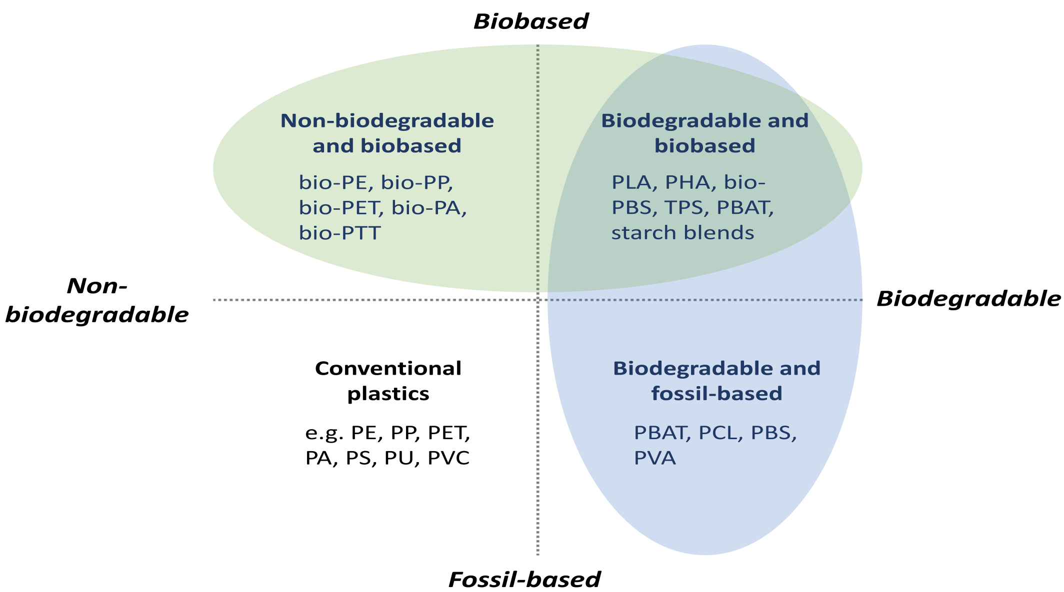

Figure 2. Overview of commercial plastics sorted according to material source and biodegradability. The plastics listed within the colored sections are collectively included in the term bioplastic. Abbreviations are explained in the abbreviation and glossary section.

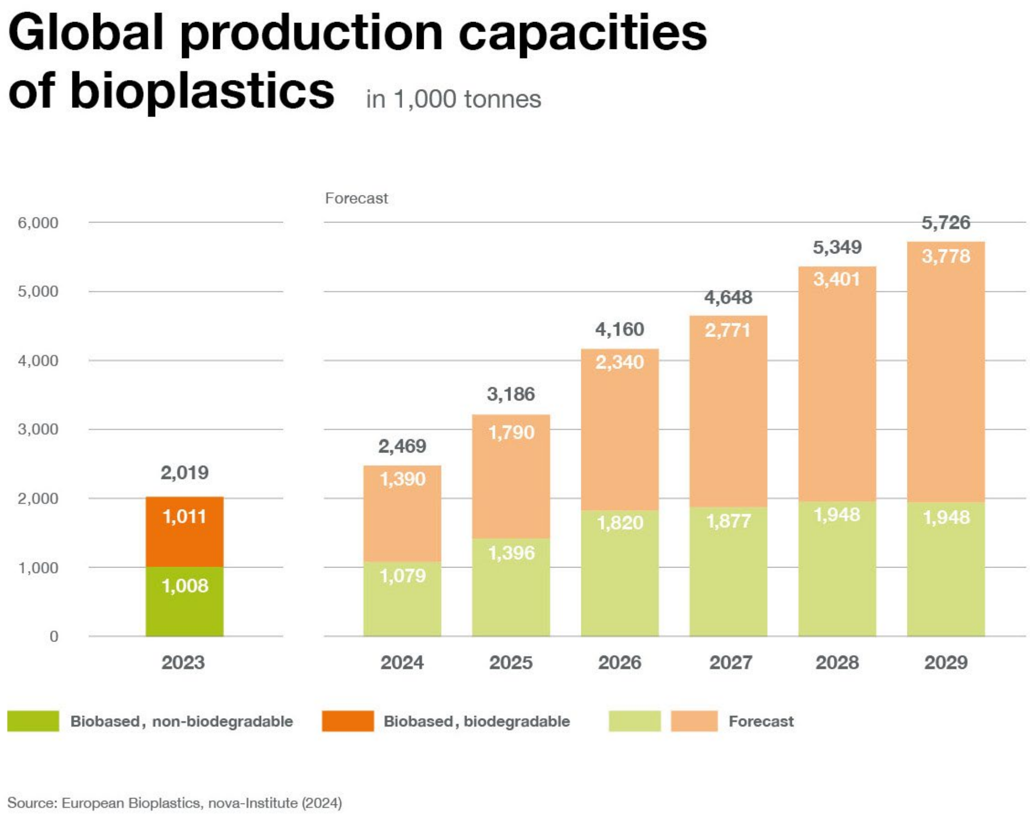

Figure 3. Global production statistics for biodegradable and non-biodegradable biobased plastics in 2023 and future predictions towards 2029 (source: Market – European Bioplastics e.V. https://www.european-bioplastics.org/market/).

1.2 Regulation

There is currently no national or international law in place that addresses biobased, biodegradable and compostable plastics in a comprehensive manner.

An EU policy framework issued on 30 November 2022 on the sourcing, labelling and use of biobased, biodegradable and compostable plastics aims to improve the understanding of these materials and clarify under which conditions and applications they may provide genuine environmental benefits (EU policy: https://environment.ec.europa.eu/topics/plastics/biobased-biodegradable-and-compostable-plastics_en). The framework also aims to promote a shared understanding across the EU on the production and use of these plastics, and to guide citizens, public authorities and businesses in their policy, purchasing and investing decisions.

There is currently one harmonized European Standard for biodegradable mulch film in soil (EN17033:2018). It requires a minimum 90% conversion of the material to CO_2 within two years at 25°C and restrictions on the use of hazardous substances monitored by ecotoxicity testing. There is also a European Standard for industrial composting of plastic packaging (EN13432:2000), which requires that no more than

10% of residual material be larger than 2mm after twelve weeks at 58°C. A similar standard for the United States of America (ASTM D6400) requires 60% degradation within 12 months. There are currently no general standards for marine or freshwater biodegradation.

The EU framework on biobased, biodegradable and compostable plastics suggests that there is a need to map knowledge about the products marketed as biodegradable plastics, their biodegradation efficiencies in the environment and environmental effects and consequences related to the range of intended use and waste handling of these plastics. In this project we will focus on identifying and summarizing published research on the environmental factors that may influence the (bio)degradation of biodegradable plastics used in agriculture, horticulture and aquaculture relevant for Norwegian and Nordic conditions, and the environmental effects and consequences that may be associated with the use of these plastics.

1.3 Environmental effects of biodegradable plastics

The biodegradability of biodegradable plastic products is not only dependent on the polymeric material's inherent biodegradability, but it also relies on the product's final material properties, which are influenced by additives and physical forces during production. For products intended to biodegrade in the open environment, the biodegradation process is dependent on the conditions in complex natural systems, which may vary and shift with time and space, type of environment, metabolic potential of microorganisms present and environmental factors that regulates microbial growth and activity. As such, the biodegradation process of biodegradable plastics needs to be considered as a **system property** (SAPEA, 2020).

The environmental risks of biodegradable plastics are not merely related to the physical and chemical stress they may pose on organisms and the environment, but also their effects as an added complex carbon source on microbial activity and ecology and the impacts of metabolites formed in natural ecosystems. The transformation process of materials and associated chemical substances during (bio)degradation is difficult to monitor in natural systems. There is a potential for leakage and spreading of plastic particles as well as chemical leachates to other compartments of the environment of application as well as translocation to other types of environments.

The multifaceted aspect of the potential environmental effects of biodegradable plastics on microbial ecology and ecosystem functioning requires a dedicated focus on the application, transformation, translocation and fate of these plastics in different types of environments and to identify relevant endpoints to assess and monitor their overall environmental impact (Figure 4).

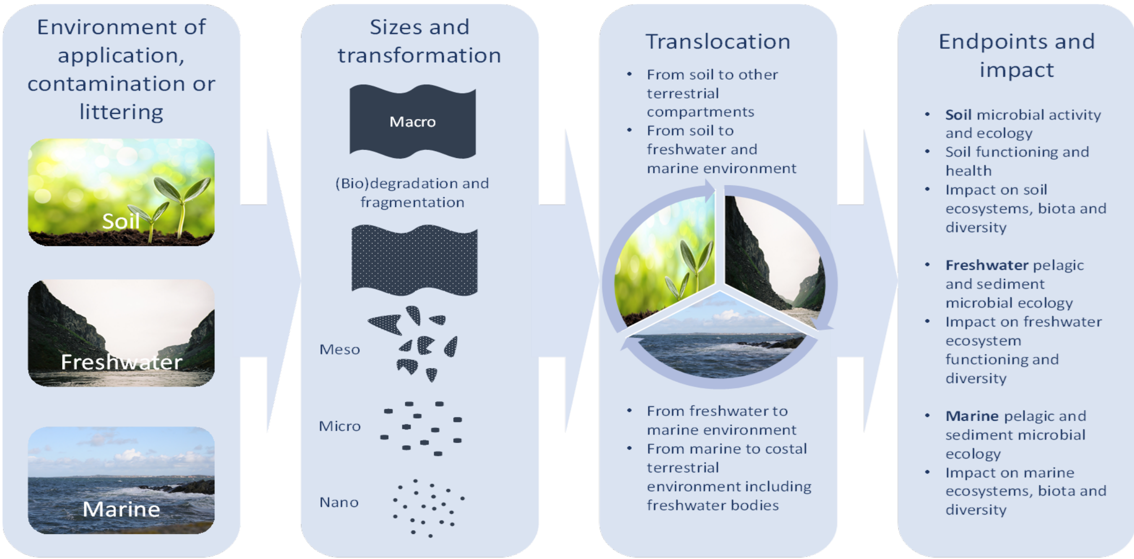

Figure 4 Illustration of possible environmental entry points of biodegradable plastics, material sizes and transformation in the environment, translocation potential and relevant endpoints and impacts. The pictures in the illustration are from VKM (soil) and NORCE (freshwater and marine).

2 Terms of reference

According to the mandate for performing a scoping review, this self-task study will map and review literature addressing biodegradable plastics and their effects on the environment with focus on studies relevant for Norwegian and Nordic countries conditions.

There is an urgent need to map knowledge about the composition of products marketed as biodegradable plastics, their biodegradation efficiency in the environment and associated environmental effects in order to understand and predict the environmental consequences of the range of intended and increased use of these plastics in Norway.

The mandate for the project is as follows:

- Conduct a scoping review of the research on biodegradable plastics and possible effects on the environment (microbial, ecotoxicological), focusing on Norwegian/Nordic conditions.
- Identify and describe the environmental factors that may have a bearing on microbial degradation of biodegradable plastics used in agriculture, horticulture and aquaculture in Norway.

3 Aim of the scoping review

The aim is to map scientific literature addressing biodegradable plastics and their effects on the environment with focus on conditions relevant for Norway and other Nordic countries.

More specifically, the aim is to 1) determine the extent of evidence summarised in reviews and original research papers within this emerging research area and 2) map the evidence according to the materials and chemicals studied, types of environments and geographical regions covered, the hypotheses addressed, the type of endpoints studied as well as the reported key findings.

The following scientific topics are included in the scope of the review:

1. Material properties and application (material science)
2. Biodegradation and microbial ecology (microbial dynamics and response, microbial ecotoxicology)
3. Ecotoxicology (toxic effects of materials, additives and other chemical substances)

The following elements will be addressed:

- Product types, their composition and application
- Certification, labelling and regulation
- Environmental risk assessment (ERA)
- Life cycle analysis (LCA)
- (Bio)degradability in the environment (abiotic as well as biotic)
- Biodegradation rate in different environments
- Environmental effects related to biodegradation
- Formation and persistence of biodegradable microplastics
- Formation and persistence of biodegradation products
- Materials, additives and other chemical substances
- Leaching of chemical substances from biodegradable plastic materials
- Environmental effects of leachates from biodegradable plastics
- Leakage rate of chemical substances during biodegradation of biodegradable plastic products (concentrations, thresholds and accumulation potential)
- Ecotoxicology of materials, additives and vector effects (absorption/desorption of environmental stressors)

3.1 Delimitation

This scoping review does not target biodegradation of biodegradable plastics in composting facilities (compostable plastics) or bio fermentation (biodegradable plastics in general) but does address the eventual release of biodegradable microplastics to the environment from compost or bio residuals produced from these processes, or through littering.

Literature on the bioprospecting for and testing of new biodegradable plastics and polymers that have similar properties are not included.

Even though some conventional plastic polymers may be subjected to biodegradation, the process is too slow to be considered in line with biodegradable plastics designed to biodegrade and mineralize within a short timeframe under environmental or industrial composting conditions.

Studies addressing the transport and fate of microplastics deriving from conventional plastics is not considered to represent the transport and fate of microplastics derived from biodegradable plastics and are thus not included.

4 Methods

We will conduct a scoping review, which is a type of knowledge summary that maps and describes existing literature and research activity on a particular theme. In a scoping review, the evidence on a topic is mapped in a systematic way, and main concepts, theories, sources, and knowledge gaps are identified (Colquhoun et al., 2014; Levac et al., 2010; Page et al., 2021; Tricco et al., 2018).

Scoping reviews are conducted using scientific, systematic, and transparent methods enabling critical appraisal of methods, results, and conclusions. In this way, scoping reviews resemble systematic reviews except that scoping reviews do not synthesise results in a meta-analysis or assess the confidence in the effect estimates for each outcome. Scoping reviews often have a broader scope than systematic reviews and aim to describe the available research literature in a field.

In this project we will adhere to the “Preferred Reporting Items for Systematic Reviews and MetaAnalyses extension for Scoping Reviews (PRISMA-ScR) Checklist” (Tricco et al., 2018).

Our literature search strategy is based on the APRIO model adopted by EFSA for development of the problem formulation of scientific assessments (Paoli et al., 2022). A.P.R.I.O. stands for Agent, Pathway, Receptor, Intervention, and Output. The APRIO is a paradigm which outlines the key elements to consider in systematic literature search and provides guidelines to the making of assessments questions and sub-questions.

The problem formulation established for biodegradable plastics in the open environment is outlined in Appendix 1.

4.1 Eligibility criteria

Table 1 lists the eligibility criteria for the search on published research on biodegradable plastics including materials assessed, types of environments studied, types of exposure, reference exposure(s), relevant endpoints and study design. We primarily target research studies published within the last 10 years, but also older studies may be included based on the option to perform additional manual literature searches. Assuming that the published research studies within the Nordic region may be scarce, we do not set any geographical limitations for the main search.

Table 1 Eligibility criteria for research studies on biodegradable plastics. *By no exposure means no addition of test material.

Materials	Composition, polymer, additives, size, morphology, product types
Environment	Soil (surface, buried), terrestrial, freshwater and riverine, the marine environment
Exposure	Use of biodegradable plastic products intended to biodegrade in a particular type of environment. Release of biodegradable microplastics from biodegradable plastics due to abiotic factors or incomplete biodegradation, from compost or bio residuals from anaerobic digestion. Release of biodegradable plastics to the outdoor environment through littering. Spreading of biodegradable plastics from the environment of primary use to other types of environments. Release of additives, chemical substances or metabolites during biodegradation of biodegradable plastics.
Comparison	No exposure* (control) Exposure dose and time Conventional plastics, other materials
Endpoints	Any environmental effects, including but not restricted to: Microbial activity and metabolites produced. Microbial ecology and composition, transient and long-term effects. Material fate, fragmentation, formation of biodegradable microplastics and their persistence in different environments. Ecotoxicology
Study design	Experimental studies: • Laboratory studies • Mesocosms • Field studies Reviews
Publication year	2014-2024 i.e. studies published within the last 10 years, but studies prior to this may be included through manual search efforts.
Country	There will be no geographical restrictions on the search and study selection, but in the data charting process we will highlight findings relevant to Norway and other Nordic countries.
Language	English, Norwegian, Danish, and Swedish

4.2 Information sources

We aim to search electronic databases. The search strategy is drafted in cooperation with a research librarian, who will conduct the literature searches. The electronic database searches will be supplemented by checking reference lists of review studies and manual searches in, but not limited to, Scopus, Endnote and Google.

4.3 Literature search

The search words to be used by the research librarian for the literature search are listed in Appendix 2.

4.3.1 Test search
A test search was performed by the research librarian at FHI in CAB to assess the developed search strategy and evaluate the matched literatures. CAB Abstracts is the leading specialist database dedicated to agriculture and applied life sciences.

The test search yielded 972 abstracts. Two members of the project team, Gunhild Bødtker and Siamak Yazdankhah, reviewed the first 50 articles and concluded that the APRIO based search strategy was suitable for our purposes.

4.3.2 Main search
We will search the electronic databases CAB Abstracts (2014 to 2024), Ovid MEDLINE(R), Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions (1946 to 2024), and Scopus.

We will perform a follow-up search for updates on new literature before publication of the report.

4.3.3 Identification of studies
The literature records identified from the systematic database and manual searches will be reported according to the PRISMA 2020 guidelines as presented by a flowchart (Appendix 3).

4.4 Study selection

Authors will independently, in pairs of two, assess 1) titles and abstracts for relevance using Rayyan software, and 2) full text articles against the eligibility criteria (table 1). Disagreements will be resolved by consensus or by consulting a third author.

4.5 Data charting process

Authors will extract data from a random sample of the included publications according to the data-charting form presented in table 2. The size of the random sample will be dependent on the volume of the identified records, and measures will be taken to ensure a representative selection of publications within the three main scientific categories established. Discrepancies will be resolved through discussions. If necessary, the data-charting form will be modified. Disagreements will be resolved by consensus or by consulting the working group.

4.5.1 Data items

Below are the variables for which data will be sought and registered for review papers and primary studies. The number of systematic review papers within this research area may be limited, so we aim to include non-systematic reviews. The reasoning for including financial source and conflict of interest as criteria is related to the commercial potential of biodegradable plastics and the current need for objective science-based knowledge to support environmental risk assessment and regulation.

Reviews (systematic and/or non-systematic reviews)

We will extract the following data on study characteristics for all reviews:

- authors
- title
- journal
- year of publication
- funding
- reported conflict of interest
- main objective(s)

For systematic reviews, the following data will be charted in addition:

- number and study design of primary studies included
- biodegradable polymers and material composites included in the reviews
- biodegradable plastic products included in the review
- list of the main endpoints considered
- list of key findings that relate to the review questions

We will extract the following data on details of the primary studies included in reviews:

- geographic area (mesocosms, field studies)
- type of environment (soil, freshwater, marine)
- scientific field(s) (specific or cross-disciplinary)
- main objective(s)
- stated hypotheses
- experimental study design (laboratory, mesocosm, field)
- type of exposure (material type and sizes and/or chemical substances)
- endpoints measured
- timeline of study
- comparison (no exposure (control), exposure dose and time, conventional plastics)
- endpoints measured

Primary studies

We will extract the following data on study characteristics of each primary study:

- authors
- title
- journal
- year of publication

- funding
- reported conflict of interest
- main objective(s)
- stated hypotheses
- experimental study designs (laboratory, mesocosm, field)
- geographic area (mesocosms, field studies)
- type of environment (soil, freshwater, marine)
- scientific field(s) (specific or cross-disciplinary)
- biodegradable polymers and material composites
- biodegradable plastic products
- type of exposure (material type and sizes and/or chemical substances)
- timeline of study
- comparison (no exposure (control), exposure dose and time, conventional plastics)
- endpoints measured

4.6 Synthesis of findings

We will summarize the charted data to provide information on the body of research on biodegradable plastics and their impacts on the environment as follows:

- Present the sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage (Page et al., 2021).
- Summarise characteristics of the studies, reporting geographic area, types of biodegradable plastics/products and/or chemical substances assessed, study design, type of environments exposed and endpoints measured, comparisons made, and the conclusions.
- Present the hypotheses addressed according to environmental effects.
- Present the overall risk of experimental biases related to studies.

Text, figures, and tables will be used to present the results with focus on the main findings.

In line with recommendations for scoping reviews we will not conduct any analysis or synthesis of the results identified (Tricco et al., 2018). We will arrange the studies into categories according to study design, the outcomes reported, type of exposure, and the studied environment. At least two authors, independently of each other, will categorize the selected publications. Any disagreements will be resolved by discussion.

Table 1 The data-charting structure established as basis for registration, sorting and presentation of research data information from the literature data extraction. Level 1 and level 2 refer to different levels of records information that may be relevant for the data charting of studies on biodegradable plastics. There is an option to modify the list of criteria if needed.

Records information	**Level 1**	**Level 2**
Type of publication	Review papers	
	Primary study	
Novelty	Publication year	
	Search date of review	

Geographic region	Africa	
	Americas	
	Asia	
	Europe	
	Oceania	
Type of environment	Soil	Agriculture
		Horticulture
		Natural soil
	Freshwater	River
		Lake
		Sediment
	Marine	Ocean
		Coastal
		Sediment
Organisms	Microorganisms	Bacteria
		Archaea
		Fungus
		Microalgae
	Invertebrates	Marine
		Freshwater
		Soil
	Vertebrates	Marine
		Freshwater
		Terrestrial
	Plants	Marine
		Freshwater
		Soil
Exposure substance	Biodegradable plastic materials, products or parts of products	Macroplastic
		Microplastic
	Chemical substances	Additives
		Leachates
Exposure level/concentration/repeated	Will be defined based on record data findings	
Comparison	No exposure	
	Exposure dose	
	Exposure time	
	Conventional plastics	
Outcome	Effects on microorganisms	Activity and metabolites
		Microbial composition
		Microbial diversity
	Effects on invertebrates	Ecotoxicological
	Effects on vertebrates	Ecotoxicological

	Effects on plants	Ecotoxicological

5 Uncertainty

The scientific quality of randomly selected publications will be evaluated to get an overview of the extent to which the design, methodology and conduction of the studies are likely to be associated with bias or misinterpretations. The aim is to assess the qualitative degree of systematic errors related to methods applied and the use of definitions and terminology.

We will apply the EFSA report on uncertainty analysis in scientific assessments as guidance, employing their generic lists of common types of uncertainties affecting scientific assessment related to inputs and methodology (Benford et al., 2018):

Uncertainties associated with assessment input:
1) Ambiguity
2) Accuracy and precision of the measures
3) Sampling uncertainty
4) Missing data within studies
5) Missing studies
6) Assumptions about inputs
7) Statistical estimates
8) Extrapolation uncertainty (i.e. limitations in external validity)
9) Other uncertainties

6 Knowledge gaps

Will be described in the project report.

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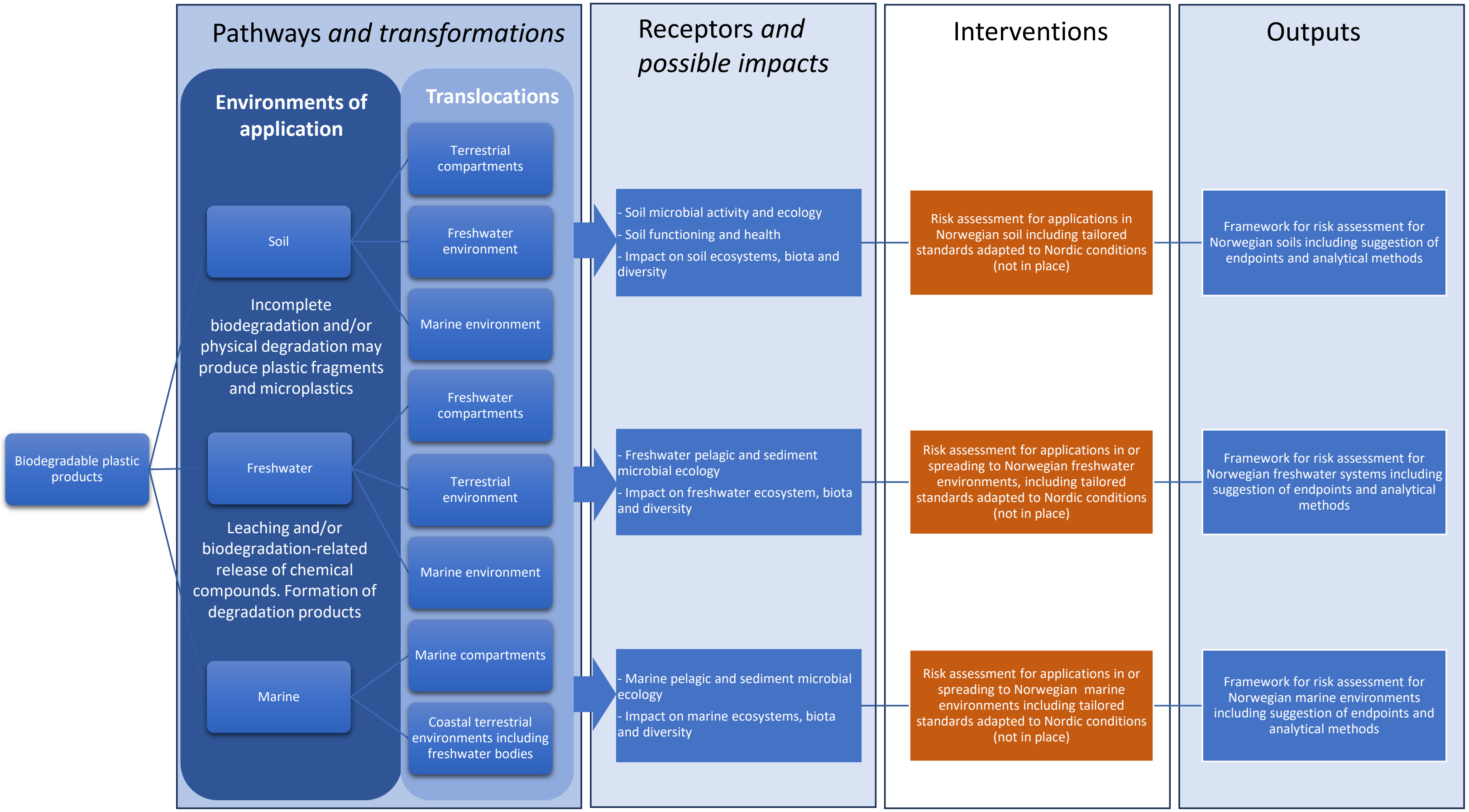
Appendix 1

The

AQ(s) and SQs generically defined	Agent (A)	Pathway (P)	Receptor (R)	Intervention (I)	Output (O)	AQ(s) and SQs formulated using APRIO
AQ 1: Impact of biodegradable plastics on the environment at Nordic/Norwegian conditions.	All products of/containing biodegradable plastics intended for biodegradation in the open environment	Environments of intended application and risk of spreading to other environments	Terrestrial environment, soil, riverine, freshwater, and marine environment	Control measures based on appropriate risk assessment (*complete/sufficient regulatory frameworks are not in place*)	Identify and describe potential environmental risks associated with intended applications and establish a framework for risk assessment	What is the status of knowledge about biodegradable plastics applied in Norway, within which regulatory frames and/or best practices are they applied, and to what extent is knowledge in place and/or currently produced aimed at/useful for forming the basis for appropriate risk assessment of these plastics for application in Norway?
Tier-1 SQ 1.1: When applied in soil (e.g., agriculture)	All products of/containing biodegradable plastics intended for biodegradation in soil	From the soil of intended application to surrounding environment(s)	Terrestrial environment, soil, riverine, freshwater, and marine environment	Assess existing regulatory framework for soil applications	Probable environmental risks and possible environmental benefits	What is the knowledge status about the effects of biodegradable plastic applications in Norwegian soils, what regulatory frames and/or best practices are applied, and to what extent is knowledge in place and/or currently produced aimed at/useful for forming the basis for appropriate risk assessment of these plastics for their future applications in Norwegian soils?
Tier-2 SQ 1.1.1: List of relevant scientific knowledge and analytical data	Types of biodegradable plastic polymers and polymer + chemical composition of biodegradable plastic products	Potential for secondary pollution by spreading to surrounding environments, including in the form of microplastics and chemical leachates	Impacts on organisms (physical, ecotoxicological), their habitats and ecosystem functioning (structural, physicochemical, biodiversity)	Endpoints applied in current risk assessments and regulatory frameworks of biodegradable plastics in soil	Probable environmental risks and possible environmental benefits	Same as above
Tier-1 SQ 1.2: When applied in the marine environment	All products of/containing biodegradable plastics intended for biodegradation in the marine environment	Within and from the marine environmental compartment of intended application to other marine environmental compartments or costal terrestrial environments (e.g., from water column to marine sediments or costal terrestrial environment)	Marine environmental compartments, costal terrestrial environments including soil and freshwater	Assess existing regulatory framework for marine applications	Probable environmental risks and possible environmental benefits	What is the knowledge status about the effects of biodegradable plastic applications in Norwegian marine environments, what regulatory frames and/or best practices are applied, and to what extent is knowledge in place and/or currently produced aimed at/useful for forming the basis for appropriate risk assessment of these plastics for their future applications in Norwegian marine environments?
Tier-2 SQ 1.2.1: List of relevant scientific knowledge and analytical data	Types of biodegradable plastic polymers and polymer + chemical composition of biodegradable plastic products	Potential for secondary pollution by spreading to surrounding environments, including in the form of microplastics and chemical leachates	Impacts on organisms (physical, ecotoxicological), their habitats and ecosystem functioning (structural, physicochemical, biodiversity)	Endpoints applied in current risk assessments and regulatory frameworks of biodegradable plastics in the marine environment	Probable environmental risks and possible environmental benefits	Same as above
Tier-1 SQ 1.3: When applied in freshwater environments	All products of/containing biodegradable plastics intended for biodegradation in freshwater environments	Within and from freshwater environments of intended application to other freshwater environmental compartments, terrestrial and marine environments	Freshwater environmental compartments, terrestrial environments including soil and marine environments	Assess existing regulatory framework for applications in freshwater	Probable environmental risks and possible environmental benefits	What is the knowledge status about the effects of biodegradable plastic applications in Norwegian freshwater environments, what regulatory frames and/or best practices are applied, and to what extent is knowledge in place and/or currently produced aimed at/useful for forming the basis for appropriate risk assessment of these plastics for their future applications in Norwegian freshwater environments?
Tier-2 SQ 1.3.1: List of relevant scientific knowledge and analytical data	Types of biodegradable plastic polymers and polymer + chemical composition of biodegradable plastic products	Potential for secondary pollution by spreading to surrounding environments, including in the form of microplastics and chemical leachates	Impacts on organisms (physical, ecotoxicological), their habitats and ecosystem functioning (structural, physicochemical, biodiversity)	Endpoints applied in current risk assessments and regulatory frameworks of biodegradable plastics in freshwater environments	Probable environmental risks and possible environmental benefits	Same as above

assessment questions and sub-questions developed as basis for the project's problem formulation.



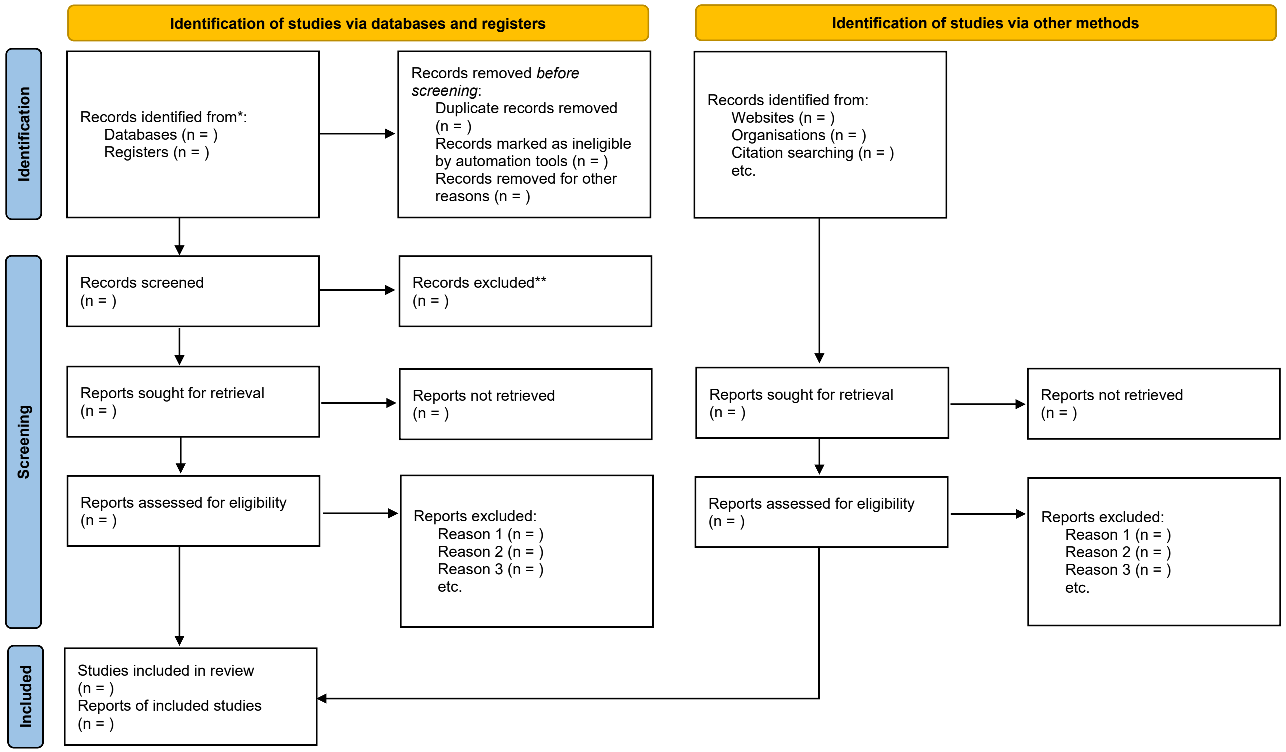
Problem formulation model showing the pathways from application, release and environmental transformation of biodegradable plastics to potential environmental effects and harms. Note that interventions are not in place for risk assessment that account for the multifaceted environmental risks associated with materials and additives fates in different types of environments.

Appendix 2

1	biodegradable plastics/
2	(biodegradable materials/ or biodegradation/ or biodeterioration/) and (plastics/ or microplastics/)
3	(((biodegrada* or compostable or degrada* or biodeteriora* or deteriora*) adj4 (plastic? or microplastic? or mesoplastic? or nanoplastic? or macroplastic?)) or ((biodegrada* or compostable or degrada* or biodeteriora* or deteriora*) adj4 ("micro plastic?" or "meso plastic?" or "nano plastic?" or "macro plastic?"))).tw.
4	or/1-3
5	environment/ or exp aquatic environment/ or exp ecosystems/ or freshwater ecology/ or marine ecology/ or exp aquatic organisms/ or exp aquatic communities/ or peat soils/ or peat/ or exp humus/ or clay soils/ or clay/ or halloysite/ or permafrost/ or exp sand/
6	(environment* or ecosystem? or "eco system?" or ecological or ecologic or habitat? or biome? or biodiversity or diversity or biota or biotic or biocenose? or "biological communit*" or freshwater? or lake? or pond? or river? or stream? or seawater? or ocean? or sea? or wetlands or boglands or bogs or fens or marshes or marshland? or swamp? or brackishwater? or soil? or peat or humus or clay? or halloysite? or permafrost? or sand? or aquatic or marine or benthos or "coral reef?" or periphyton? or seston or nekton or plankton or phytoplankton or Microalga? or Microphytes or zooplankton or krill or seagrass* or eelgrass* or seaweed? or kelp or algae or alga or Macroalgae or Gracilaria or Porphyra).tw.
7	((fresh or saline or brackish or sea or coastal) adj water?).tw.
8	or/5-7
9	4 and 8
10	limit 9 to yr="2014 -Current"

Appendix 3

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.