MARINE BIOTECHNOLOGY STRATEGIC RESEARCH AND INNOVATION ROADMAP

INSIGHTS TO THE FUTURE DIRECTION OF EUROPEAN MARINE BIOTECHNOLOGY

MarineBiotech

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Authors: Dermot Hurst (Marine Institute, Ireland); Torger Børresen (TabCon Marine Biotech & Seafood, Denmark); Lisa Almesjö (Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning Sweden); Fien De Raedemaecker (Flanders Marine Institute, Belgium); Steinar Bergseth (Research Council Norway, Norway)

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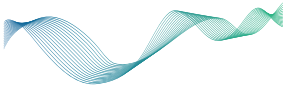


EXECUTIVE SUMMARY

The EU 7th Framework Programme for Research and Technological Development funded Marine Biotechnology ERA-NET (ERA-MBT), prepared a roadmap for future marine biotechnology research and innovation.

The preparatory work to the roadmap involved partners in the ERA-MBT project conducting desk studies, on-line questionnaires, interviews, stakeholder workshops, a foresight-like study and extensive engagement with an advisory group of international experts (*Appendix 1*). A goal of ERA-MBT is to support the development of marine biotechnology research and innovation, enabling its growth within a self-sustained enterprise driven network.

The EU Blue Growth strategy embeds marine biotechnology in the Bioeconomy Strategy for Europe recognising its role in helping to meet the societal and other challenges faced by Europe. In developing this roadmap, ERA-MBT identified an optimistic future for marine biotechnology; one closely aligned with the sustainable utilisation of marine bioresources in ways that establish new markets, generates revenue and increases employment.

Exploring the potential of marine biodiversity has increased, indicating it to be a rich source of novel natural compounds. Some of these compounds are already used in food, cosmetic, agricultural, chemical and pharmaceutical products, but their diversity has not been fully characterised and utilised. Further opportunities exist for the use of ocean bioresources in markets for industrial enzymes, functional foods, cosmeceuticals, biomaterials, bioprocessing and medical devices.

The ERA-MBT research and innovation roadmap highlights research and innovation as spanning scientific, technological, economic and societal challenges and in doing so, sets a marine biotechnology research and innovation agenda to 2030. The roadmap identifies five thematic areas; the first three enable the *exploration of the marine environment*; support *biomass production and processing;* and contribute to *product innovation and differentiation*; whilst the remaining two, *policy support and stimulation;* and the provision of *enabling technologies and infrastructure*; provide the essential foundation to support growth in the bioeconomy.

EXPLORATION OF THE MARINE ENVIRONMENT

Exploring the chemical and biological diversity of our oceans as a source of novel materials and food is the essence of this strategic research area. Despite the promise of the oceans, the technical challenges of accessing areas outside the shallow coastal zone, and the costs of deepwater exploration, mean much of the oceans' depths remain to be discovered. The provision of a pipeline of new organisms to screen for novel compounds is an essential support for future innovation.

BIOMASS PRODUCTION AND PROCESSING

The main sources of marine biomass are species harvested from the wild and those that can be cultured. Securing sustainable marine biomass presents challenges, particularly if the sole source is from wild stocks, where overexploitation can threaten marine biodiversity as well as future supply of the target species. The strategic management of wild species coupled with plans to deliver more coherent and effective species management are essential if wild stocks are to remain viable sources of biomass and ecosystem health and services are to be maintained. Consistency, security and quality of biomass supply have to be balanced in ways that address environmental challenges and demands for sustainability. The well-managed and controlled culture of marine biomass, whilst similarly facing production challenges, offers sustainable sources of biomass.

PRODUCT INNOVATION AND DIFFERENTIATION

Emerging opportunity areas and completely novel applications for marine-derived compounds exist. The health sector, which targeted marine-derived molecules as new pharmaceutical entities, continues to emphasise the potential of marine origin materials in drug discovery. Target markets for marine origin lipids, proteins including enzymes, pigments, and flavours include human and animal nutrition, industrial chemicals, cosmetics, pharmaceuticals, personal care, the agri-food sector and many more.

ENABLING TECHNOLOGIES AND INFRASTRUCTURE

Despite the progress enabled by EU programmes, there remains an acute need to continue to create research and innovation capacity in both the research and enterprise sectors. Doing so will enhance the scientific and technological research infrastructures, thereby providing access to an array of new research support "tools" and facilities to support marine biotechnology. Many of the tools and techniques used in marine biotechnology are widely used in other areas of science and technology. Engaging in collaborative research projects is one way of providing access to these facilities and encouraging multi-disciplinary research. A challenge faced by marine biotechnology researchers is to align their discovery and development activities with the needs of target markets. Establishing a link between researchers and the array of end-users is essential in stimulating innovation. Though there are strong links between the marine biotechnology research community and areas of fundamental and applied sciences, the need for dedicated research tools and facilities to fully exploit marine biological resources remains.

POLICY SUPPORT AND STIMULATION

The ubiquitous nature of marine biotechnology results in the research and innovation activities being shaped by a wide range of European and international policy instruments and regulations. Policy links exist between the environment, fisheries and aquaculture, food, health, natural resources and industrial sectors, which both highlight the expectations for marine biotechnology and stimulate activity. Research activities also generate knowledge that informs and influences policy. Knowledge derived from marine biotechnology research contributes to how the marine environment can be managed sustainably and fulfil its role in providing environmental services to the planet. It can contribute to ocean governance and to the development of regulations concerning the use of ocean resources. Strong supportive policies are fundamental to the creation of successful marine biotechnology activity; importantly, they create the environment for the sustainable exploitation of marine bioresources. National and European policies and strategies determine the extent to which funding and other initiatives can stimulate companies to engage in marine biotechnology related research and innovation.

The marine biotechnology research and innovation roadmap proposes a series of short- and long-term actions in each thematic area. Individual actions are those that offer the greatest potential to deliver economic and societal returns and to where future funding and other supporting initiatives should be directed. These are summarised in *Table 1*.

TABLE 1 A summary of short- and long-term actions in each thematic area that offer the greatest potential to deliver economic and societal returns.

	SHORT-TERM ACTIONS 2016–2020	LONG-TERM ACTIONS 2020–2030
Exploration of the marine environment	Continue to target traditional sources of marine biomass, including samples held in repositories; maximise the use of available methods to identify species, and to isolate, characterise and assess compounds from marine organism for bioactivity.	Explore targeted environments and hot-spots; develop next generation sampling methods; and develop novel methods for the taxonomic, chemical, and biochemical evaluation of marine species as sources of bioactive compounds.
Biomass production and processing	Develop processes to support the harvesting and culture of available biomass and refining methods for the production of food, feed and other non-food related products.	Establish integrated processing of mixed feedstock and the optimised culture of species for food use and as novel compounds, while sustaining the health of cultured species.
Product innovation and differentiation	Expand the range of functional foods/ ingredients, nutraceuticals, cosmeceuticals, fine chemicals, enzymes and other biomaterials derived from marine organisms and also explore their use in sensors and as biological indicators.	Develop a new generation of therapeutics and other biocompatible materials obtained from marine organisms; develop new concepts of bioremediation and novel processes based on marine organisms and compounds.
Enabling technologies and infrastructure	Maximise the role of national research networks in forming new collaborations to support marine biotechnology research activities; expand the range of available analysis and assessment tools and methodologies; continue to map marine habitats and biodiversity.	Continue to build research networks and international collaborations to expand marine biotechnology research activity. Strengthen marine biotechnology research and innovation by developing new tools and approaches to find biological and environmental hotspots, and characterise the bioactive potential of marine compounds. Create pilot facilities, materials repositories and related datasets.
Policy support and stimulation	Implement national agreements on access to marine habitats and environmental regulations concerning the harvesting of marine organisms. Expand the provision of national and EU funds to generate knowledge about marine organisms, which is required to develop an expanded range of marine biotechnology enabled products.	Implement global agreements on access to resources and access beyond national jurisdictions. Introduce common licensing systems concerning the access to and use of marine organisms. Encourage the creation of dedicated Venture Capital funds for businesses based on marine biotechnology research. Establish marine biotechnology targeted public/private partnerships.

PREFACE

Governments around the world are seeking opportunities for sustainable economic growth, recognising that economic success cannot come at further cost to the planet's threatened ecosystems. Many of the most exciting opportunities are found in what is termed the "bioeconomy", where the application of biotechnology to biomass, is delivering new products and services for population health, sustainable industries and primary production. Today's bioeconomy is advancing faster and showing greater promise than ever before, driven by both scientific advances and markets demanding sustainable solutions to today's global grand challenges of food and fuel security, sustainable industry and population health.

As demands on the bioeconomy increase, there is a pressing need to find new, sustainable sources of biomass to meet demand. The marine environment harbours one such source, and one that remains largely underutilised, so far exploited largely by capture fisheries oriented toward human consumption of fish and related ingredients. However, unsustainable harvesting of wild stocks has led to a decline of some species, and although conservation and improved resource management have allowed some species to recover, the scope to increase production from the wild is limited and more efficient use of existing resources is necessary. Over the last 40 years, commercial aquaculture and mariculture have demonstrated the potential for greater marine biomass production, creating new biomaterial supply-chains for selected marine organisms. Marine biotechnology is the key to unlocking the value of marine biological resources, providing biobased and other industries with access to sustainably produced and renewable biomass. Marine bioresources found in some of the most extreme and unique ecosystems on the planet, are rich sources of novel materials and bioactive compounds that can help to meet the demand for improved health and wellbeing, and support a wide range of other consumer and industrial applications. Whilst recent attention is directed to the greater utilisation of algae for products other than food, the diversity of marine organisms (including micro-organisms) make them highly attractive in a broad range of other applications. Marine biotechnology is a critical component of today's bioeconomy, enabling marine biomass to be cultivated, harvested and processed to support the production of innovative products, stimulate new industrial activity, and support existing industry to become more competitive. Now is the time to broaden and diversify our research efforts; moving from a well-established demonstration of the merits of biotechnology applied to marine biomass, to a broad range of products meeting market demands sustainably.

The marine biotechnology roadmap produced by the ERA-MBT project provides a framework for future marine biotechnology research and innovation activities creating new biomaterial supply chains. It also identifies the dependence of future marine biotechnology activity on contributions from a wide range of scientific and technological disciplines, and from existing European policy shaping marine biotechnology research and innovation in the "Blue Growth" strategy. The view of the ERA-MBT International Advisory Group is that this roadmap provides a practical and realistic approach by which marine bioresources and biotechnology can contribute to economic and societal progress.

Dr Rachael Ritchie, Genome British Columbia, Canada
Chair of the ERA-MBT International Advisory Group

ACKNOWLEDGEMENTS

ERA-MBT is grateful for the support and encouragement of members of the ERA-MBT International Advisory Group — Dr. Fernando de la Calle, Prof. Alan Dobson, Dr. Fredrika Gullfot, Prof. Frank Oliver Glöckner, Prof. Adrianna Ianora, Dr. Ernst Kloosterman, Ms. Nathalie Moll, Dr. Rachael Ritchie, Prof. Patrick Sorgeloos, Dr. Helena Vieira and Prof. Uwe Waller over the course of this project, and appreciates the contribution of the International Advisory Group in defining the marine biotechnology roadmap.

This roadmap is made possible through the help and support from consortium partners and the wider scientific, policy and industrial community who generously contributed to this document and to the ERA-MBT Foresight process.

CONTENTS

INTRODUCTION

With plans to continue to develop the European bioeconomy, contributions from marine biotechnology research and innovation will help firms in different industry sectors to diversify their products. Marine biotechnology enables the production and use of marine biomass. The definition of marine biotechnology as used in this roadmap builds on that provided by the OECD[1] in its general definition of biotechnology:

"The application of science and technology to living organisms from marine resources, as well as to parts, products and models thereof, to alter living and non-living materials for the production of knowledge, goods and services."

Research and innovation are behind the use of marine origin compounds in new product and process development, helping firms to create novel pharmaceuticals, food products, functional ingredients and nutraceuticals, medical and other diagnostic devices. In addition to these health applications, marine-derived compounds are used as novel industrial materials — composites, biopolymers, and enzymes in different industries[2]. The long established use of algal components in animal and plant health applications is expanding with new markets for the use of algae in feed, personal care and cosmeceuticals. Other areas where marine biotechnology underpins future growth include the remediation and management of environments, and in aquaculture, in particular, breeding, feed, and health. The successful performance of marine biotechnology in delivering products that contribute to meeting the global challenges of food supply, improved health for all and stimulating the growth and sustainability of industries is beginning to drive further product and process innovation.

Opportunities exist for marine biotechnology to continue to support activities directed towards securing greater value from marine organisms. The increase in marine biodiscovery related activity is likely to expand the range and availability of novel marine origin materials. The reported research and innovation successes to date emphasise contributions from traditional sources of biomass such as algae, fish and shellfish in developing food products and food ingredients with physical-chemical functional properties. There are also early signs that further successes in health applications, particularly new pharmaceuticals, derived from sponges and other marine invertebrates, algae, fungi and marine microorganisms are possible[3].

New, more sustainable processes are required to transform marine biomass into products. Some enzymes, drugs, nutrients, fine chemicals and other products are produced using specially designed organisms and processes. The knowledge and expertise developed in this area may be useful in creating new approaches to processing marine biomass.

Activities of the Marine Biotechnology ERA-NET (ERA-MBT) are designed to support Europe's goals to create a lasting bioeconomy. In doing so, ERA-MBT works with stakeholders across Europe to identify future biotechnological needs and to support opportunities that maximise the use of marine bioresources. The approach of ERA-MBT is to enhance all elements of the value chain, from research and development, to supporting proof of concept and stimulating the uptake of research outputs by industry, and thereby contribute to the development of the European bioeconomy. A description of the ERA-MBT roadmap process and insights to the objectives of ERA-MBT are given in *Appendix 1* and *Appendix 2* respectively.

In seeking to create a lasting network of funding for marine biotechnology, the ERA-MBT project developed this strategic research and innovation roadmap to highlight future marine biotechnology related activities. This provides a framework on which to continue to develop research competences and support the development of the European bioeconomy while addressing the societal challenges of health, demographic change and wellbeing; food security; and the supply of raw materials.

The vision for marine biotechnology as defined by ERA-MBT is: To support Europe's marine biotechnology community to participate in a lasting, enterprise-driven network that adds value to marine biological resources in ways that nurture and sustain the lives of European citizens.

CHAPTER 01

MARINE BIOTECHNOLOGY AND THE BIOECONOMY

"The application of marine biotechnology is essential for the sustainable development of aquaculture."

PETTER ARNESEN — BREEDING DIRECTOR, MARINE HARVEST ASA

MARINE BIOTECHNOLOGY — AN ENABLING TECHNOLOGY

Marine biotechnology is a key enabling technology that supports the development of the bioeconomy. It is a multi-disciplinary, knowledge and capital-intensive technology that is relevant throughout the value-chain and spans different sectors as illustrated below in *Figure 1*. In doing so, it provides new opportunities for industry to further develop significant competitive advantage, stimulate growth and create new jobs by exploiting the potential of marine biological organisms.

> "Marine biotechnology is a key enabling technology that supports the development of the bioeconomy."

MARINE BIOMASS

Oceans and seas comprise upwards of 70 percent of the surface of our planet and are home to 90 percent of Earth's biosphere[4]. Marine biomass originates from the extensive marine biodiversity of the oceans and comprises many forms, including e.g. whole fish, discards from wild harvest or processing, aquaculture products, macro-algae — both wild and cultivated, micro-algae, marine invertebrates and marine micro-organisms. The production and processing of marine biomass include both individual marine species and biomass that comprises multiple species. The starting point or input to the process of extracting value from marine bioresources is the culture and harvesting of available marine biomass.

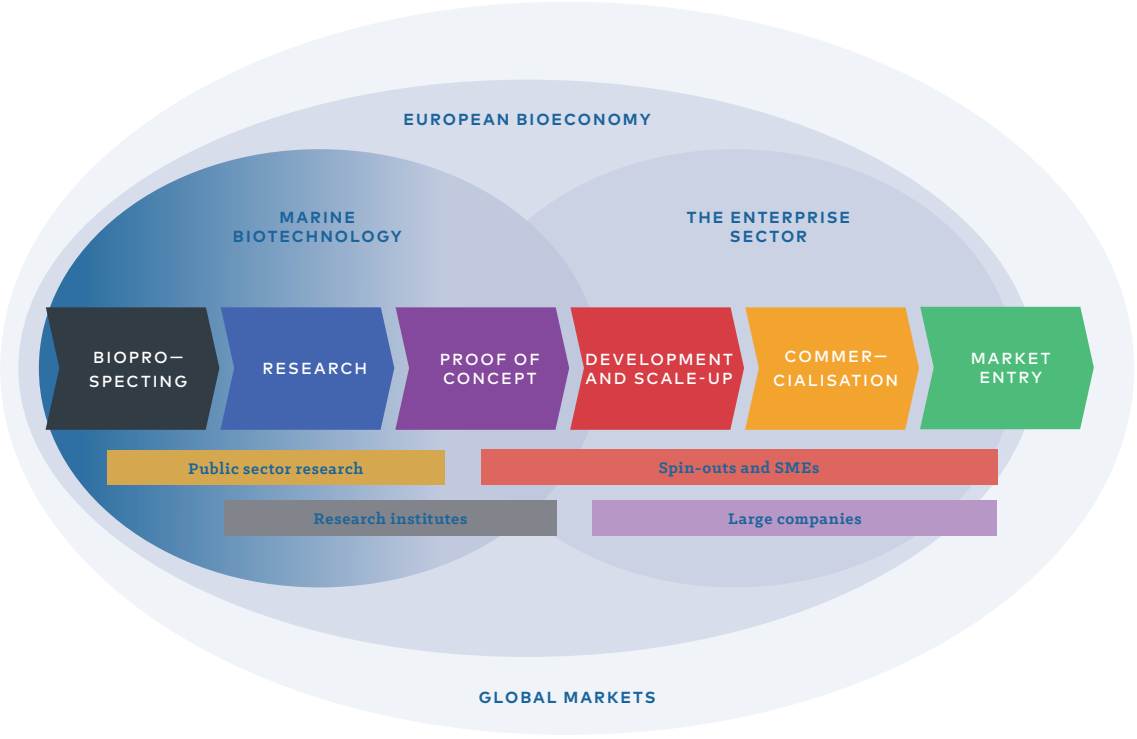


FIGURE 1 The contribution of marine biotechnology to global markets

Whether the desired end-result is a compound for a new pharmaceutical, a novel enzyme, food ingredient or biomaterial — marine biomass is transformed.

ROLE OF BIOSCIENCES

The marine ecosystem comprises many environmental niches that are home to a large number of organisms across many trophic layers. Because these species have evolved to live in diverse environments with variations in salinity, nutrients, temperature, light and pressure, they are a source of chemical and biochemical diversity with potential applications in novel products and processes.

> "Scientific and technological developments within the biosciences has significantly improved our knowledge of marine biological resources."

The rapid and extensive scale of scientific and technological developments within the biosciences has significantly improved our knowledge of marine biological resources. These new developments include next-generation gene sequencing, bioinformatics, post-genomics, functional genomics, transcriptomics, proteomics, protein structures, metabolomics. In addition, new chemical methods that characterise the complex chemistry, and assays to assess the bioactivity of marine origin compounds support the search for novel biomaterials, proteins, and safe, sustainable and healthy food.

CONTRIBUTION TO THE BIOECONOMY

The EC describes Europe's bioeconomy as "those parts of the economy that use renewable biological resources from land and sea — such as crops, forests, fish, animals and micro-organisms — to produce food, materials and energy"[5]. The development of Europe's bioeconomy is focused on the conversion of renewable resources from terrestrial and marine environments into food, animal feed and related bio-based products and is recognised as helping to meet Europe's grand challenges for the 21st century[6].

Europe's Blue Growth Strategy, which describes *"...opportunities for marine and maritime sustainable growth"* was published in 2012[7]. It contains five distinct high-growth areas of which marine biotechnology, termed "blue biotechnology", is one. Blue Growth is embedded in the overarching "Bioeconomy Strategy for Europe" adopted by the EC. There is a long-standing and persistent reference to the scope of marine biotechnology within policy and research communities, which highlights the opportunity for "blue biotechnology" to contribute to meeting Europe's societal and other challenges.

The Standing Committee on Agricultural Research (SCAR) in their 4th Foresight Exercise[8] published in October 2015 identified how marine resources could contribute to the European bioeconomy. Although the current volumes of marine biomass are relatively minor compared to terrestrial biomass, the potential for converting marine biomass into valuable products is high and seen as supporting a sustainable bioeconomy.

INDUSTRY ACTIVITY AND GLOBAL MARKETS FOR OCEAN BIORESOURCES

Major opportunities exist to extend the use of ocean bioresources in markets for industrial enzymes, pharmaceuticals, functional foods, cosmetics and agricultural products. Further, there are fast emerging applications in new end-use areas including bioprocessing, environmental remediation and monitoring, chemicals, cosmeceuticals, biomaterials and in medical devices: whilst the global population growth continues to fuel the demand for food products from the oceans and seas.

"Major opportunities exist to extend the use of ocean bioresources in markets for industrial enzymes, pharmaceuticals, functional foods, cosmetics and agricultural products."

Several estimates of the market value for marine biotechnology enabled products exist; however, these vary depending on which market segments are included. The report for DG Maritime Affairs and Fisheries *"Study in support of Impact Assessment*

"The global market for marine biotechnology has the potential to reach $4.8 billion by 2020, rising to $6.4 billion by 2025."

work on Blue Biotechnology"[9] projected revenue from blue biotechnology could reach €1 billion within 5 years if a market growth of 6-8% per annum was maintained, and result in the creation of 10,000 new jobs.

A 2015 market report from market analysts Smithers Rapra *"The future of marine biotechnology for industrial applications to 2025"*[10] indicates the global market for marine biotechnology has the potential to reach $4.8 billion by 2020, rising to $6.4 billion by 2025. This report identifies new applications for marine-derived enzymes and the use of marine algae and micro-algae in biofuel production as key drivers of the market growth. On the back of extensive aquaculture activity, including culturing macro-algae for hydrocolloids, the Asia-Pacific market is described as the fastest growing one. Europe is recognised as a high-potential region for future growth resulting from an extensive, yet largely unexplored marine resource. Many firms using materials produced by marine biotechnologies are from industry sectors not generally recognised as part of the marine sector.

Levels of research activity involving marine natural products were described in a 2009 analysis of patent activity, which reported marine resources being used in five application domains — food, cosmetics, agriculture, chemistry and pharmacology[11]. There are also reports of increased patent activity in these sectors over the period 1973 to 2007, with patents from the chemical and pharmacology sector increasing by 53.5 and 32.2 percent respectively[12].

The involvement of biotechnology in exploring the potential of marine biodiversity has increased, resulting in the widespread recognition that the biodiversity of the marine environment is now a rich source of natural compounds. Research driven advances in marine biotechnology are responsible for many successes in areas of human health and wellbeing and in how marine environments are managed. Potent natural products obtained from marine organisms continue to demonstrate many bioactivities including anti-tumour, anti-inflammatory, analgesia, immunomodulation, allergy, and anti-viral properties[13]. The pharmaceutical industry was early in recognising the potential of marine biodiversity as the basis for new drugs with more than 1,000 novel marine chemicals in preclinical trials between 1998 and 2011[14]. Against a background of lengthy development timescales for new therapeutic compounds, as of December 2015, seven FDA approved marine origin drugs were in clinical use and a further 28 at various stages of clinical trials[15]. Fish, sponges, tunicates, molluscs and bacteria are the main sources of compounds in these trials.

By 2018 the global market for nutraceutical products is expected to be worth $250 billion[16]. This market includes products described as food or nutritional supplements, functional foods, special dietary foods, sports drinks and medically formulated foods. The market for Omega 3 polyunsaturated fatty acid is projected to grow at nearly 14 percent per annum and reach close to $19 billion by 2020[17]. Industry sources estimate marine products comprise 32% of the nutraceuticals market[18].

The market for cosmeceuticals has emerged as the fastest growing segment of the global cosmetics industry. These products are relatively recent additions to the cosmetics and personal

care markets, providing therapeutic like benefits to users. The global market for cosmeceutical products was estimated as $30.5 billion in 2010 and set to rise at a rapid pace; growing at a rate of around 9% per annum between 2015 and 2020[19]. Marine compounds have a long history of use in the cosmetics sector[20].

Consumer demand for products based on natural materials contributes to growth in the cosmetics and cosmeceuticals markets. Whilst terrestrial plant extracts remain a major source of natural ingredients, marine origin ingredients have emerged as an alternative[21]. Compounds derived from salmon eggs, micro- and macro-algae, fish skins, and plants found in coastal regions are processed by specialist ingredient suppliers and supplied to manufactures of cosmetic and cosmeceutical products. A further industry study

> "The projected high-growth opportunities for health, food and biomaterials-related applications offer considerable scope to create high-value products from marine bioresources."

points to 13% of the global cosmetics market being products that incorporate marine ingredients[22]. The projected high-growth opportunities for health, food and biomaterials-related applications offer considerable scope to create high-value products from marine bioresources. Residues remaining following the extraction of high-value compounds from marine bioresources are a source of biomass with energy use potential.

POLICY

Marine biotechnology related research and innovation is recognised by policy makers and the enterprise sector as offering significant potential to fill market gaps for new products, processes and services. The challenge of developing marine biotechnology capabilities has already been embraced by EU member states and some have developed plans to improve their bioeconomy by increasing the use of aquatic resources[23]. There are also examples of national research strategies developing a sustainable bioeconomy on the back of marine biotechnology research and innovation activities[24,25]. Previous and current European research funds target unexplored and underexploited marine resources as a source of high-value products.

PROGRAMMES, INITIATIVES AND PROJECTS

Before the advent of the EU's 6th Framework Programme for Research and Technological Development (FP6), marine biotechnology contributed to projects where the main aim was basic research, food or feed production, health etc. In the follow-on research programme, FP7, call topics specifically targeting marine biotechnology were included in the "Oceans of Tomorrow" initiative[26]. Europe's current research programme Horizon 2020, includes several marine biotechnology related research themes/topics.

Europe's Blue Growth Strategy describes *"...opportunities for marine and maritime sustainable growth"*, in which the development of marine biotechnology activities is set to grow incrementally as below.

- **Firstly, in the short-term as a niche market development focused on high-value products for the health, cosmetic and industrial biomaterial sectors,**
- **A second stage up to 2020 in which markets expand with the production of metabolites and primary compounds as input for the food, feed and chemical industries, and finally**
- **Some 15 years later where the sector becomes a provider of mass-market products, together with a range of high added-value specialised products.**

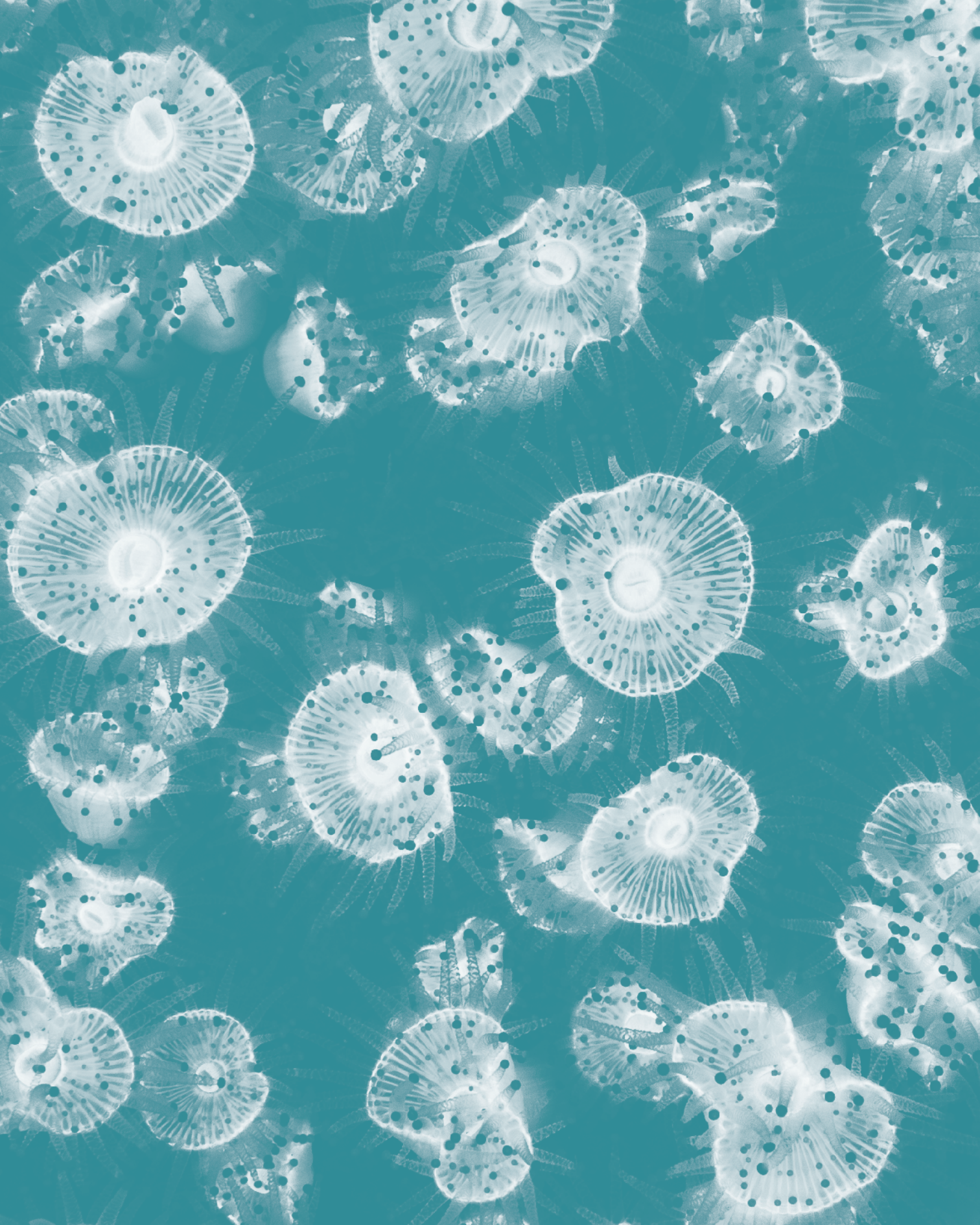
The Blue Growth Strategy emphasises the importance of marine bio-based products as alternative sources of carbon and energy, with specific reference to the role of renewable resources such as micro-algae. This challenge was taken up the Bio-based Industry Consortium in a Joint Undertaking with the European Commission as part of an Institutional Public Private Partnership, which launched a call in 2015 for research projects to reduce the costs of bioprocessing algae by applying a multi-stream biorefining concept[27]. The need to enhance the bioprocessing of marine biomass was also the theme of a call for research proposals (biorefining), by ERA-MBT in 2015, resulting in the provision of €8.5 million to support six transnational, joint research projects.

ADDRESSING SOCIETAL CHALLENGES — A ROLE FOR MARINE BIOTECHNOLOGY

With a focus on supporting research needed to meet Europe's *Societal Challenges*, the Horizon 2020 research programme is fundamentally different to the earlier research framework programs. Marine biotechnology is relevant to major challenges in Horizon 2020,[28] in particular, health, demographic change and wellbeing; food security, sustainable

agriculture and forestry, marine and maritime and inland water research and the bioeconomy; secure, clean and efficient energy; climate action, environment, resource efficiency and raw materials; and Europe in a changing world — inclusive, innovative and reflective societies.

Current EU research programmes highlight the need to go beyond rigid thematic approaches and are designed to increase collaboration across the research landscape to the benefit of society. The Lund Declaration adopted in 2009[29] and updated in 2015[30] stresses how meeting the grand challenges in Europe would require a strengthening of the frontier research, and by Europe taking a global lead in the development of enabling technologies (such as biotechnology, information technology, materials and nano-technologies). It also highlights measures designed to support business development and public policy goals; the creation and maintenance of world-class research infrastructures; and a risk-tolerant and trust-based approach in research funding.



CHAPTER 02

THEMATIC AREAS OF THE ERA-MBT ROADMAP

"Marine biotechnology can unlock the pharmaceutical potential of marine origin materials leading to new treatment options."

FERNANDO DE LA CALLE – HEAD OF MARINE MICROBIOLOGY R&D PHARMAMAR SA

INTRODUCTION

The Earth's seas and oceans are largely underutilised and many gaps exist in our understanding of the potential of these marine territories as a future source of novel materials, as a source of safe, healthy food and of their contribution to the wellbeing of the planet.

> "Marine biotechnology is well positioned to contribute new knowledge and approaches in respect of managing the marine environment and the sustainable exploitation of marine organisms."

In line with the broad thrust of Horizon 2020, the ERA-MBT research and innovation roadmap highlights research areas that span scientific, technological, economic and societal challenges, and in doing so, sets a marine biotechnology research and innovation agenda to 2030. The five thematic areas of the roadmap are illustrated in *Figure 2* and described below.

Enabling technologies and infrastructure are central to and have an influential role in the activities of other thematic areas. Together they enable the exploration of the marine environment; support biomass production and processing; and contribute to product innovation. Their further development relies extensively on policy support and stimulation measures, as do the other thematic areas of the roadmap. The extent to which product innovation and differentiation activities are successful are likely to influence future policy support and stimulation initiatives.

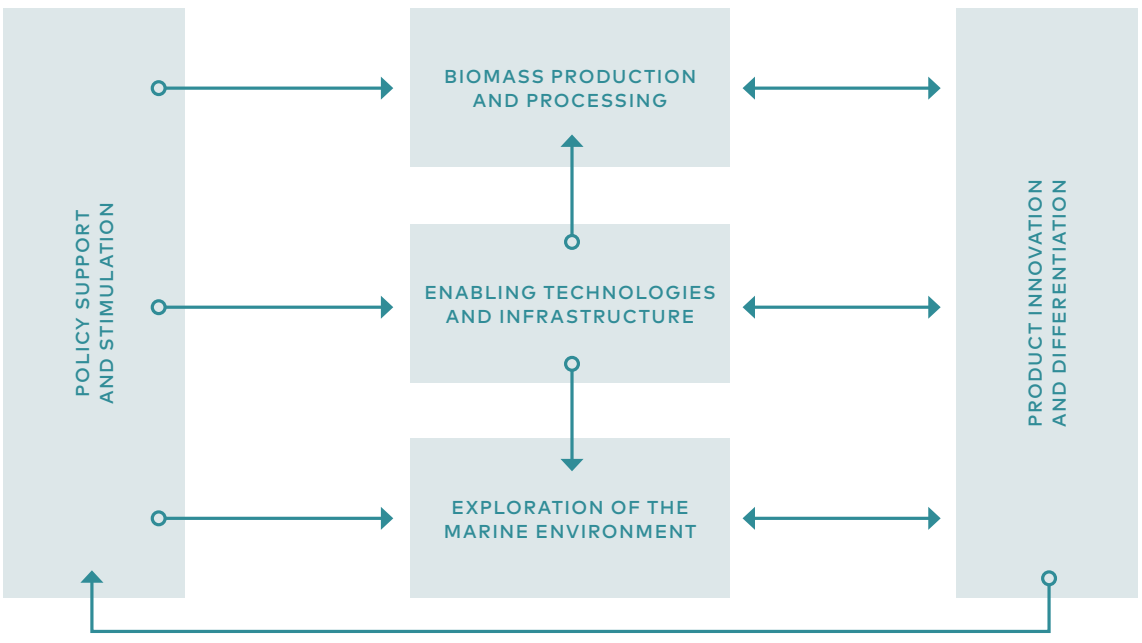


FIGURE 2 The five thematic areas of the strategic research and innovation roadmap

The core of each thematic area is the generation of knowledge to support product and process innovations, leading to the creation of sustainable research networks. There are also elements within themes that enable an expansion of marine biotechnology research and innovation. Each thematic area is built on the vision of marine biotechnology as an enabling technology. A technology that is cross-cutting and capable of contributing to the development of Europe's plans for a knowledge-intensive bioeconomy; able to tackle societal challenges; and encourage a collaborative approach in creating industrial leadership. The fundamental principles in developing the bioeconomy are sustainability and minimising the generation of waste. Marine biotechnology is well positioned to contribute new knowledge and approaches in respect of managing the marine environment and the sustainable exploitation of marine organisms.

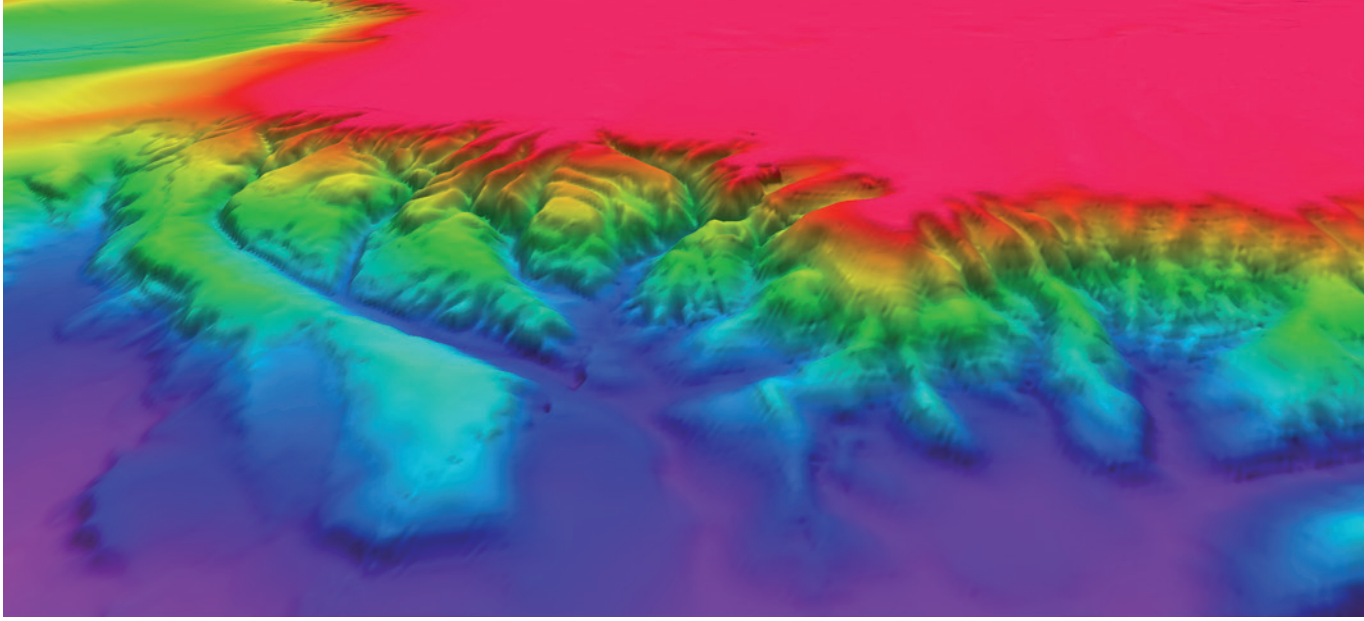
"Marine exploration is largely dependent on collaborative research activity and technologies developed outside the biological area."

EXPLORATION OF THE MARINE ENVIRONMENT

Exploring the chemical and biological diversity of our oceans as a source of novel materials and food is the essence of this strategic research area. Against a backdrop of successful food, health and material innovations based on marine organisms, considerable optimism surrounds the future role of marine bioresources to contribute to Europe's plans to expand the bioeconomy.

Despite the promise of the oceans, the technical challenges of accessing areas outside the shallow coastal zone, and the costs of deepwater exploration, mean much of the oceans' depths remain to be discovered. However, even in the absence of a significant pipeline of new organisms to screen for novel compounds, marine environments already provide materials used in the production of industrial chemicals, pharmaceuticals, food and food ingredients.

Exploration and discovery activities are not limited to remote ocean areas and deep-waters. Europe's extensive coastal regions are home to many species of microbes, algae, fish, crustaceans and invertebrates, all of which offer ease of access to marine bioresources for discovery type research.



Materials discarded during harvesting, cultivation and processing of marine species are used as human and animal food ingredients, fertilisers, nutritional supplements, biochemicals, proteins and lipids. Further exploration and examination of known sources of bioproducts is needed to expand the possible range of applications for such materials.

Marine exploration is largely dependent on collaborative research activity and technologies developed outside the biological area. The development of devices such as remotely operated vehicles allow for the collection of samples; data mining techniques can help to target areas of high marine biodiversity; remote sensing and geoinformatics provide insights to seabed structures and habitats, and metagenomics allows DNA to be recovered from microorganisms that cannot be cultured in the laboratory. The development of these new tools and methods is behind the renewed focus on marine exploration and bioprospecting. Using an array of modern analytical approaches it is possible to explore and characterise chemical compounds from within marine organisms as potentially useful products. Expanding the exploration of marine environments, some of which had previously remained out of reach, will provide researchers and industry with greater access to novel marine organisms thus enlarging the discovery pipeline.

> "Two main sources of marine biomass are wild and cultured species."

Future exploration activities can be built on capabilities and networks developed in EU research programmes and those evolving within Horizon 2020. A major exploration opportunity for European marine biotechnology is to increase the rate of discovery of new organisms and build the RTDI capacity to utilise their potential. The roadmap identifies opportunities for,

- **Continued targeting of microorganisms in deep-sea sediments, microbial symbionts from sponges and other organisms; macro- and micro-algae; bivalves, crustaceans, fish and fish processing discards, and marine fungi as sources of biologically active natural products;**
- **The discovery of new marine species including microorganisms, as a source of novel materials;**
- **Exploiting the potential of genetic resources in the discovery process; and**
- **Exploring the chemical and biological diversity of marine organisms.**

BIOMASS PRODUCTION AND PROCESSING

Europe's plans to develop a bioeconomy are largely driven by knowledge of increases in global population, shrinking resources, increasing environmental pressures and climate change. In recognising the need for Europe to bring about changes in how biological resources are used, the bioeconomy strategy opens the way for Europe to adopt new approaches to managing its bioresources. In planning to create a resilient and resource efficient society, Europe recognises the need to overcome specific challenges in the sustainable production and use of biomass. Achieving sustainability in primary production and processing is fundamental to the creation of new products and to the future of the bioeconomy. Though presently a minor source of biomass, the potential of marine bioresources to meet these twin challenges is widely acknowledged.

Two main sources of marine biomass are wild and cultured species. Securing sustainable marine biomass presents challenges, particularly if the sole source is from wild stocks, where overexploitation can threaten marine biodiversity, as well as ecosystem functions and services. Consistency, security and quality of biomass supply have to be balanced in ways that address environmental challenges. The well-managed and controlled culture of marine biomass, whilst similarly facing production challenges and being limited to certain species, needs to be further developed as sustainable sources of biomass in parallel with the development of sustainable harvesting of marine species from the wild. Creating useable products from marine biomass requires feedstock to undergo some form of transformation. Typically this is a refining or extraction process, which yields intermediate or final products. Biomass processing generally involves several intermediary steps from harvesting to end-use. Long-term goals to improve the biorefining process include shortening the supply chain by integrating the cultivation and processing stages; optimising the production of customised feedstock; employing multi-stream bio-refining techniques; and creating circular sustainable supply chains — where products and materials flow in loops, assets are fully utilised and in which waste is eliminated.

There are also calls for flexible biomass transformation processes, where multiple sources of marine biomass can be refined into specific fractions. Technological advances may allow the use of biological resources to create biomass, leading to marine micro-organisms possibly becoming future bioprocessing "factories".

Key elements of the marine biotechnology production and processing roadmap include:

- **Increasing the production of biomass from sustainable marine resources, including exploring the potential to develop on land, offshore and deep-water aquaculture.**
- **Establishing the controlled culture of marine biomass at sea and on land, and developing techniques to culture marine organisms not currently in culture.**
- **Creating efficient transformation and refining processes, including concepts of multi-stream inputs and the refining of mixed biomass feedstock.**

"The health sector, which targeted marine-derived molecules as new pharmaceutical entities, continues to emphasise the potential of marine biomass in drug discovery"

- **Reducing the complexity of the supply chain by integrating biomass production and refining, reducing energy demand and waste in processing marine biomass.**

- **Removing bottlenecks in marine biomass transformation and conversion by identifying novel processes and marine enzymes that can modify biomass, tailor its chemical and biological properties and reduce the energy demand of transformation.**

- **Engaging in research to support the expansion of cultured biomass production including measures to minimise and mitigate environmental impacts; addressing waste management; enhance biosecurity and the introduction of new production systems (breeding/hatchery/genetics/nutrition and health etc.) and expand the use of molecular methods.**

- **Harnessing knowledge and expertise from other sectors of the bioeconomy to support the rapid development of pilot scale equipment and scale-up of marine biomass refining.**

PRODUCT INNOVATION AND DIFFERENTIATION

Only a small fraction of marine biomass is presently used outside the food and feed sectors. Emerging market opportunities and completely novel applications for marine-derived compounds exist. The health sector, which targeted marine-derived molecules as new pharmaceutical entities, continues to emphasise the potential of marine biomass in drug discovery; filling gaps that more traditional sources of small molecules have not been able to fill. In the search for new biocompatible materials, the marine is home to a myriad of biological materials of interest to the engineering and medical devices sectors.

Though attention is often directed to the creation of new products from novel marine materials, more accessible marine origin materials should not be overlooked. With the projected increases in aquaculture output, greater levels of fish landings at European ports, and changes in the Common Fisheries Policy, fish processing activities are set to increase. Whilst processors aim to maximise the recovery of the edible portion of fish, inevitably, not all materials are fully used. Termed "rest-raw materials" or "co-products", this marine biomass is a rich source of polysaccharides, lipids, proteins, pigments, flavours, polymers and other chemical compounds all of which have product and process applications. Target markets for these materials

"Establishing a link between researchers and the array of end-users is essential in stimulating innovation."

"Innovative policy direction can stimulate interaction between research and industry."

include human and animal nutrition, industrial chemicals, cosmetics, pharmaceuticals, personal care and food ingredients. Collagen and gelatine extracted from fish, and alginates, carrageenan and agars from algae, are widely used by the food sector.

Not only is marine biomass proving to be the source of new product applications; considerable scope also exists for it to contribute new processing methods. The extensive marine biodiversity is an excellent source of novel biocatalysts. Initially pioneered by the foods sector, marine-derived enzymes have attracted the attention of the chemical, pharmaceutical, cosmetics, agriculture and environmental sectors, and can support an expansion of industrial bioprocessing.

The interest of the agriculture and horticulture sector in marine materials is increasing as a result of evidence pointing to the beneficial effect of algal extracts in animal and plant health. Similar interests exist in the aquaculture sector, where there is an increased demand for alternative feedstock to replace traditional fishmeal both for nutritional and health benefits.

Some seaweeds have a high capacity for nutrient absorption, making them attractive in multi-trophic aquaculture where the waste products from one species contribute to the growth of another. However, they accumulate heavy metals and other pollutants, which could limit options to use them for animal and human applications. Significant scope exists to build upon, and add to the knowledge base of marine origin materials by supporting actions to:

- **Assess, profile, and maximise the sustainable use of marine bioresources for applications in human and animal food, as food ingredients, therapeutic compounds, medical devices and biomaterials, cosmetics and cosmeceuticals and as novel industrial materials and processes.**
- **Further isolate and analyse materials from marine biomass to enhance the understanding of their structures and modes of action in human and animal health and food/feed related areas.**
- **Create novel biosensors based on marine-derived materials or marine organisms and explore their use in monitoring environmental status and food safety.**
- **Assess the potential of marine origin materials to contribute to improved aquaculture performance including addressing health and disease issues within cultured populations, disease resistance and minimising environmental impacts of production.**
- **Investigate the inherent biocompatibility of some marine materials and assess their potential for use in medical devices, for drug delivery or in the repair, replacement or regeneration of tissue.**
- **Harness the potential of marine organisms to act as experimental models in health-related research.**

ENABLING TECHNOLOGIES AND INFRASTRUCTURE

European marine biotechnology activity has made significant progress over the past decade in building a research community and infrastructure to support research and innovation. Despite this progress, there remains an acute need to continue to build research and innovation capacity — in both the research and enterprise sectors and to enhance the science and technology research infrastructure.

Many of the tools and techniques employed in marine biotechnology are used in other areas of science and technology. Engaging in collaborative multi-disciplinary research projects is one way of providing access to these facilities. Establishing a link between researchers and the array of end-users is essential in stimulating innovation. Expectations about enhancing the available research infrastructure to support product and process innovations have to be met; so too must access to essential core infrastructure. Such infrastructures include research vessels, exploration platforms, laboratories, pilot plant, databases and repositories and an array of increasingly complex analytical tools. Opening up, expanding and creating new infrastructure will broaden marine biotechnology research and innovation activity, attract industry collaborations, and deliver knowledge to support product and process development.

Though there are strong links between the marine biotechnology research community and areas of fundamental and applied sciences, the need for dedicated research tools and facilities to fully exploit marine biological resources remains. Without advances in technologies that allow the discovery and mapping of the oceans depths, provide insights to new species, or provide for a greater understanding of the genetic and chemical diversity of marine bioresources, the impact of marine biotechnology on socio-economic progress could be limited. Future developments in the "omics" based approaches and single cell technologies; together with the development of novel heterologous expression systems will be key in this respect. These methods and advances in chemical/biochemical analysis will enhance our understanding of the composition, structure and function of marine organisms, thereby increasing our ability to identify opportunities to use the diversity of marine species as the basis for bio-based products.

Opportunities exist to bring new expertise and to build interaction between disciplines to support marine biotechnology, particularly leveraging the benefits from the involvement of information technology specialists and bioinformatics expertise. Marine biotechnology research is largely reliant on contributions from across the scientific and technological horizon to provide the all-essential "toolkit" necessary to explore marine environments and develop new products. Through measures that encourage the convergence of different disciplines, technologies and industry sectors, it will be possible to strengthen marine biotechnology research and innovation. Building lasting supportive infrastructures requires research to:

- **Develop alternatives to the traditional collection or harvesting of marine organisms, including the development of methods to allow in-situ assessment and screening of marine organisms to increase the rate of the discovery of novel materials.**
- **Create predictive tools to improve the identification and targeting of biological "hot-spots" in the oceans; including the use of "omics" based technologies.**
- **Identify and build new competencies and networks to support marine biotechnology research and innovation, e.g. applied bioinformatics.**
- **Develop automated equipment for use in habitat mapping, biological resource assessment and sample collection.**
- **Reduce the costs associated with discovery-related activities.**
- **Create pilot facilities to support scale-up activities.**
- **Provide shared and open access marine data and biological repositories.**

POLICY SUPPORT AND STIMULATION

The ubiquitous nature of marine biotechnology results in research and innovation activities being shaped by a wide range of European and international policy instruments and regulations. Policy links to marine biotechnology include areas such as environment, fisheries and aquaculture, food, health, natural resources and industrial policy. Research activities can generate knowledge to inform policy, which in turn stimulates innovation.

Innovative policy direction can stimulate interaction between research and industry. The importance of such collaboration is crucial in enabling marine biotechnology-based innovation. New policy initiatives backed up by operational support can broaden the scope, performance and impact of marine biotechnology.

Knowledge derived from marine biotechnology research informs how the marine environment can be managed sustainably and fulfil its role in providing environmental services to the planet. It can contribute to ocean governance and to the development of regulations concerning the use of ocean resources. Information secured from the marine environment informs decision-making in the public and private sectors. Marine biotechnology research has a lasting role in informing policy and decision-making in the public and private sectors.

International conventions and treaties seek to establish principles and legal frameworks for managing ocean resources. For example, the United Nations Convention on Biological Diversity[31] and, Convention on the Law of the Sea (UNCLOS)[32], and the Nagoya Protocol on Access to Genetic Resources[33] can influence how future marine biotechnology research develops.

The evolution of international and European marine policy offers marine biotechnology researchers and industry with a wealth of new opportunities. Increased monitoring of the marine environment, biomass stock assessment, harmful algal blooms etc., requires new assessment tools to be developed. Data, samples and other material collected during exploration voyages need to be deposited in marine biobanks/repositories. Over time, these data can provide baseline information to inform policy concerning environmental status as well as be used in profiling marine biodiversity.

The marine bioresources policy arena is not totally reliant on scientific and technological knowledge; other research areas such as socio-economic, environmental and international law also inform how marine biotechnology might develop. Further policy opportunities exist as outlined below to:

- **Identify ways to expand access to marine bioresources for discovery purposes in European waters and in the high seas**
- **Develop a comprehensive, planned policy research programme to apply the knowledge gained from marine biotechnology research to inform public policy, governance and regulation of marine environment and marine-derived products**
- **Support the introduction of common regulations across member states regarding the harvesting, culture and exploitation of marine biomass**
- **Establish efficient and responsive regulation and policy development relating to marine bioresources**
- **Identify mechanisms to attract greater industry participation in marine biotechnology related research**
- **Identify policy developments to advance marine biomass production and processing capabilities and to reduce barriers to the development of new markets for marine-derived products**

CONNECTING THE THEMATIC AREAS

Each thematic area is interlinked as shown in *Figure 3*. They form a chain of activity connecting policy, available tools and infrastructures, to research and the commercialisation of outputs. The whole chain is dependent on industry involvement, public and private funding and the formation of partnerships between researchers and enterprise, coupled with strong policy direction and support.

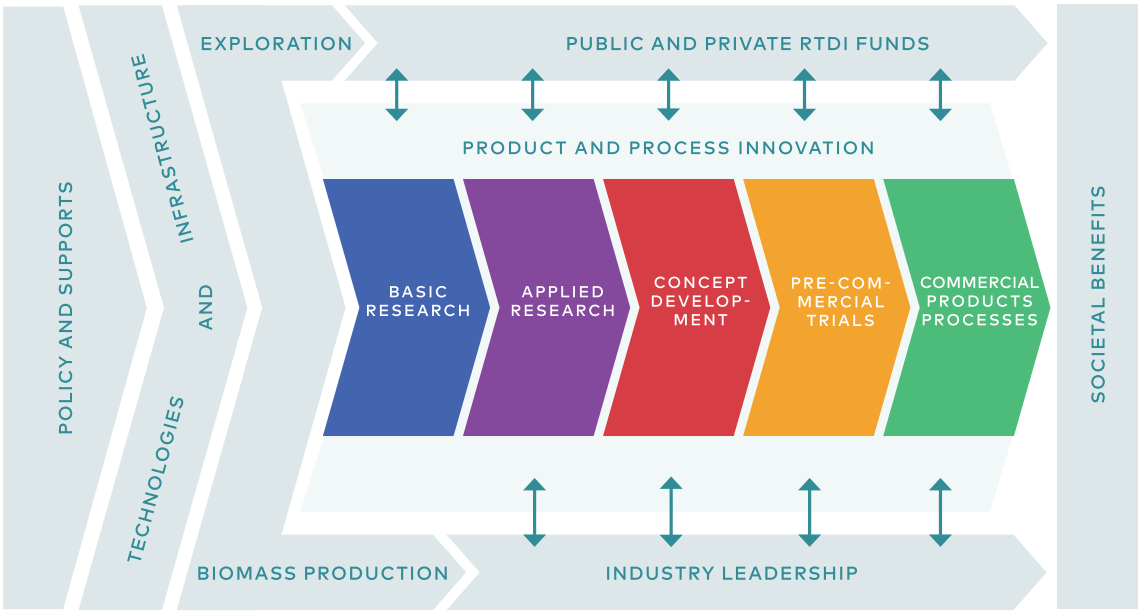


FIGURE 3 Connecting the research areas to support the delivery of value and benefits to society

CHAPTER 03

ROADMAP FOR SHORT- AND LONG-TERM ACTIONS

"Marine biodiversity constitutes a great source for novel ingredients and new components for the food and feed industry."

TORMOD THOMSEN — DIRECTOR GLOBAL CATEGORY SEAFOOD, FIRMENICH S.A.

The Strategic Roadmap does not predict what will happen but rather indicates how, based on extensive interaction with stakeholders, marine biotechnology can develop the sustainable use of marine resources for new products and processes.

Research topics in each thematic area are positioned as short-term (2016 to 2020) or long-term (2020 to 2030) investment opportunities likely to provide economic and/or societal returns.

Short-term actions resolve known problems and target the so-called "low-hanging fruits", whereas long-term actions involve significant scientific, technological or other challenges.

EXPLORATION OF THE MARINE ENVIRONMENT

This thematic area comprises three interconnected sub-themes, on which the exploration of the marine environment and the discovery of novel materials depend — accessing marine habitats; targeting sources of marine biomass; and characterising marine organisms, including their chemical and biological composition.

Macro-algae and fish are the main sources of marine biomass currently used in commercial applications, principally as food and food ingredients. The results of various bioprospecting and discovery activities illustrate the possibilities for a wider range of applications for compounds derived from marine organisms. Marine organisms from extreme environments are targeted in the search for specific components for use as pharmaceuticals, enzymes and fine chemicals.

Discards and residues from fish processing are important and available sources of biomass that are readily transformed by marine biotechnology.

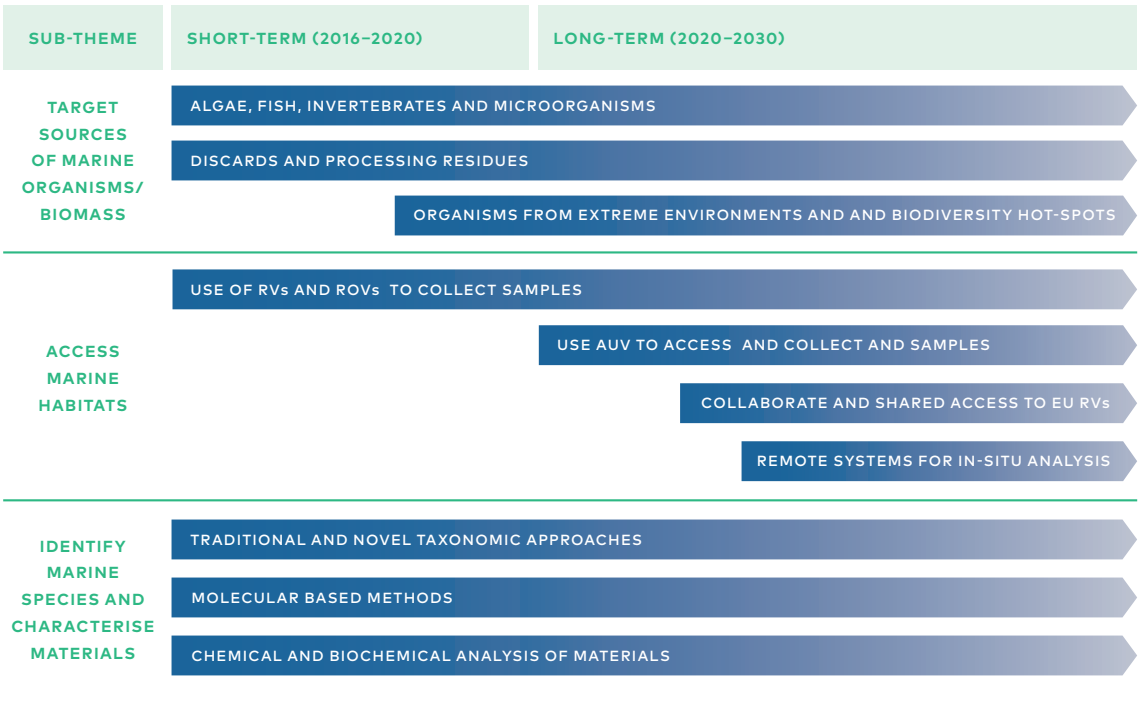


FIGURE 4 Exploration of the marine environment

Europe's reformed common fisheries policy places a new emphasis on extracting value from the catch. Similarly, though at a much smaller scale in Europe, seaweeds (macro-algae) are also being processed, having long been identified as sources of polysaccharides, minerals and other nutrients, whilst micro-algae have emerged as an important source of lipids. The utilisation of such biomass is likely to become well established in the long term.

There is a vast array of samples from marine organisms in repositories, though few countries maintain national repositories or biobanks for marine materials. This immediate research opportunity to explore and profile these samples is likely to be a long-lasting research challenge, set to benefit from new analysis and screening techniques. The collection of new samples from targeted marine areas will gradually add materials to existing repositories. Technological developments such as molecular systematics are likely to support novel approaches to taxonomy, strengthen the understanding of marine organisms and increase the capacity to explore the accumulated samples.

Accessing remote marine environments will be supported by technological developments. Already the collection of marine samples from deep waters is a task performed by remotely operated vehicles (ROVs). The introduction of more advanced sampling and identification techniques will accelerate the exploration process. New generations of autonomous under-water vehicles (AUVs) to access and collect samples may be combined with remote systems for in-situ analysis, adding additional capacity to support long-term research and enabling more rapid screening of marine compounds.

BIOMASS PRODUCTION AND PROCESSING

The challenge of sustainability is highlighted as a major component within this thematic area. Research and innovation sub-themes comprise the capture and use of wild species, the cultivation of marine species and the subsequent transformation or refining of marine biomass. The capture of wild species as an input to bioprocessing has to be sustainable and achieved without creating adverse impacts on the marine ecosystem.

The capture of wild species as an input to bioprocessing has to be sustainable and achieved without creating adverse impacts on the marine ecosystem. The bulk of the *wild* harvested species comprises fish, crustaceans and macro-algae. In the short term, a more selective targeting of species including, where feasible, the sustainable harvesting of macro-algae is required. In the long-term, species considered as "invasive species" and entirely new species identified during bioprospecting, may become valuable sources of useful biomass.

The *culture* of marine organisms is confined to the production of finfish, shellfish and to a lesser extent algae (macro-algae) in near-shore aquaculture activities. Some species of micro-algae are established as a recognised source of lipids and other high value products (e.g. pigments) and are cultured in land-based bioreactors. It is expected that these activities will continue with production levels increased and expanded to include new species and new culturing regimes where this is possible. Offshore and deep water aquaculture and integrated multi-trophic aquaculture (IMTA) are active research topics. Changes in culturing processes are likely to expand the use of cultured biomass from food to include non-food use as well as develop new sources of feed. Marine biotechnology, including new breeding and genomics, is set to support more diverse and productive culturing of marine organisms. This optimised approach is a long-term opportunity that could open the way for the production of specific high-value compounds from selected species. The conversion of marine biomass, whether from wild or cultured sources into useful fractions capable of supporting an array of product applications, is a

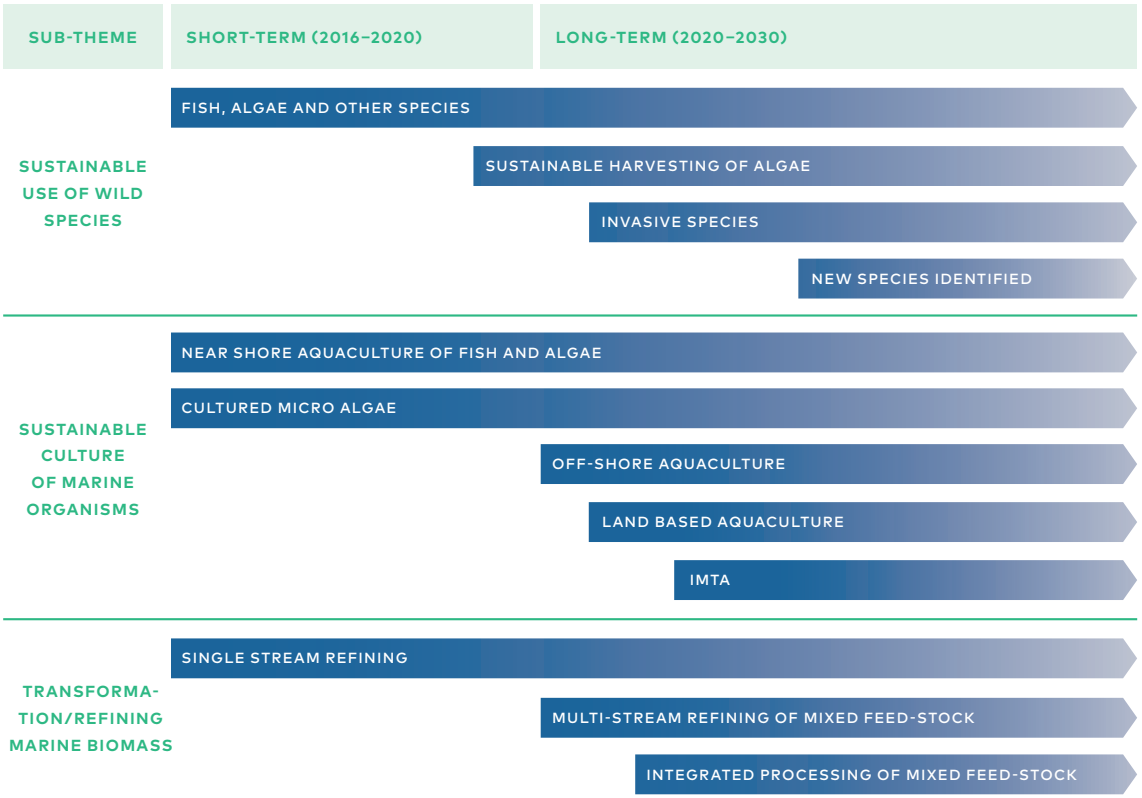


FIGURE 5 Biomass production and processing

transformation process. Such processes, including bio-processing, should be sustainable, minimise waste, be energy efficient and carbon neutral, and operate without any negative environmental impact. In the short-term, these requirements will result in a move from single-stream refining towards multi-stream biorefining, to become fully embedded in new biorefining processes. Long-term activities include the development of processes that allow the integration of the production and processing of marine biomass and the creation of biorefineries capable of processing of mixed/multiple feedstock.

PRODUCT INNOVATION AND DIFFERENTIATION

Human and animal health products, food and feed products, industrial products and processes, and environmental measures are sub-themes within this thematic area. The two first sub-themes focus on the development of nutrition and healthcare products for human and animal markets. Food, feedstock and other agri-products, nutritional supplements, nutraceuticals, functional foods and cosmetics will remain research targets. The sub-themes also include products that offer longer-term opportunities such as pharmaceuticals, therapeutics and biocompatible materials. Developing new pharmaceuticals and other medical applications is typically a lengthy and highly regulated process that is known to take up to

30 years from discovery to final product approval. Technological advances will have a strong influence on the extent to which it may be possible to reduce time to market for marine origin health products. Human and animal wellbeing, including the development of customised diets follow-on from marine-derived prebiotic and probiotic products and identified as offering long-term potential. Maintaining the health of animals used in the human food chain is a global priority and hence is identified as a long-term activity.

Marine compounds are already used in cosmetic and cosmeceutical products. Identified as an expanding global market, opportunities for greater use of marine compounds in these products exist and as such span short- and long-term horizons of the roadmap.

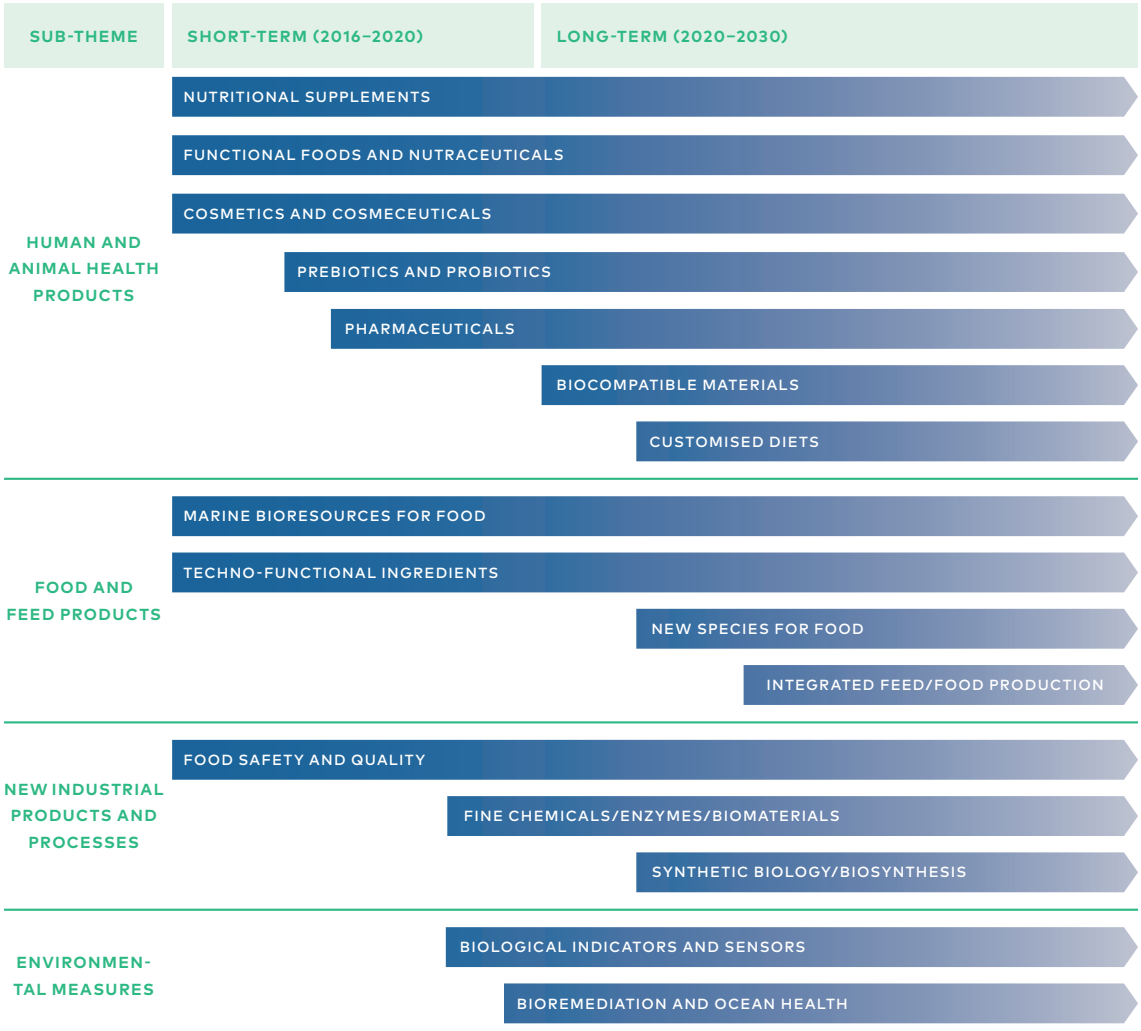


FIGURE 6 Product innovation and differentiation

The search for new food and feed products is expected to continue in response to projections of increased global populations and the associated demand for new protein sources. The capacity of the marine area to support these areas is likely to be challenged unless new sustainable feed to support aquaculture and species diversification is developed. An integration or combination of food and therapeutics is seen as a long-term target; strongly connected to the increased use of marine compounds in functional foods and ingredients. Exploiting the physical-chemical properties of marine compounds such as gelling agents, pigments and fibre derived from algae, and collagen from fish is set to continue. New approaches to support long-term marine foods production include shortening the supply chain by integrated feed/food production systems.

New concepts of biorefining marine biomass will enable the development of fine chemicals, enzymes and biomaterials. The short-term focus is on applications that enhance food safety and quality, whilst longer-term targets include customised products based on optimised bioprocessing. Scope also exists to maximise the potential of synthetic biology to contribute to the development of novel marine biological systems and processes.

The known potential of marine biotechnology to contribute to the development of sensors and biological indicators is a lasting opportunity. Using marine organisms, or derived products and processes for bioremediation are important long-term opportunities closely linked to efforts to improve interactions between human activities and the oceans in general.

ENABLING TECHNOLOGIES AND INFRASTRUCTURE

The availability of a relevant and accessible research infrastructure comprising physical and human resources and capabilities is essential to continue the development and utilisation of outputs from marine biotechnology. Though scientific and technological developments have evolved to explore marine environments, the need to enhance the array of physical, chemical and genetic analytical tools, on which marine biotechnology relies, remains. Increasingly, marine biotechnology relies on scientific and technological developments from other disciplines. The provision of new and improved infrastructures can lead to the creation of new scientific expertise, stimulate research activity and facilitate greater collaboration.

Providing marine biotechnology with access to enabling technologies and infrastructures is

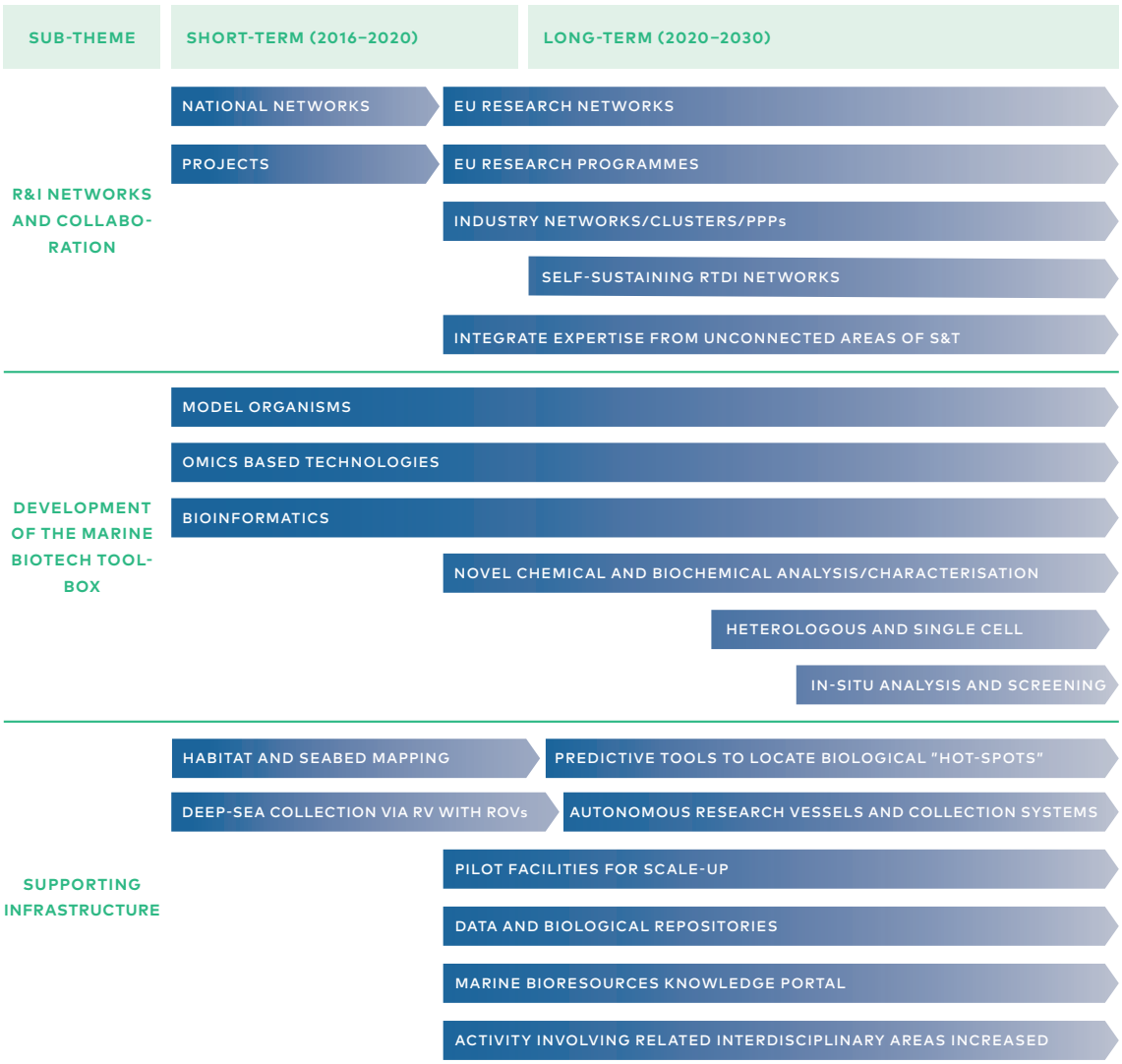


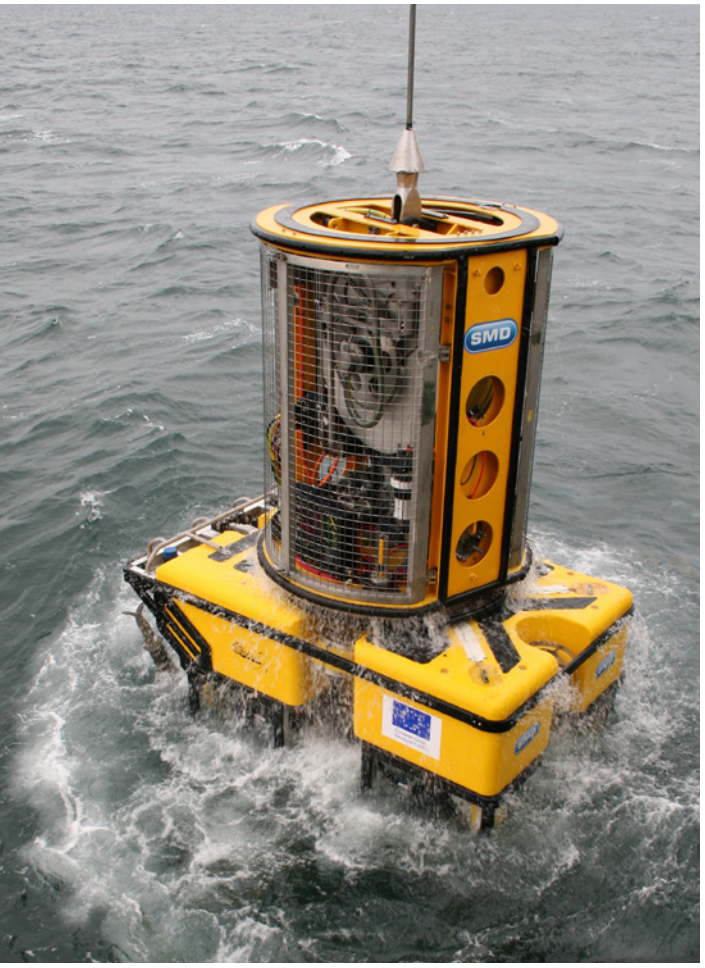
FIGURE 7 Enabling technologies and infrastructure

underpinned by activities within three connected sub-themes — research and innovation networks; the development of tools and methods; and providing the supporting infrastructure.

At the core of these sub-themes is the development of the suite of analytical tools and methodologies to explore and characterise marine organisms. Some "tools" exist, and already support marine biotechnology, whilst others are yet to be fully utilised or customised for specific use. The ERA-MBT survey of research infrastructure identified opportunities to improve the research environment by providing better access and strengthening collaboration. In the short-term, there is a focus on building national and industry networks, clusters and public-private partnerships such that they become a foundation for long-

term improvements. These include the creation of self-sustained marine biotechnology research and innovation networks that are closely associated with and facilitate the integration of expertise from currently unconnected areas of enabling technologies.

A major opportunity to enhance the marine biotechnology toolbox is by the widespread adoption of rapid screening and "–omics" technologies. This will increase the capacity to explore and characterise marine organisms and compounds. Though there are examples where these tools are used, a long-term challenge is to expand their use. New developments including in-situ analysis and screening, heterologous single cell approaches and biosynthesis are long-term priorities. Current interest in model organisms and novel bioassays from marine organisms is likely to remain.



In parallel with the development of the "toolbox", there is a need to continue to provide physical infrastructures. Some of these such as pilot facilities to scale-up from laboratory scale are process oriented, whilst further development of sample collection systems, and making data from biological repositories more widely available are discovery related, however, all require long-term support.

Existing habitat mapping of marine areas is set to continue and be expanded in the long term to include all Europe's marine territories. This knowledge will support the development of predictive tools designed to identify marine biological "hotspots". Meeting this long-term challenge will improve the efficiency of sampling, as will the development of autonomous research vessels.

A lasting challenge is the dissemination of knowledge about marine bioresources, research capabilities, equipment and facilities, all of which are essential in realising the benefits from increased marine biotechnology activities. The current and largely informal information and knowledge infrastructures could be developed into a dedicated marine bioresources/biotechnology knowledge portal.

POLICY SUPPORT AND STIMULATION

This theme concerns policy issues relevant to the governance, regulation and stimulation of marine biotechnology activities. It is a theme that will draw from knowledge generated elsewhere and apply it to develop policy measures that support the role of marine biotechnology in exploiting marine bioresources. Research activities conducted across other thematic areas will inform policy and other

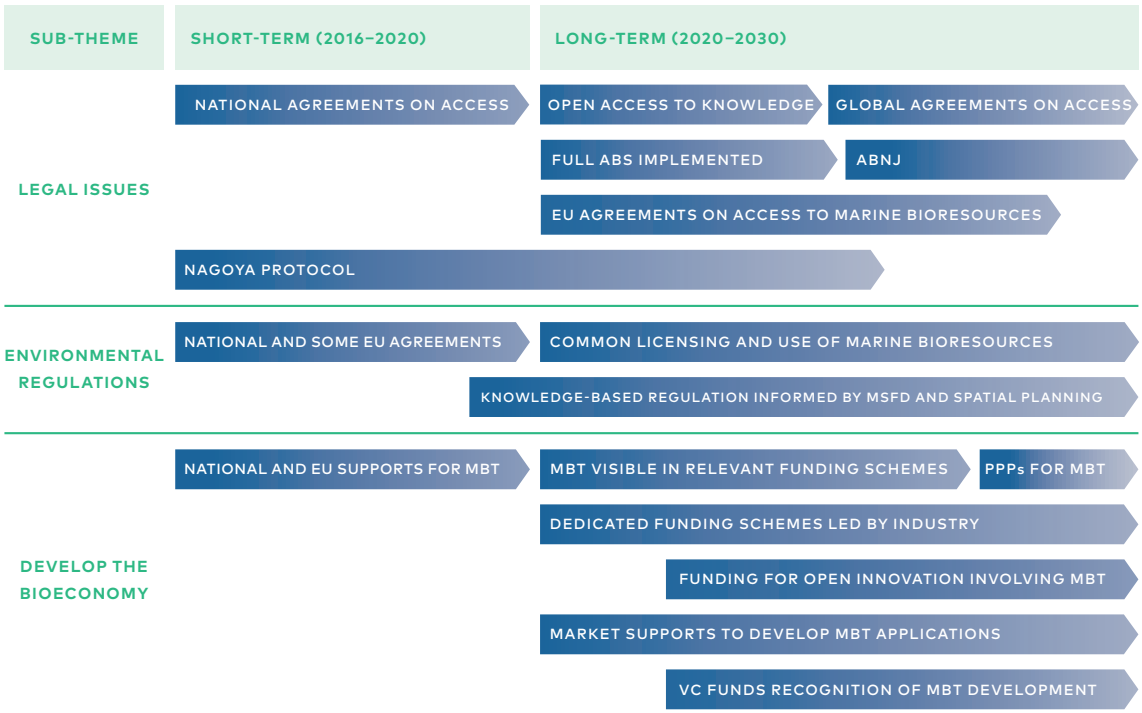


FIGURE 8 Policy support and stimulation

measures relating to the legal and environmental frameworks within which marine biotechnology operates. In addition, such research outputs will strengthen the use of marine biotechnology in driving economic and societal development. The strong emphasis of marine biotechnology research on the sustainability of marine environments and bioresources enhances the positive image of marine biotechnology. Policy decisions will influence decision-making around funding and other initiatives designed to expand the contribution of marine biotechnology to Europe's bioeconomy.

With a projected expansion of exploration activity, the overarching legal issues concern access to and ownership of biological resources from marine areas. The Convention on Biological Diversity (CBD) and the Nagoya protocol – a supplementary agreement to the CBD, provides the basic framework for national and international agreements in this regard and are likely to continue to do so. Regulations concerning Access and Benefit Sharing (ABS) are likely to become relevant in parallel with the development of the marine bioeconomy. Despite the need for actions to protect and preserve marine biodiversity and ocean resources, the implementation of full ABS is set to remain a long-term activity, as are international agreements for ABNJ (Areas Beyond National Jurisdiction).

Environmental regulations, including the introduction of common licensing systems for harvesting marine resources, are short-term priorities. Systems as these can be further enhanced by knowledge captured during the implementation of the Marine Strategy Framework Directive (MSFD), to become enablers of sustainable marine biotechnology activity. Marine spatial planning activities are also likely to influence marine biotechnology related activities, and open the way for new biotechnology driven opportunities.

Marine biotechnology related activities benefit from direct and indirect national and EU support. However, new and more substantial initiatives are needed to accelerate the uptake and impact of marine biotechnology in Europe. Changes in existing funding initiatives could facilitate such developments. In building on increasing market success, support should be such that funding schemes respond to, and encourage new marine biotechnological developments, including the participation by industry in research projects. Such actions could provide venture capital funds with the confidence to recognise marine biotechnology as a central, enabling technology in the creation of high-potential, enduring investment areas based on the use of marine biological resources. Until marine biotechnology literacy has improved, this type of investment remains a long-term challenge. Other mechanisms to expand the role of marine biotechnology in the broader bioeconomy include funding to encourage open innovation and the creation of dedicated public-private partnerships (PPPs) where marine biotechnology is recognised as an enabler of enterprise activity.

THE WAY FORWARD FOR MARINE BIOTECHNOLOGY — IMPLEMENTING THE ROADMAP

ERA-MBT operates until the end of 2017 by which time it should give direction to the future development of marine biotechnology research and innovation. A major goal of ERA-MBT is to position marine biotechnology within a self-sustained enterprise driven network that is supported by national and European funding agencies. Reaching this goal delivers the vision for European Marine Biotechnology set by the ESF-Marine Board in its 2010 position paper[34], that sought to create by 2020,

"... an organised, integrated and globally competitive European Marine Biotechnology sector that will apply, in a sustainable and ethical manner, advanced tools to provide a significant contribution towards addressing key societal challenges in the areas of food and energy security, development of novel drugs and treatments for human and animal health, industrial materials and processes and the sustainable use and management of the seas and oceans."

The ERA-MBT roadmap identifies marine biotechnology as a key to the sustainable exploitation of marine biological resources. It offers new sources of materials, and as an emerging high-potential element of the bioeconomy is set to stimulate growth and create new jobs by exploiting the potential of marine biological resources in many different industry sectors.

As an emerging opportunity area, marine biotechnology supports the achievement of the objectives of Blue Growth[35], the Bioeconomy Strategy for Sustainable Growth[36] and hence contributes to Europe's plans to develop a bioeconomy.

The ERA-MBT roadmap provides a framework for marine biotechnology related research and innovation activity up to 2030; it builds upon current knowledge and achievements and identifies future research and innovation opportunity areas. The holistic approach adopted in developing the roadmap ensures its relevance in supporting Europe's long-terms commitment to addressing economic, environmental and societal challenges.

The roadmap will be useful to national and European organisations in developing policy measures to address the challenges of each thematic area, and those funding agencies that provide supports to encourage marine biotechnology. Within the ERA-MBT, the roadmap will inform "calls" for research proposals.

APPENDIX 1

THE ROADMAP PROCESS

This roadmap for marine biotechnology was developed by the ERA-MBT project between October 2014 and March 2016. The aim of the process was to identify the research and innovation activities required to the year 2030.

Developing long-term plans typically involves obtaining contributions from wide stakeholder groups. The ERA-MBT employed four different approaches to secure creative, robust and relevant views concerning future marine biotechnology research and innovation as outlined below in *Figure 9*.

The extensive desk study of marine biotechnology activities provided insights into the current status

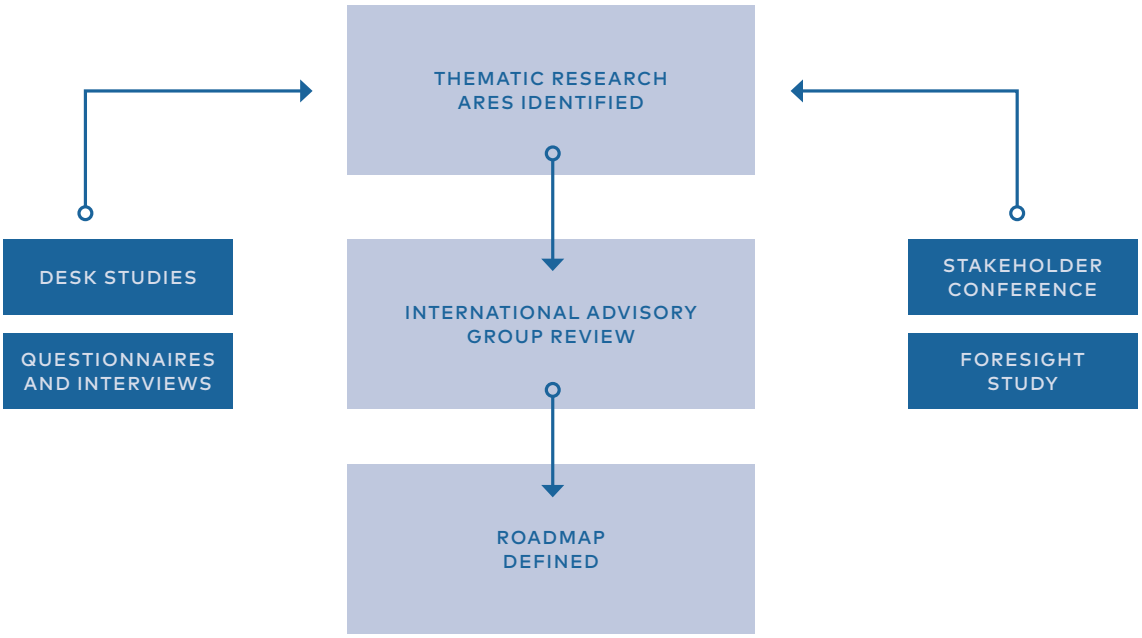


FIGURE 9 Sources informing the development of the research roadmap

of relevant and related RTDI activities. This review also took account of various national and European policies that had created the environment, within which marine biotechnology activities could develop. In addition, it identified a vast array of research and innovation programmes and projects targeting the discovery and exploitation of various forms of marine biomass.

The ERA-MBT project stakeholder event in 2014 yielded a broad consensus on future research opportunities, bottlenecks and actions required to continue to drive European marine biotechnology activities. In parallel, ERA-MBT launched an online survey for stakeholders to identify research needs and uncover factors that inhibit innovation. A series of targeted telephone interviews with firms across EU member states validated the findings of the survey.

Finally, the ERA-MBT project conducted a foresight-type exercise, termed "OUTLOOK". This exercise recruited a panel of 14 experts from various disciplines associated with marine biotechnology and challenged them to identify the most important factors influencing the future application and use of marine biotechnology. The OUTLOOK panel created possible future scenarios and proposed thematic research areas required to stimulate marine biotechnology product and process innovation.

The roadmap developed by the ERA-MBT project and presented in this report results from the convergence and analysis of the various stakeholder contributions and expert opinions and identifies areas of marine biotechnology research required to maximise the contribution of marine bioresources to the European bioeconomy and help to address Europe's grand societal challenges.

APPENDIX 2

MARINE BIOTECHNOLOGY ERA-NET (ERA-MBT)

About ERA-MBT

ERA-MBT brings together 19 partners from 14 countries across Europe to work with stakeholders in identifying marine biotechnological needs and gaps in the value chain in an attempt to increase the valorisation of marine bioresources. The ERA-MBT project was launched in December 2013 and will operate until the end of 2017.

Marine biotechnology can create value from marine bioresources, however, to do so requires the current level of collaborative research in this area to expand. Measures that encourage expertise from the marine related biological and chemical sciences to work more closely with other areas of science and technology are necessary to achieve such collaboration. Research capacity, knowledge and resources, including research infrastructures, are needed to fully engage in marine biotechnology. To further develop marine biotechnology research and innovation capacity and capabilities, Europe should target efforts towards finding and exploiting competitive niches. The trans-European collaboration planned by ERA-MBT aims to build synergies and create greater value for the money through coordinated European funding and by prioritising research and innovation activity within this area.

ERA-MBT goals

The objectives of ERA-MBT are to:

- **Stimulate trans-European marine biotechnology research, innovation and enterprise activity.**
- **Build communities and capacity considering the maritime regions' different perspectives and potential.**
- **Deliver a lasting network to fund and support marine biotechnology research and enterprise activity.**
- **Further increase the level of coordination between European research funding bodies in the area of marine biotechnology.**
- **Seek complementarities between national and international activities.**
- **Pool resources to undertake joint funding of trans-national RTDI projects.**
- **Increase the awareness of marine biotechnology as an enabler for value creation from marine biological resources.**

The ERA-MBT is designed to enhance the coordination of marine biotechnology related research funding programmes at international, national and regional levels. By building on the achievements of the Coordination and Support Action in Marine Biotechnology — CSA MarineBiotech, ERA-MBT aims to draw attention to new research and innovation opportunities and create new funding initiatives to direct research towards priority areas. ERA-MBT will launch at least three transnational calls for research proposals; these will be informed by stakeholder feedback and the development of a strategic roadmap for marine biotechnology research and innovation.

Achieving the broad goals of ERA-MBT requires a detailed understanding of the key drivers and other factors that will influence the future development of marine biotechnology. The ERA-MBT will initiate a series of actions to inform this understanding including,

- **Performing various desk studies**
- **Hosting stakeholder events and undertaking surveys**
- **Completing a foresight exercise**
- **Developing a research and innovation roadmap**

These activities contribute to the core elements of ERA-MBT, principally the initiation of joint calls for research in priority areas and laying the groundwork to build a sustainable network of funding agencies that are committed to continue developing marine biotechnology related research and innovation actions.

More details concerning the ERA-MBT are available at **www.marinebiotech.eu**.

ABBREVIATIONS

ABS	Access and Benefit Sharing
ABJN	Areas Beyond National Jurisdiction
AUV	Autonomous Underwater Vehicle
CSA	Coordination and Support Action
DNA	Deoxyribonucleic acid
EC	European Commission
ERA-MBT	Marine Biotechnology ERA-NET
ERA-NET	European Research Area Network
EU	European Union
IMTA	Integrated Multi-Trophic Aquaculture
MBT	Marine biotechnology
MSFD	Marine Strategy Framework Directive
OECD	Organisation for Economic Co-operation and Development
OUTLOOK	The ERA-MBT foresight process
PPP	Public–Private Partnership
ROV	Remotely Operated Underwater Vehicle
RTDI	Research, Technological Development and Innovation
SME	Small and Medium-sized Enterprise
UNCLOS	United Nations Convention on the Law of the Sea

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LIST OF AGENCIES

The Marine Biotechnology ERA-NET is a consortium of 19 national funding bodies representing 14 countries seeking complementarities between national activities and resources to undertake joint funding of transnational projects in the area of Marine Biotechnology.

Agentschap Innoveren en Ondernemen — **VLAIO**, *Belgium*
Executive Agency for Higher Education, Research, Development and Innovation Funding — **UEFISCDI**, *Romania*
Federal Ministry of Education and Research — **BMBF**, *Germany*
Flanders Marine Institute — **VLIZ**, *Belgium*
Foundation for Science and Technology — **FCT**, *Portugal*
Icelandic Food and Biotech R&D Institute — **MATIS OHF**, *Iceland*
Innovation Fund Denmark — **IFD**, *Denmark*
Innovation Norway — **IN**, *Norway*
Marine Institute — **MI**, *Ireland*
Ministry of Education, Science and Sport — **MIZS**, *Slovenia*
National Research Council — **CNR**, *Italy*
New Caledonia Economic Development Agency — **ADECAL**, *New Caledonia*
Region Västra Götaland — **VGR**, *Sweden*
Research Centre Jülich — **JÜLICH**, *Germany*
Spanish Ministry of Economy and Competitiveness — **MINECO**, *Spain*
Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning — **FORMAS**, *Sweden*
The Icelandic Centre for Research — **RANNIS**, *Iceland*
The National Center for Scientific Research — **CNRS**, *France*
The Research Council of Norway — **RCN**, *Norway (Coordinator)*

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