Study in support of Impact Assessment work on Blue Biotechnology

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Policy Context

There is currently no overarching Blue Biotechnology policy or strategy in Europe as a whole although Ireland, Denmark and Norway already have national policies in place. A number of strategic documents have been published as an outcome of science policy and research initiatives which have been implemented over the last decade or so. These have laid the foundations for a future vision and strategy for Blue Biotechnology across Europe. This activity has provided Europe with a future direction for Blue Biotechnology which addresses coordination and collaboration within Europe, identified research priorities, defined common interests within Europe, and highlighted the opportunities and potential for marine biotechnology as well as identifying some challenges to the growth of a Blue Biotechnology sector.

The European Commission has acknowledged the potential of Blue Biotechnology in Europe through its Communication on Blue Growth[1] and European Bioeconomy Strategy[2], both of which identify Blue Biotechnology as a sector which has the potential to contribute to the bioeconomy and economic growth in general. Furthermore, EU research policy has been responsive to the growing awareness of the importance of Blue Biotechnology: the EU has funded, and will continue to fund, key research into marine biotechnology through its Framework Programmes for Research: FP6, FP7 and Horizon 2020. The EU's new Horizon 2020 strategy and support programme[3] specifically mentions Blue Biotech and marine biomass as contributors to the economy of the future. There have been major projects under FP6 and FP7 that have been focused on science policy, coordination, infrastructures and support of marine biotechnology, the outcomes of which provide key contributions to developing a European strategy.

This study was conducted in support of the development of potential policy options for the EU and a possible impact assessment for marine or Blue Biotechnology as it can be termed in the context of furthering the aims of Blue Growth. To this end, a review of the status of Blue Biotechnology within the EU has been conducted along with the construction of a database of stakeholders in Blue Biotechnology and a patent profiling across the field. Furthermore, a stakeholder workshop has been held in order to obtain direct inputs from participants regarding opportunities and challenges of the sector. Additional views have been obtained from of the EU public consultation on the initiative.

State of Play: Importance of Blue Biotechnology

The Blue Biotechnology sector is diverse and encompasses a number of sub-sectors in which marine biotechnology applications are used. There are overlaps between the Blue Biotechnology and other biotechnology sectors and industries. However, there is a defining and unique characteristic of the Blue Biotechnology sector and that is its use of resources of marine origin. Processes and actions specific to this help define it and allow it to be distinguished from other biotechnology sectors.

[1] European Commission, 2012, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Blue Growth: Opportunities for marine and maritime sustainable growth, COM (2012) 494 final

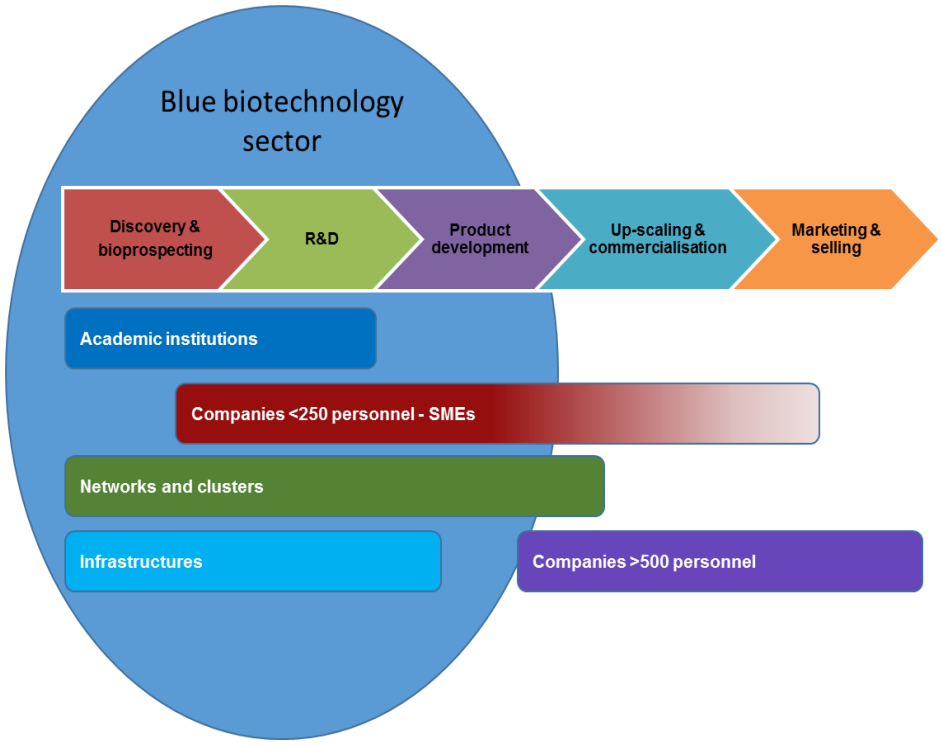
[2] European Commission, 2012, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Innovating for Sustainable Growth: A Bioeconomy for Europe, COM (2012) 60 final

[3] European Commission, Horizon 2020 Work Programme 2014-2015 in the area of Food security, sustainable agriculture and forestry, marine and maritime and inland water research and the bioeconomy, Important notice, http://ec.europa.eu/programmes/horizon2020/h2020-sections

Due to the lack of a clear definition and statistical delineation of the Blue Biotechnology sector, it is difficult to determine the economic value and the employment it creates. However, an extrapolation from the whole EU bio-economic sector, based on a conservative estimate that marine biotechnology accounts for 2-5% of the sector as a whole, leads to an annual turnover in the range of € 302 – 754 million. The annual growth rate of the EU Blue Biotechnology sector revolves around 4-5%, somewhat below that of biotechnology as a whole (6-8%). Based on the stakeholder database developed in the context of this project, overall employment is currently expected to be in the range of 11,500-40,000 people employed – with productivity ratio's leaning towards the lower end of the boundary. The importance of these employment data is above all derived from the fact that these tend to be high-end jobs which are the product of considerable public investment in education and training.

Blue Biotechnology products pass along a value chain with the value and potential return from the product increasing as it becomes transformed by biotechnological techniques (Figure 1). The Blue Biotechnology sector would not necessarily encompass the whole of the value chain; once the stages or processes in the value chain become part of the wider industry they are separated from the marine component and should no longer be considered part of a Blue Biotechnology sector *per se*.

Figure 1 **The value chain stakeholder composition in the marine biotechnology process.**



A Blue Biotechnology sector could also be defined through current marine biotechnology stakeholders. Building on the value chain approach, the position of key stakeholders in the Blue Biotechnology value chain and/or the types of activity can then be considered (i.e. R&D, production, services and marketing) is considered.

Marine bioprospecting can involve difficult and expensive marine research infrastructure (MRI) such as research vessels in order to reach deeper oceans and more extreme marine environments. Material so obtained is passed to R&D marine laboratories which, in the EU, are mostly in public

funded universities or institutes. The costs of bioprospecting may be significant. There is also considerable public investment in the science with € 130 million having been allocated under Framework 7 and an increased allocation through Horizon 2020 which could reach € 350 million. Europe has an array of marine research infrastructures and there are a number of initiatives and networks in place which aim to coordinate their efforts and facilitate access to them. The recently launched Marine Biotechnology ERA-NET is one such initiative which will promote and coordinate collaboration between national and regional research funding organisations as well as SMEs. However, stakeholders still report that access to Blue Biotechnology infrastructure is limited.

SMEs are an important aspect of the Blue Biotechnology chain as they play a key role bridging the gap between public sector R&D activities and commercialisation of products, mainly by large private, often multinational, companies. Their role is the identification, validation and de-risking of industrial opportunities from marine bioresources. They are often single-focus marine bioactives companies and thus contribute to the 'Blue' sphere. SMEs tend to be placed at the initial product development stage of the value chain, essentially the high risk 'cash-burn' phase where the screened products, often lodged in 'biobanks' are transformed into bankable potential products for up-scaling and commercialisation. Due to the risks involved, financing – often but not always from venture capital – is unpredictable and fickle. As a consequence these SMEs are very vulnerable; for example there has been a 17% fall in venture capital investment since 2008. This interface between the SMEs and the commercial is emerging as one of the weakest links in the chain.

The European Blue Biotechnology sector appears to be strongest in its R&D effort, as demonstrated by their contribution of 25% of all global publications on the topic. However the contribution to world patents, as an indicator of economically commercial products, is only 13%, mainly taken out by large private sector companies.

The uptake of commercial products of marine origin is spread across diverse and dynamic sub-sectors including health, cosmetics, food, energy, aquaculture and marine environmental services (including bioremediation). These sub-sectors are at different stages of development and have encountered different stages of growth to date. A huge array of potential products and services across all of the sub-sectors has been identified, which demonstrates the potential of the Blue Biotechnology sector. These are reviewed in the report. The greatest users of Blue Biotechnology products in commercialisation are the health, cosmetics and food sub-sectors with most products having a large expected societal as well as economic value.

Underlying problems and barriers

Within the context of the project three fundamental sources are being used to identify the underlying problems and barriers, these are:

- Literature review and desk-based research;
- Stakeholder information provided via the international workshop; and
- Stakeholder information provided via the public consultation.

Overall the study identified that the EU Blue Biotechnology sector is not living up to its full growth potential. This limited potential is considered to be the result of a range of barriers that are particular to the EU Blue Biotechnology sector:

- Difficulty in sampling the huge diversity of resources;
- Potential high cost of sampling some of these;
- The consequent preponderance of public funding for Research and Development;
- The complexity of property rights under marine governance mediated by UNCLOS;
- The lack of clarity on the mechanism for benefit sharing particularly in marine systems re Nagoya;

- The uncertainty of the status of genetic resources in Areas Beyond National Jurisdiction;
- The dependence upon SMEs to translate R&D results into a marketable product for commercialisation;
- The high risk and vulnerability of SMEs; and
- Problems of economic data availability within a poorly defined sector.

The regulatory review carried out pointed to a number of barriers that are cross-cutting and interwoven. They relate to Access and Benefit Sharing (ABS) from the discovery of new marine bioactives both on the high seas in Areas Beyond National Jurisdiction (ABNJ) as well as between states with joint efforts. The lack of clarity can cause legal uncertainty regarding the source and traceability of marine resources used in Blue Biotechnology products thereby increasing the risks to investment. The existence of these barriers along with the lack of clarity also has implications for policy in overcoming these barriers to release the potential of Blue Biotechnology across the EU.

Objectives and policy options

Based on the general problems as identified above, the following general objectives have been identified. These are objectives that the policy aims contribute to:

1. Enhance cooperation across the value chain;
2. Facilitate access to knowledge and exploratory infrastructure;
3. Facilitate access to finance across the value chain; and
4. Facilitate access to resources.

A closer analysis of the general objectives allows a larger number of possible specific objectives to be identified. These specific objectives are crucial as they set out what the policy interventions are expected to concretely achieve. Four specific objectives have been selected on the basis of the underlying evidence, the importance considered by stakeholders, and the scope for EU action.

1. Enhance cooperation between research institutes, SMEs and businesses involved in up-scaling;
2. Promote integration of exploratory infrastructure for bioprospecting purposes;
3. Facilitate access to finance for second and third round product development stages; and
4. Improve clarity and completeness of legal framework.

For each of these specific objectives, a number of operational objectives have been defined, analysed and then translated into policy actions.

Policy options

A number of areas of potential EU approaches have been put forward by the European Commission to guide sector development towards meeting the above detailed specific objectives. These include a baseline scenario, a soft option and finally a more stringent approach. These three options have been assessed in light of the problem areas and the specific objectives and have been amended with an additional option which promotes the mainstreaming and integration of Blue Biotechnology into the currently existing policy framework relevant for biotechnology as a whole.

The four broad policy options are as follows:

- Option 1: Baseline scenario/no additional action option;
- Option 2: Facilitation and promotion/soft measure;
- Option 3: Mainstreaming Blue Biotechnology; and
- Option 4: Formal policy measures.

The policy options have been analysed in view of their ability to address the specific problem areas and their potential economic, social and environmental impacts have been assessed and compared. Based on the results a selected number of policy actions – ones perceived to have the most significant impact - within the options have been retained for further analysis.

The analysis and comparison of options has shown that a combination of policy options 2 and 3 is likely to be the most effective, efficient and coherent when addressing the overall problems of the sector. The two policy options contain effective measures addressing the researchers, private enterprises and the financial investors thereby facilitating and increasing collaborations as well as improving the potential of enterprises to develop and market commercially viable products.

The combined impact of the proposed policy actions would – if well-designed and implemented - address the barriers specific to Blue Biotechnology in the EU. Opportunities provided by the financial instruments specifically targeting the growth of SMEs and the support of start-up companies in the field could contribute to a reduction of the brain-drain, especially so from the United States. The opportunities provided by bridging funds can effectively and directly support investment and aid private enterprises.

Taken together, these actions would eliminate or at least address the reasons why the annual compound growth rate of Blue Biotechnology (currently 4-5%) is less than that of biotechnology as a whole – currently up to 6-8%. Currently the European Biotechnology industry has an estimated annual revenue of € 15 billion while the Blue Biotechnology sector`s higher-end revenue generation is estimated to be around € 754 million. An estimated annual compound growth rate of Blue Biotechnology of 6-8% in 5 years could lead to an annual revenue generation of up to € 1 billion. This growth rate could effectively result in an increase in demand of high-end jobs as well as an increase of end-products. The employment increase in the Blue Biotechnology sector, given the ambitious overall growth rate, could amount to up to 10,000 additional work places in 5 years time. It would also help to boost the return on investment from previous, current and future R&D funding programmes already implemented or committed, especially so through the Horizon 2020 programme.

Most importantly, the wider impacts of the sector`s development can result in numerous inventions benefiting the wider society – including those in the areas of health, food, pharmaceuticals and energy.

1 Introduction and policy context

1.1 Background and Objectives

Background

Interest in marine biotechnology has grown in recent years due to the scientific and technological advances in the last decade that have led to an increased understanding of and access to marine bioresources. One notable area of development has been in 'omic' sciences and related technologies which have identified marine bioresources as important sources of new biological and chemical processes and products from which bioactive compounds can be isolated, modelled or created. Marine bioresources have such significant biotechnological potential due to their biological, chemical and genetic diversity. Marine biotechnology is slated to contribute to key global societal challenges of food and energy security, health and green growth and sustainable industries.

Objectives

The general objective of the study and of this report is to support the impact assessment process of the European Commission by providing information, data and specific analysis with the ultimate aim of deepening and further analysing the growth potential of the Blue Biotechnology sector. Thereto, the Commission has set forth three policy options that should be considered within the frameworks of the study, these are:

1) No policy change/baseline, which would mean that no consolidated action for the Blue Biotechnology sector would be developed at EU level;
2) A soft policy framework to foster the Blue Biotechnology sector in the EU through better analysis of the sector, promotion of dialogue and regional cooperation, as well as guidance to Member States and stakeholders on best practices on how to overcome the main challenges and obstacles; and
3) A more stringent consolidated European strategy for the Blue Biotechnology sector, including an action plan. This comprehensive strategy would include, where and if necessary, proposals for legislative action. It would also encompass a targeted communication approach specific to European Blue Biotechnology.

The methodology and approach to the study is detailed in the Inception Report which was submitted on 11th November, 2013.

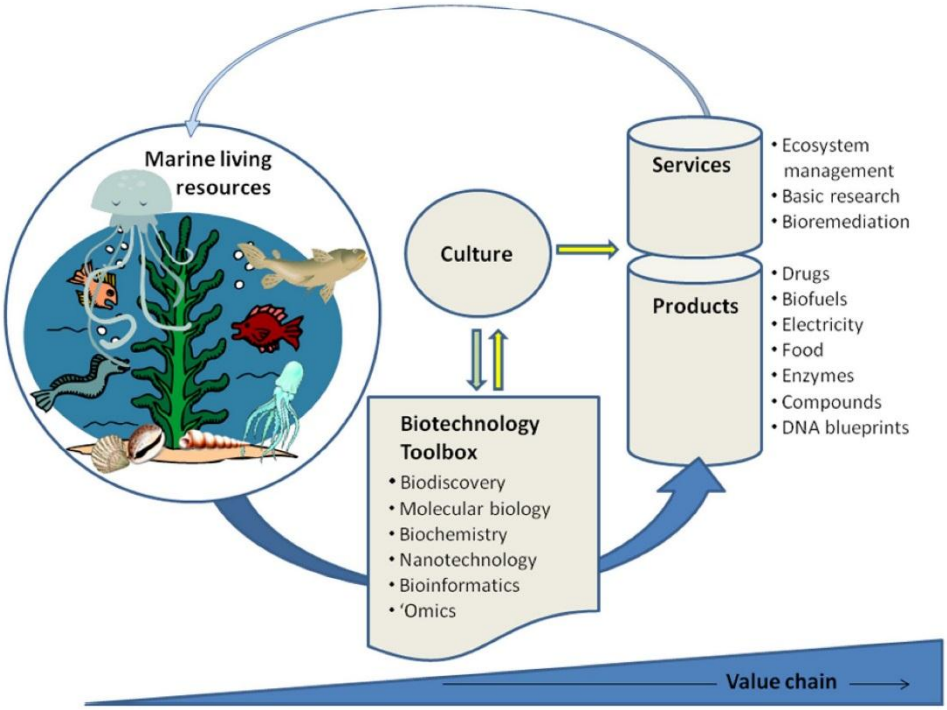
1.2 Definition of Blue Biotechnology sector

1.2.1 Definition of marine biotechnology

The OECD[4] broadly defines biotechnology as 'the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living and non-living materials for the production of knowledge, goods and services'. Marine biotechnology, put simply, is the use of marine bioresources as the target or source of biotechnological applications; marine resources are used to develop products or services, but the marine environment can also be the recipient of biotechnology applications developed using terrestrial resources. Figure 1.1 illustrates the 'field' of marine biotechnology and provides examples of the types of tools and technologies utilised and the resulting products and services.

[4] OECD, 2013, Marine Biotechnology: Enabling Solutions for Ocean Productivity and Sustainability, OECD Publishing. http://dx.doi.org/10.1787/9789264194243-en

Figure 1.1 Marine biotechnology[5]



Scope of study

For the purposes of this study we will focus on the transformation of marine bioresources (raw materials) by biotechnological processes and their application in the following sub-sectors: health, cosmetics, food, aquaculture, energy and marine environmental services. We will not be considering the application of biotechnology developed from terrestrial resources.

1.2.2 Defining the Blue Biotechnology sector

The term 'Blue Biotechnology' is used to be consistent with the classification of other biotechnology sectors such as white (industrial), green (agricultural), yellow (environmental) and red (health and medical). The delineation of the biotechnology landscape by coloured sectors is based on two different approaches: 1) processes (e.g. white, yellow, red, green biotechnologies), or 2) the part of the biosphere where the sector is sourcing the biomaterial. Blue Biotechnology sector is unique in that it is the only biotechnology sector to be defined in terms of its source material, rather than the processes it entails or the market it serves.

A Blue Biotechnology sector is not a clear cut sector as there are overlaps with other biotechnology sectors and industry sectors as discussed in Section 2.4. There is no official definition of the sector.

[5] OECD, 2013, Marine Biotechnology: Enabling Solutions for Ocean Productivity and Sustainability, OECD Publishing. http://dx.doi.org/10.1787/9789264194243-en

1.3 Policy context

There is currently no overarching marine biotechnology policy or strategy in Europe. However, a number of strategic documents have been published as an outcome of science policy and research initiatives which have been implemented over the last decade or so. These have laid the foundations for a future vision and strategy for marine biotechnology across Europe. This activity has provided the Europe with a direction for future marine biotechnology which addresses coordination and collaboration within Europe, identified research priorities, defined common interests within Europe, and highlighted the opportunities and potential for marine biotechnology as well as identifying some challenges to the growth of marine biotechnology.

The European Commission has acknowledged the potential of marine biotechnology in Europe through its *Communication on Blue Growth*[6] and *European Bioeconomy Strategy*[7], both of which identify marine biotechnology as a sector which has the potential to contribute to the bioeconomy and economic growth in general. Furthermore, EU research policy has been responsive to the growing awareness of the importance of marine biotechnology; the EU has funded, and will continue to fund, key research into marine biotechnology through its Framework Programmes for Research: FP6, FP7 and Horizon 2020. The EU's new Horizon 2020 strategy and support programme[8] specifically mentions Blue Biotech and marine biomass as contributors to the economy of the future. There have been major projects under FP6 and FP7 that have been focused on science policy, coordination, infrastructures and support of marine biotechnology, the outcomes of which provide key contributions to developing a European strategy.

A list of events and policy documents that are considered to have made notable advances towards a common approach to a marine biotechnology strategy in Europe is presented in Annex 1.

[6] European Commission, 2012, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Blue Growth: Opportunities for marine and maritime sustainable growth, COM (2012) 494 final

[7] European Commission, 2012, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Innovating for Sustainable Growth: A Bioeconomy for Europe, COM (2012) 60 final

[8] European Commission, Horizon 2020 Work Programme 2014-2015 in the area of Food security, sustainable agriculture and forestry, marine and maritime and inland water research and the bioeconomy, Important notice, http://ec.europa.eu/programmes/horizon2020/h2020-sections

2 State of play: Importance of Blue Biotechnology

2.1 Value chain of Blue Biotechnology

Although applications of marine biotechnology may be extremely diverse, the first steps of the supply chains all rely on the discovery of new marine organisms, the identification of interesting molecules and the definition of growing protocols allowing developing potential commercial usages of these molecules. A generic value or product development chain of marine biotechnology products and services is presented in Figure 2.1.

Figure 2.1 Generic value chain of marine biotechnology

Key components of the value chain that have been identified include:

1. **Discovery and bioprospecting**: investigating environments and collecting living organisms from these environments; making extracts of organisms; isolating genes from organisms; identifying active gene products; preliminary de-replication; establishing preliminary evidence for activity in some kind of lab-bench test; establishing uniqueness and proprietary position;
2. **Research and development**: taking extracts or fractions of extracts and identifying the molecular components; isolating specific genes and gene products and identifying their nature; de-replication of molecules and gene sequences/products; molecular characterisation of active molecules; structural identification; confirmation of proprietary position; synthetic strategies; validation of preliminary bioactivity in further tests;
3. **Product development**: sustainable production strategies; chemical synthesis; gene isolation, transfer to an industrially-utile organism and effective expression; demonstration of scale-up; stabilisation of production process; preliminary demonstration of cost-efficiency; Life Cycle Analyses; enough material to confirm and extend activity profile, to justify scale-up;
4. **Up-scaling and commercialisation**: industrial-scale and economic production of target organisms or molecules; validated and stabilised extraction, purification and derivatisation processes for target molecules, materials; positive economics for production;
5. **Marketing and selling**: Based on the end-products of the process, for example pharmaceuticals, enzymes, hydrocolloids, nutraceuticals, cosmetic ingredients, biomimetic materials etc.

The value chains appear to become sub-sector specific at the product development stage, prior to that (i.e. discovery/bioprospecting and R&D, and some elements of product development) appear common to all marine biotechnology applications and are a pre-requisite to the application of marine biotechnology in a particular industry. Product development is often a lengthy process and specific to the biotechnology or industrial sub-sector for which the application is destined. However once a product has reached the stage at which up-scaling and commercialisation is required the 'blue' component is reduced and stakeholders/actors involved are no longer specific to marine biotechnology but are part of other biotechnology or industry sectors. Therefore these stages are not an area of focus for this study.

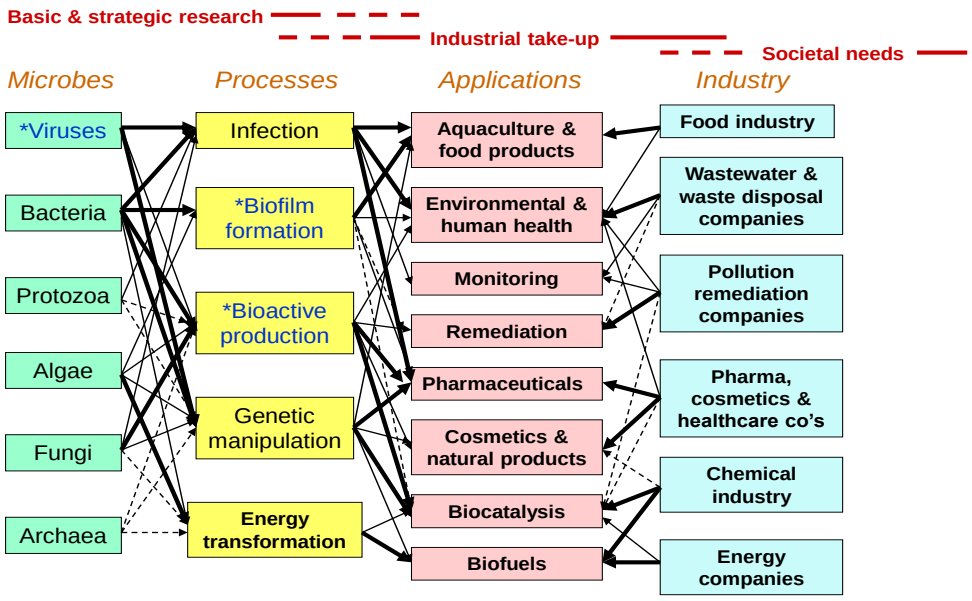
2.1.1 Discovery, bioprospecting and R&D- the blue components of the value chain

Bioprospecting is the search for interesting and unique genes, molecules and organisms from the marine environment with features that may be of benefit for society and have value for commercial development in a number of applications such as drugs/pharmaceuticals, industrial products/enzymes, fine chemicals, ingredients in food and feed, environmental bioremediation, petroleum and energy exploitation, and cosmetics. Organisms may be microscopic (bacteria, Archaea and other microbes; viruses; microalgae) or macroscopic (seaweeds, invertebrates such as sponges, sea-slugs, starfish; vertebrates such as shark, fishes, mammals, whales). Bioresources may include known genes from known organisms or meta-genomes, the totality of genetic material from samples containing unidentified organisms. Living organisms may also be harvested i.e. sourced *en masse*, such as seaweeds, fish etc., but if their characteristics and uses are known, there is no element of bioprospecting.

Bioprospecting can involve the collection of organisms as well as the subsequent screening for a specific molecule or activity of interest. An alternative to prospecting directly for bioactives is to search for DNA sequences encoding activities of interest, either from single organisms or by mining metagenomic sequencing data derived from marine organisms. Such approaches can help bypass a number of steps required in molecule screening.

Marine bioprospecting has tended to target macro-organisms such as corals and sponges because of their evolutionary diversity, but significant efforts have also targeted the deep ocean, particularly around hydrothermal vents because of the largely untapped biodiversity and unknown adaptations present in such extreme conditions. Current interest in bioprospecting in the oceans has been fuelled by the integration of high-throughput DNA sequencing methods to evaluate marine microorganism diversity and their gene repertoires. Such genomic data can provide a useful starting point to identify new enzymes involved in the biosynthesis of secondary metabolites.

Figure 2.2 The web of linkages from marine bioresources to industrial use[9]



[9] Acknowledgments to Dr P Williamson, UK NERC

The main risks at this level of bioprospecting (see Figure 2.2 above) are that too many novel organisms and molecules will be found, creating a bottleneck in screening, selecting and identifying desirable bioactivity; organisms containing novel molecules may not be culturable in the lab; even if culturable organisms may produce different molecules each batch that is grown; molecules may be too complex for chemical synthesis; genes may be isolatable but not expressed on transfer to a common industrial system; successful production of target materials is not replicable when culture is scaled-up. The risks here are cumulative, to the extent that end-users in industry may not see the opportunities in Blue Biotechnology. Small and medium sized enterprises (SMEs), whether facilitators or validators, need to be able to address this to enhance attractiveness for end-user investment.

Metagenomic techniques are currently seen as one of the major breakthroughs for screening organisms and biological material and allowing identification of new molecules in this process. Quite often certain organisms are targeted for study if there is reason to believe they will produce the type of molecules that are being searched for, such as:

- Pharmaceutical companies tend to target fixed organisms (shellfish, corals, tunicates, sponges etc.) that rely on chemical responses to combat other species to grow on them. Molecules discovered may limit cell multiplication, which could be used to combat cancer and as antibiotics;
- Chemical companies looking for antifouling solutions would follow the same approach as pharmaceuticals companies as they are searching for the same type of effect: blocking organisms growth processes;
- Bacteria producing biofilms that could be of interest for the pharmaceutical or plastics industry are usually found in extreme environment (extreme temperatures, high salinity etc.).

2.1.2 Closing the marine biotechnology loop: the 'blue' application of marine biotechnology'

Marine biotechnology is beginning to play an increasingly important role in the protection and management of the marine environment. The use of marine biotechnology products and services in the marine environment can be thought of as 'closing the loop, in the field of marine biotechnology (as presented in Figure 1.1). There are a range of potential marine biotechnology applications in the marine environment, including biofouling control, environmental monitoring, marine habitat restoration, bioremediation and natural resource and environment management[10]. While the majority of marine biotechnology applications in the marine environment are in their infancy, and activity is very much in the research and development phase, there is huge potential for products that can be used to improve the environmental health of the oceans thereby supporting marine ecosystem services.

2.2 Overall size and structure of the Blue Biotechnology sector

2.2.1 Size

Although the "Blue Biotechnology" keyword has been on top of political agendas for some years the lack of an official or commonly agreed definition of what the Blue Biotechnology sector is creates challenges in quantifying the extent of the sector. Without a unique entity in national or international statistics, interpretations of its boundaries and overall size vary. This creates difficulties in assessing the size and structure as well as socio-economic performance (as is discussed in Section 3.1.4). Despite this, it is worth trying to look at orders of magnitude of value of

[10] e.g. Giuliano L, Barbier M Eds. (2012) *New Partnerships for Blue biotechnology Development* CIESM Marine Policy Series 1 June 2012, CIESM Monaco ISSN 2306-4897

Blue Biotechnology as a guide to prioritising future investments and policy initiatives. Annex 2 provides a detailed approach towards valuing the Blue Biotechnology sector in Europe.

The only series of reports attempting to regularly define a value for the Blue Biotechnology sector is published by Global Industry Analysts, a market research agency, which forecasts that the marine biotechnology sector is to reach USD 4.1 billion (EUR 3 billion) by the year 2015 with a compound annual growth rate (CAGR) of 4%-5%.[11]. This is expected to rise further, reaching USD 4.8 billion (EUR 3.5 billion) by 2018[12]. Given these figures the study calculated that Blue Biotechnology contributes (at the moment) to about 2%-5% of the total Biotechnology industry[13]. Additionally, this means that in 2012 the size of the European Blue Biotech sector can be estimated to be between EUR 302 million - 754 million (in terms of revenues).

The OECD has recently released its first publication on marine biotechnology with a very cautious approach concerning market value estimates, as no global figures has been produced, but only topical examples of the potential global market value of specific products[14].

2.2.2 Structure

An analysis of a representative set of marine biotechnology stakeholders (see Annex 3) identifies nine institutions and/or organisation types with which stakeholders affiliated themselves. Of these, academic institutions i.e. universities or research institutes (conducting research in the field of marine biotechnology), companies with less than 250 employees i.e. SMEs and marine biotechnology networks or clusters are the key stakeholder categories. Companies with more than 500 personnel and infrastructure related institutions are also important stakeholder categories. The remaining stakeholders are categorised as policy makers, funding agencies, companies with between 250 and 500 personnel and outreach professionals. France, Netherlands, Germany and the UK have a larger proportion of stakeholders which can be attributed to the variety of stakeholders present in these countries.

Academic institutions

Universities and research institutions are integral to the discovery, bioprospecting and R&D stage of the value chain, and they are at the core of the fundamental research on identifying new species and molecules from various marine environments.

SMEs

As highlighted by the Blue Growth Marine Sub-Function Profile Report[15], a diversity of start-up and small companies are concentrating their development on niche markets: marine cosmetics, enzymes development, new bioplastics etc. SME stakeholders are not confined to only one area of activity or one position in the value chain, for example an SME may be active in research and development as well as production or services or marketing or all activities. As such, approximately 70% of SME stakeholders are active in R&D as well as being active in other areas. An in-depth review of SMEs in the field of marine biotechnology is provided in Section 3.1.5.

[11] Global Industry Analysts Inc. “Marine Biotechnology: A Global Strategic Business Report” 2011
[12] Global Industry Analysts Inc. “Marine Biotechnology: A Global Strategic Business Report” 2013
[13] Ecorys calculation based on triangulation of ratio of Marine biotech compared to the whole biotech industry in terms of revenue using table Ernst & Young; Biotechnology Industry report 2013
[14] OECD, 2013, Marine Biotechnology: Enabling Solutions for Ocean Productivity and Sustainability, OECD Publishing. http://dx.doi.org/10.1787/9789264194243-en
[15] https://webgate.ec.europa.eu/maritimeforum/system/files/Subfunction%203.6%20Marine%20mineral%20resource_Final%20v120813.pdf

Marine biotechnology networks and clusters

Networks and clusters tend to relate to scientists, coordination of research activities, and research infrastructures, and therefore can be linked to the first stages in the value chain. Further information on marine biotechnology networks, initiatives and clusters in Europe is provided in Section 3.2.2.

Companies with more than 500 personnel

Larger corporations tend not be specialised in or limited to marine biotechnology. They tend to be broader in scope, work in a specific biotechnology or industry sector and have links to marine biotechnology, either by working closely with specialised research centres, by creating them internally, by the development of dedicated teams or by acquiring small blue biotechnological companies to reinforce their activities. They play an important role in up-scaling and commercialisation of products and the marketing of these products.

Infrastructures

Infrastructure institutions refer primarily to marine research infrastructures (MRIs) as well as other marine infrastructures which support marine biotechnology activities and can be considered to underpin the discovery and bioprospecting, R&D and to some extent product development stages in the value chain.

2.3 Global settings of Blue Biotechnology

At the international level, Blue Biotechnology is mainly concentrated in three areas: the European Union, North America and the Far East Asia. CSA MarineBiotech[16] have identified the following countries as being relatively highly active in marine biotechnology: USA, Brazil, Canada, China, Japan, Republic of Korea and Australia. There is a small group of other countries where marine biotechnology activity is growing and is increasing in importance as a research priority, including Thailand, India, Chile, Argentina, Mexico and South Africa.

Most international competitors have not developed a specific Blue Biotechnology strategy embracing all aspects of the development of the sector. As CSA MarineBiotech[17] have highlighted, where countries have published strategy documents supporting the development of elements of the biotechnology sector, the “marine” aspect is almost non-existent. However, it should be noted that specific strategies/plans can have additional effects that contribute (for example) useful techniques and technologies to the entire Blue Biotechnology sector. In the sections below we examine the situation in other locations. Annex 4 provides an example if of the U.S. National Algal Biofuels Technology Roadmap which shows that what may be initially be seen as a narrow roadmap that may actually generate positive externalities to the rest of the Blue Biotechnology sector.

In Asia Blue Biotechnology is currently heavily reliant on biodiscovery and on the identification of new molecules to be brought to the market. For this purpose, developing capacities in bioinformatics is seen by some experts as one of the key elements for a dynamic sector within the region. In terms of infrastructure, there is a concern among some European researchers that several Asian countries may threaten the development of Blue Biotechnology in Europe through intensive developments in bioinformatics, notably DNA sequencing. For example, India is pushing heavily towards the development of a diverse biotechnology sector, by providing infrastructure, financial incentives (tax relief) and venture capital. It has branded one of its biotechnology clusters, located near Hyderabad (state of Andhra Pradesh), the “genome valley”. It is claimed that over 100 companies are concentrated close to this cluster, including key players such as US Pharmacopeia,

[16] http://www.marinebiotech.eu/images/Public_reports/Global%20landscape%20of%20Marine%20Biotechnology%20RTDI.pdf
[17] A New Wave of MarineBiotech, International Innovation Report October 2012. http://www.marinebiotech.eu/library

Dupont, Novartis and Sanofi (through Shantha Biotech). Other biotechnology clusters have been created in the country, notably in Bangalore (state of Karnataka), but also in the states of Maharashtra, Tamil Nadu and Kerala. Although these developments are not branded as "Blue Biotechnology", they provide a platform for blue development to be performed in India. It is feared that low sequencing costs in India and potentially other Asian countries could attract European companies to outsource their operations to Asian countries, weakening the European potential to develop its own bioinformatics sector.

In the current context, EU competitiveness (or lack of it) in the Blue Biotechnology sector lies in the support of R&D activities across the whole sector, notably in terms of the development of key infrastructure, financial support for companies developing research activities and capacities to access new organisms. One key element that appears to be profoundly influencing the capability of the European Blue Biotech sector is the ability of European researchers and companies to access new organisms for their research. With increasing competition between countries, it is feared that access to potential material, notably from extreme environments (hot waters, cold waters, high salinity), will become increasingly difficult for European research teams and companies, with coastal countries developing legislation to ensure the protection of the genetic resources present in their EEZs.

2.4 Blue Biotechnology within the wider biotechnology landscape

Blue Biotechnology has the potential to contribute to other biotechnology and industry sectors from healthcare to bioremediation and cosmetics to energy. This leads to important overlaps as Blue Biotechnology products may feed in any other coloured biotechnology sector. Marine biotechnology already has applications in the following biotechnology industry sectors: energy (marine algal biofuels), pharmaceuticals (novel antibacterials), cosmetics, aquaculture, food and nutrition, environmental protection and depollution[18][19]. These can be considered to be sub-sectors within the Blue Biotechnology sector.

2.5 Conclusions

There is no clearly defined Blue Biotechnology sector in Europe. The Blue Biotechnology sector is diverse and encompasses a number of sub-sectors in which marine biotechnology applications are used. There are overlaps between the Blue Biotechnology sector and other biotechnology sectors and industries. However, there is a defining and unique characteristic of the Blue Biotechnology sector and that is its use of resources of marine origin. This blue component of the sector allows it to be distinguished from other biotechnology sectors

The value chain presented in Section 2.1 could be useful when considering the Blue Biotechnology sector. Given that the focus for classifying the sector is on the source of the material, a Blue Biotechnology sector would not necessarily encompass the whole of the biotechnology value chain. A Blue Biotechnology sector could align itself with elements and activities that are specific to the marine components of marine biotechnology such as bioprospecting for marine organisms, marine R&D, and to some extent product development. The "blue" in Blue Biotechnology denotes marine and it is important to keep this mind. Once the stages or processes in the value chain become

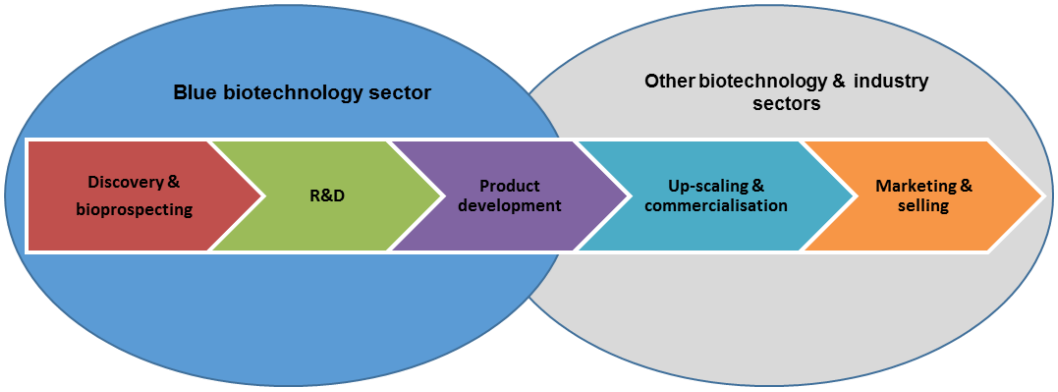
[18] OECD, 2013, Marine Biotechnology: Enabling Solutions for Ocean Productivity and Sustainability, OECD Publishing. http://dx.doi.org/10.1787/9789264194243-en

[19] European Science Foundation (ESF) Marine Board, 2010, Position Paper 15 Marine Biotechnology: A new Vision and Strategy for Europe, http://www.marine.ie/NR/rdonlyres/C076682C-2B32-437C-A781-B2EACBAA6B62/0/ESFMBmarine_biotechnology_paper15LR.pdf

specific to other industry or biotechnology sectors they become, by their very nature, separated from the marine component and should no longer be considered part of a Blue Biotechnology sector. At this point the processes, actors, products, services etc. become part of a biotechnology or industry sector. The cross-over from a Blue Biotechnology sector to other biotechnology or industry sectors may not be clear-cut and overlaps will inevitably occur, but it is important to work towards a distinction between the marine biotechnology activities/processes that are blue and those which belong to other biotechnology and industry sectors.

Figure 2.3 presents this approach to the definition of the Blue Biotechnology sector and shows the overlap between sectors.

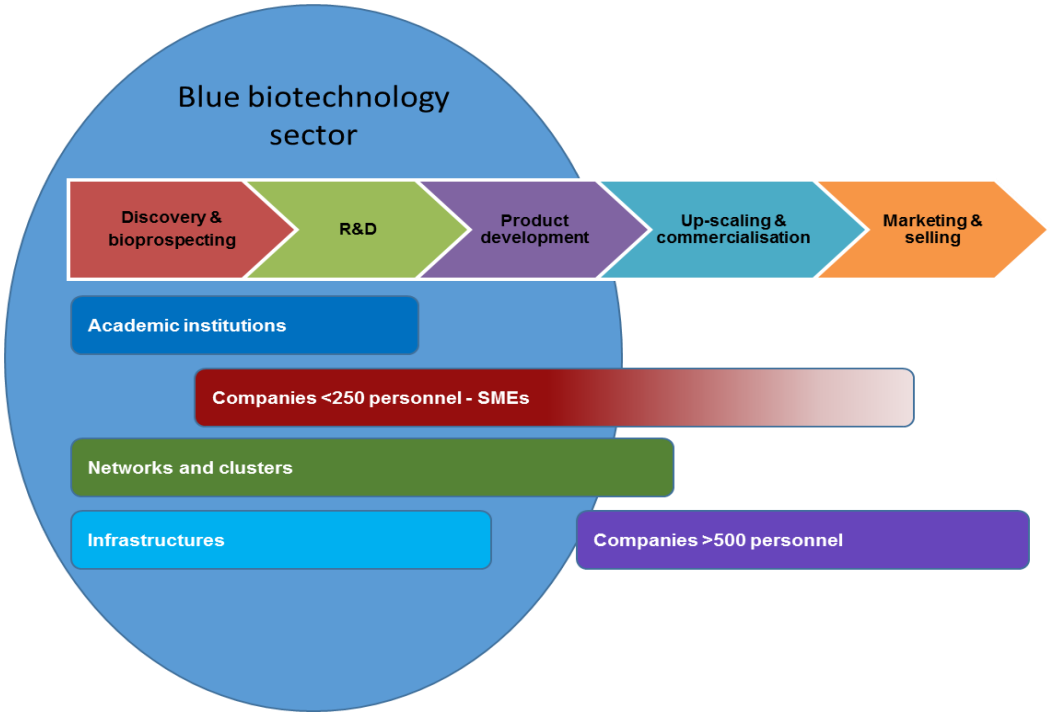
Figure 2.3 Visual representation of the Blue Biotechnology sector in Europe



A Blue Biotechnology sector could also be defined by assessing the type and area of activity of current marine biotechnology stakeholders. Building on the value chain approach towards a definition of a Blue Biotechnology sector the position of key stakeholders (identified above) in the marine biotechnology value chain and/or the types of activity they are involved with (i.e. R&D, production, services and marketing) is considered.

Based on the concentration of key stakeholder activity along the value chain a picture begins to develop of what a Blue Biotechnology sector could look like as shown in Figure 2.4.

Figure 2.4 Visual representation of stakeholder position in the marine biotechnology value chain.



The lack of official definition and statistical delineation of the sector creates difficulties determining the size of the sector, However, a Specialist market research agency, Global Industry Analysts, forecasts that the Blue Biotechnology sector is to reach USD 4.1 billion (EUR 3 billion) by the year 2015 with a compound annual growth rate (CAGR) of 4%-5%.[20]. This is expected to rise further, reaching USD 4.8 billion (EUR 3.5 billion) by 2018[21].

Europe appears to be a major player in Blue Biotechnology at the international level. Other key players are North America and East Asia. The strength of the European Blue Biotechnology sector appears to be in its research and development activities, access to marine resources and development of infrastructure to support these activities. The United States is taking a lead role in marine algal fuels and Asia is a lead player in bioinformatics.

[20] Global Industry Analysts Inc. "Marine Biotechnology: A Global Strategic Business Report" 2011
[21] Global Industry Analysts Inc. "Marine Biotechnology: A Global Strategic Business Report" 2013

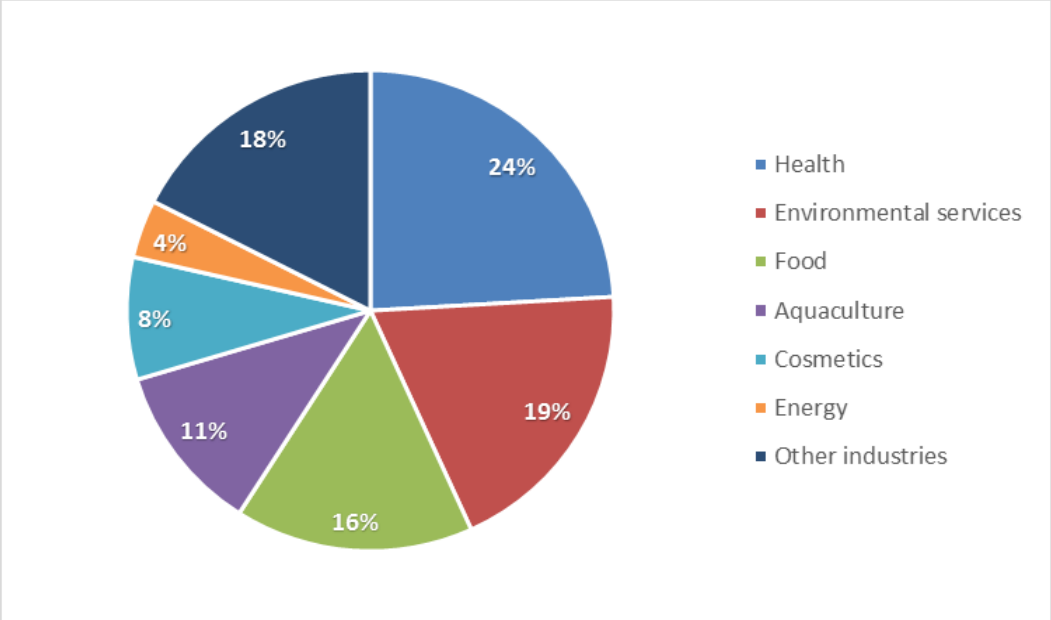
3 EU-level problem analysis

3.1 Sector review

3.1.1 Overview of sub-sectors

The Blue Biotechnology sector is comprised of a number of sub-sectors. Key sub-sectors identified for review in this study are: health, cosmetics, food, energy, aquaculture, environmental services (i.e. environmental protection and depollution) and other industrial applications. An indication of the relevance or importance of marine biotechnology to the different sub-sectors can be derived by the proportion of stakeholders affiliated to each sub-sector. Stakeholder analysis[22] shows that stakeholders are often involved in more than one sub-sector. Figure 3.1 shows the distribution of representative stakeholders by sub-sector and that the health sector, environmental services, food and other industrial applications are the main sub-sectors in which marine biotechnology stakeholders are active.

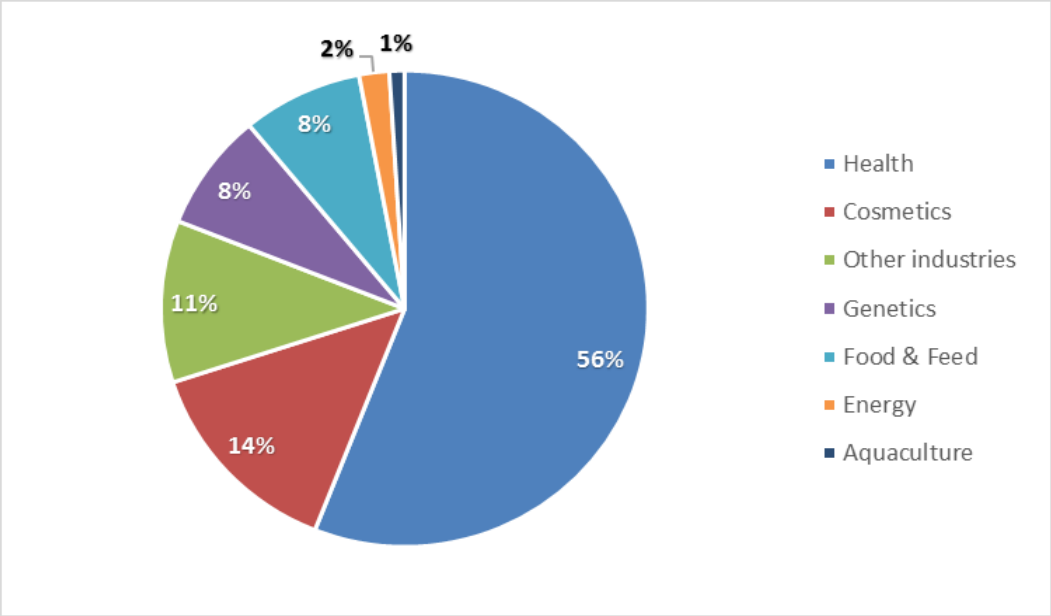
Figure 3.1 Distribution of stakeholders by sub-sector



Another indication of the relative importance of the marine biotechnology sub-sectors is the proportion of patents relating to each the different sub-sectors. Patent profiling (Annex 5) indicates that patents were filed in all sub-sectors of Blue Biotechnology, with a strong focus on health topics covering 56% of all patents (Figure 3.2). As most of the patents deal with compounds or genes with more than one application field rather than with specific production processes, many patents belong to more than one sector.

[22] A blue biotechnology stakeholder database was compiled as part of this study to identify marine biotechnology actors in Europe. Further details are presented in Annex 3

Figure 3.2 Patents in the subsectors of Blue Biotechnology



Detailed reviews of each of the individual sub-sectors are presented in Annex 6.

3.1.2 Potential product areas in research and development

Almost every class of marine organism possesses the capacity to produce a variety of molecules with unique structural features. These molecules offer an unmatched chemical diversity and structural complexity, together with a biological potency and selectivity. In recent years, the chemistry of natural products derived from marine organisms has become the focus of a much greater research effort. This is due, in a large part, to the increased recognition of marine organisms as a source for bioactive compounds with a range of applications across the Blue Biotechnology sub-sectors. Table 3.1 presents the range of potential products areas that are in the research and development phase in the Blue Biotechnology subsectors. It illustrates the vast potential of the marine biotechnology.

Table 3.1 Potential marine biotechnology products and services

Sub-sector	Potential product areas	Specific product areas
Health	Pharmaceuticals	Anti-cancer drugs, anti-viral drugs, novel antibiotics; wound healing; anti-inflammatory; immunomodulatory agents
	Biomaterials	Bioadhesives, wound dressings, dental biomaterials; alternative disinfectants (being more environmentally friendly and avoiding resistance development); medical polymers; dental biomaterials; coating for artificial bones that enhance biocompatibility; medical devices.
	Other	Tissues regeneration, 3D tissue culture
Cosmetics	Functional ingredients	UV-filter, after sun; viscosity control agents; surfactants; preservatives; liposomes, carrier systems for active ingredients; regulation of sebum;
	Raw materials	Micro and Macro-algae extracts; colourants, pigments; fragrances; hair-styling raw materials
Food	Functional foods	Prebiotics; omega 3 supplements;
	Nutraceuticals	Useful as antioxidants, anti-inflammatory; fat loss; reducing cholesterol ;; anti-HIV properties, antibiotic and mitogenic properties anti-tumour; iodine deficiency, goitre and myxoedema; anti-influenza; treatment of gastric ulcers;
	Food products and ingredients of marine origin	A stabiliser, suspending agents, bodying agents, makes a good jelly, prevents separation and cracking, suspending agent, foaming agent.
	Food packaging and conservation	Films and coatings with antimicrobial effects
Energy	Renewable energy processes (micro and macroalgae)	Microalgae; produce polysaccharides (sugars) and triacylglycerides (fats) that can be used for producing bioethanol and biodiesel. Macroalgae; large scale cultivation of macroalgae (seaweed) for the production of biofuel
	Microbial Enhanced Oil Recovery (MEOR)	Enhanced oil recovery and productive life of oil reservoirs.
	Industrial additives	Anti-blur additives for textile printing, binding agent in welding rods, drilling fluid
Aquaculture	Seed	Surrogate broodstock technologies; transgenic approaches; developing culture species; selective breeding of existing cultured species for novel and disease resistant hybrids.
	Feed	Fish oils produced from algae; pigments in fish feed

Sub-sector	Potential product areas	Specific product areas
	Disease Treatment	Diagnosis; treatment of disease; disease-resistant strains.
	Aquaculture systems	Treatment of re-circulated water.
Marine environmental health	Bioremediation	Biosurfactants (BS), bioemulsifiers (BE) induce emulsification, foaming, detergency, wetting dispersion, solubilisation of hydrophobic compounds and enhancing microbial growth enhancement; marine exopolysaccharides (EPs) induce emulsification.
	De-pollution	Removal of toxic elements including metals (lead, cadmium, zinc and metal ions); removal of dyes.
	Bio-sensing	Biomarkers and biosensors for soil, sediment and water testing; to identify specific chemical compounds or particular physio-chemical conditions, presence of algal blooms, human health hazards.
	Antifouling	Reduce drag and fuel use for boat-going vessels without any negative environmental impacts.
	Bio-adhesives	Underwater industrial adhesives.
Other	Bio-refineries (separation of functional biomass components)	Biodiesel; feedstock for the chemistry industry; essential fatty acids, proteins and carbohydrates for food, feed for animals (replacement of feed with fishmeal) and production of proteins and chemical building blocks;

3.1.3 Landscape of Blue Biotechnology infrastructures

Marine research infrastructures (MRIs) play an essential role in support of Blue Biotechnology by improving knowledge, giving access to new resources and decreasing the risk of operations[23][24][25], thereby supporting the maritime economy and blue growth. Coordination of MRIs establishes greater capacity, performance and knowledge sharing, and increases the potential of marine biotechnology applications and the overall contribution of marine biotechnology to societal challenges. MRIs include the physical equipment used to collect samples and produce data, databases and information systems that give access to data and the supercomputers and models which process data. MRI can be publically or privately owned. MRIs can be categorised into six clusters[26] as shown in Table 3.2. Annex 7 presents a detailed overview of the marine research infrastructures which are relevant to marine biotechnology.

Table 3.2 Overview of marine research infrastructures

Infrastructure cluster	Description	Relevance to marine biotechnology
Research vessels and underwater vehicles	Access to the marine environment, exploration and sampling.	Essential for bioprospecting
In situ data acquisition systems	Fixed and mobile platform technologies which allow *in situ* measurements and data transmission for monitoring and observation of marine environment.	Mostly used to measure physical, chemical and oceanographic parameters. Biological sample collection is possible but not widespread.
Satellites	Remote sensing for sea-surface and primary vegetation monitoring	Not directly relevant for marine biotechnology although could have uses in algal biomass production for biofuels.
Experimental facilities for biology and ecosystem studies	Research facilities and laboratory equipment for the processing and analysis of marine resources.	Essential supporting component for marine biotechnology e.g. marine genomics
Marine data facilities	Data management, computing and modelling facilities, data validation and storage (e.g. databases, biobanks), data dissemination, bioinformatics (omics data management)	Essential supporting component for marine biotechnology
Marine land-based facilities for engineering	Testing facilities for design, preparation and qualification of the sea/subsea sensors, instrumentation systems, mobile platforms and underwater vehicles before their operational deployment at sea.	Indirectly relevant to support other infrastructures.

[23] European Commission, Research and Innovation: Infrastructures, http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=home

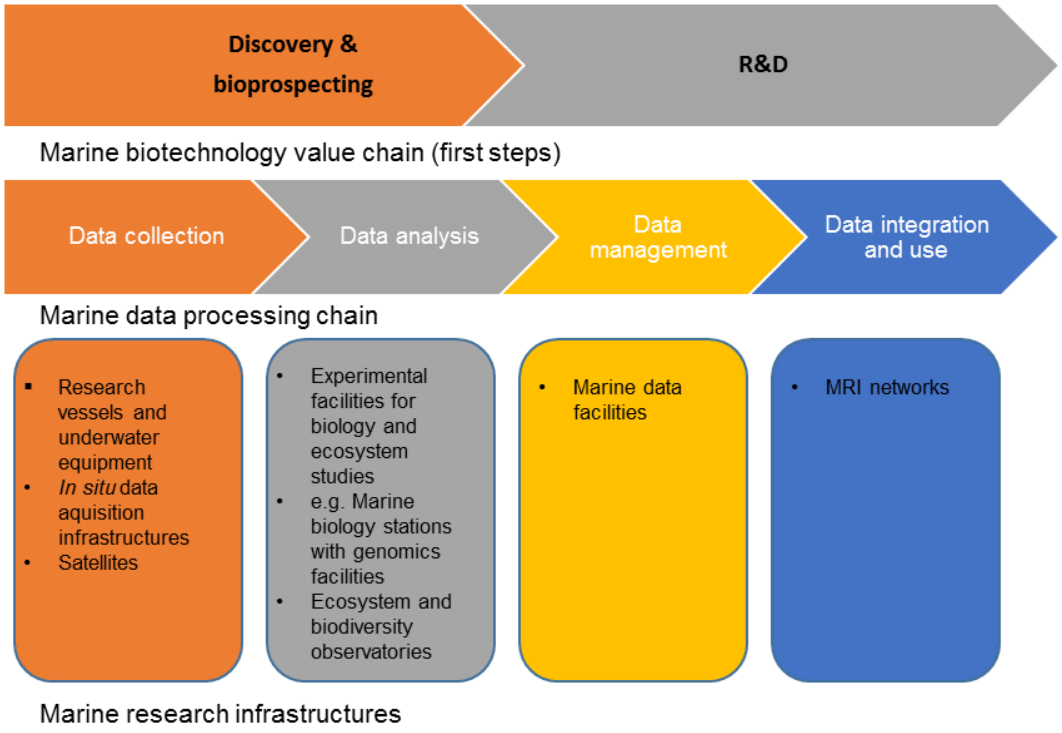
[24] European Commission, 2013, Towards European Integrated Ocean Observation, Expert Group on Marine Research Infrastructures, Final Report, http://ec.europa.eu/research/transport/publications/items/ocean_observation_en.htm

[25] Research infrastructures are facilities, resources and services used by the scientific community to conduct research and include libraries, databases, biological archives and collections (e.g. biobanks), large and small-scale research facilities (e.g. laboratories), research vessels, communication networks, and computing facilities.

[26] SEAS-ERA, 2012, infrastructures: Marine Research Infrastructures updated overview, European integration and vision of the future, Work Package 4 - D4.1.1, Milestone M4.1.1, http://www.seas-era.eu/np4/19.html

MRIs can also be grouped according to their place in the data processing chain which is an integral part of the discovery, bioprospecting and R&D stages of the marine biotechnology value chain as shown in Figure 3.3.

Figure 3.3 **Links between the marine biotechnology value chain, marine research infrastructures and the data processing chain.**



There are a number of initiatives and networks in Europe which specifically exist to coordinate marine research infrastructures and to facilitate access to them. These are listed in Annex 7.

Cost of MRIs

A prominent feature of marine biotechnology is the cost of prospecting for and capturing novel genetic resources, as the vessels and platforms used can be extremely expensive to operate. This is particularly true in respect to deeper water exploration which is often required when extreme environments, such as thermal or sulphur vents and hypersaline intrusions, need to be sampled. These environments are considered of great value for Blue Biotechnology as they often have very specialised micro-floral communities that have evolved enzymes that can work at extreme temperatures/salinities and/or metabolisms adapted to deal with unusual substrates. There are a number of such extreme environments on the bed of the Mediterranean, for example, albeit in 2,000 metres of water or more.

Private sector ocean going vessels cost approximately EUR 27,000 per day. The average daily cost of the Member State's ocean going research vessels was EUR 11,800 per day and that the EU research fleet spent some 14,350 days at sea in 2009; resulting in an annual spend of EUR 218 million a year, out of a total public sector marine data collection cost of just under EUR 1 billion per year[27]. The vessels are typically run by EU marine research laboratories. Because they are used for a number of different tasks simultaneously[28] there is no data available on the proportional use of these vessels for the acquisition of genetic resources.

[27] European Union (2010). Marine data infrastructure. DG Mare, Brussels.
[28] Their tasks include fulfilment of the data collection responsibilities of member states under the Data Collection Framework of the Common Fisheries Policy, and environmental data under the Marine Strategy Framework Directive.

The cost of bioprospecting is related to the accessibility of the environment within which with the marine organisms exist, however the relative importance of each type of environment to biotechnology is not known yet. While the targeting of deep-sea resources and the costs of accessing resources is such extreme environments are high and may represent an important constraint on development, there are also companies are using what appear to be relatively mundane materials, such as the company Glycomar which is investigating the properties of mucus from the surface of invertebrates, such as sea urchins that are more readily available in coastal waters.

3.1.4 Socio-economic performance

Socio-economic indicators

As of yet no common set of indicators have been agreed for the Blue Biotechnology sector, largely as a result of the current lack of a common definition of marine biotechnology and its sector; this is needed for statistical data collection. The marine biotechnology sector is also considered to be too young to be assessed by purely economic output indicators. Instead it is possible to assess the sector in terms of input indicators and more general indicators such as those listed below.

In Table 3.3, the biotechnology indicators used by the OECD are listed and allocated plus and minus signs (+/-) to indicate their potential to reflect the current socio-economic data (as opposed to future development and progress) of the sector, which can include sector Gross Value Added (GVA), number of companies, number of employees etc. Looking at the OECD indicators we have identified a handful that could be directly related to establishing market value, employment and investment potential. A number of other indicators were better fit to describe complementary factors that could impact on sector development, such as policy environment, education focus, RDI trends. A brief explanation is provided on the indicators and a more detailed analysis on the actual applicability can be found in Socio-economic data section.

Table 3.3 Applicability of indicators to estimate industry size

Indicators	Applicability to reflect socio-economic data	Data
Number of marine biotechnology firms – field/sector	+	This data is not available through official statistics such as Eurostat or national statistical offices. However, estimations can be made based on the database compiled for this study.
Patents – applications and granted, share of worldwide patents	-/+	Patents can give some indication on the value of upcoming products. However in the case of Blue Biotechnology a number of external factors limit the accuracy of establishing market value figures (prolonged clinical trials, investor confidence etc.)
Trends in clinical trials (or other trials) of marine biotechnology products (closer to the market than patents)	-	Trends in clinical trials are more of an indirect indication on future development potential especially with regards to product commercialisation. However shortening trial periods might not necessarily lead to a sectoral boom. External and exogenous factors such as access to raw materials, competition etc. can still slow down the pace of development.

Indicators	Applicability to reflect socio-economic data	Data
Publications and citations – share of worldwide	-	Publications and citation are indicative of baseline research and development trends but will not provide a direct link to sector size and market value.
Products – in development and on the market	+	The number and value of products can serve as a good indication on the value of the sector and future growth potential.
Funding and manpower devoted to marine biotechnology R & D	+/-	Research and development potential is no solid indication of actual commercial product value. A number of factors might hinder commercialisation postponing or even discontinuing research.
Value of Blue Biotechnology market	+	The gross value added of the sector s one of the key socio-economic indicators, signalling market and investment value.
Employment in marine biotechnology sector – marine biotech employment as a percentage of total employment	+	Employment in the sector is an important socio-economic indicator signalling sector size.
Education in marine biotechnology i.e. number of university degree courses	-	Number of students or courses in marine biotechnology are and indirect indication of future development potential and available skilled labour.
Total business marine biotech R&D expenditures - as a share of total business sector expenditures in R&D– intensity of business investment in marine biotechnology - investment in (marine) biotechnology is strongly related to the underlying industrial structure.	-/+	Business expenditures into RDI can be a good indication of private investment potential complimenting venture capital or more short-tem/high-risk investment sources. However alone this indicator will not provide solid figures regarding socio-economic outlook.
Distribution of total business R&D in biotechnology by application	-	Distribution of R&D by application is a good indicator of market expectations towards certain sub-sectors and their future development potential but alone it might not provide an indication of current market size and value.
Public R&D expenditures in biotech as a percentage of total public expenditures on R&D - gives us an idea of how much targeting might be going on.	-	Public R&D expenditures are a good indication of national commitment and policy support. However they are no direct indication of the actual market -, product value, investment or employment potential.
Venture capital investment	+	Venture capital investment is a good indication of current socio-economic sectoral position signalling investment trust and quick revenue/turnaround

Socio-economic data

The Blue Biotechnology sector is not an independent statistical sector and up until now no official statistics have been released on the number of companies, GVA or employment figures for the sector.

In Annex 2 (Towards a value of the Blue Biotechnology sector) it is estimated that the European Blue Biotechnology sector would make up 2-5% of European biotechnology in terms of revenue. Estimating the size of the industry in terms of number of employees is a more complex process. In the European Union over 99% of all enterprises are SMEs that employ 66.5% of European workforce[29]. While the share of small and medium sized enterprises varies by sectors on average SMEs tend to make up over 93-99% of companies active in one particular industry. Taking into consideration that biotechnology as well as Blue Biotechnology would have a high share of SMEs and would be characterised by a rather even distribution of workforce (as in number of employees) it can be assumed that similarly to revenues, the number of employees would also make up 2-5% of biotechnology as a whole. A 2013 industry report found that there were about 1 799 private biotechnology companies in Europe[30]. Mirroring the 2-5% size comparison used on revenues onto employment implies that there would be 36-90 private companies active in Blue Biotechnology in the European Union. The mirroring exercise however omits the fact that Blue Biotechnology as an industry is still in development and would potential to have a high number of start-up and spin-off companies.

Therefore, in order to verify and cross-check the primary estimates that Blue Biotechnology would have between 36-90 private companies in Europe we have looked at the stakeholder database compiled at the inception stage of this study. The stakeholder database lists close to 300 European Blue Biotechnology stakeholders, including private enterprises. It is meant as a representative sample of the industry. An analysis of the stakeholder database identified 97 enterprises out of which 71 (73%) are small and medium sized enterprises (SMEs) (less than 250 employees) and 26 (27%) are large companies (eight of them employ between 250-500 people and the remaining 18 employ above 500 people). These 97 enterprises make up just over 5% of the number of biotechnology companies identified in the 2013 industry report. Therefore, we can assume that 90-100 private companies would be a fair estimate on the number of companies while we understand that these assumptions build on a limited number of publicly available sector information and are further constrained by the differing interpretation of sector boundaries.

Based on this information, and assuming that the majority (up to 75%) of individual companies active in the Blue Biotechnology sector have been identified, we have continued using the database to estimate the number of employees for SMEs (based on the EU definition of small and medium sized enterprises and using the maximum and minimum ranges of number of employees). In order to estimate the lowest number of employees in the sector the number of companies has been multiplied by the lowest number of possible employees in their category; for example, in the case of companies with less than 250 people a minimum estimate average of five employees has been used. In order to estimate the maximum number of employees the number of companies has been multiplied with the highest number of possible employees in their category; for example, in the case of companies with over 500 employees we conducted calculations with a maximum estimate of 1 000 people.

[29] European Commission (2013); Annual Report on European SMEs 2012/2013, http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/performance-review/files/supporting-documents/2013/annual-report-smes-2013_en.pdf

[30] Ernst & Young; Biotechnology Industry report 2013

Table 3.4 Employment estimation for Blue Biotechnology

Number of enterprises	Size of company	Minimum number of employees	Maximum number of employees
71	<250 people	355	17,750
8	250-500	2,000	4,000
18	>500 people	9,000	18,000
Total		**11,355**	**39,750**

Assuming that the identified 97 enterprises are representative (in at least 75%) of the size of the EU Blue Biotech sector we have found that the number of employees could range from around 11 355 to 39 750 people[31], as shown in Table 3.4. We understand that the range provided to reflect the number of employees in the sector is rather large which is due to the fact that data and information regarding the number and size of the companies (including the share of the workforce at multinationals relevant for Blue Biotechnology) is limited.

On the basis of this order of magnitude, Blue Biotechnology is unlikely to provide mass employment in Europe – at least in the short- to medium term. Basically, the key people involved are groups of specialised, highly trained, researchers, innovators and entrepreneurs. The jobs, however, are high end jobs staffed by people who were expensive to train. The main economic contribution is likely to be from the value added derived from these attributes and intellectual property rights. In addition, as with sector value, the Global Industry Analysts figures indicate a growth rate of 5-15% with a most probable global value to USD 4.8 billion by 2018. Using the OECD value proxy of percentage of patents taken out would suggest that some 13% (Ecorys 2012) would derive from the EU.

Data on Blue Biotechnology employment is not yet collected making determining employment within the sector difficult. The OECD is, once more, very circumspect in its search for such indicators. There are the researchers in the public sector Research and Development facilities and also those working on development of marine genetic products in SMEs but even these specialists may also be working also on non-biotechnological themes. Once taken up by a large commercialising company the marine genetic product could just be one of a number of product lines serviced by the same staff. Never the less, the new marine product may or may not create new jobs but it will certainly sustain jobs.

Table 3.5 summarises the distribution of employment for the key sectors in which there are marine biotechnology applications, which includes industrial biotechnology[32] as well as other sectors such as cosmetics, aquaculture or pharmaceuticals. At this stage we have no information on the proportion of Blue Biotechnology stakeholders that would concentrate on one or the other industries and it is also a likely scenario that Blue Biotechnology stakeholders would be supplying research, innovation and/or practical product development to more than one of the related sectors.

[31] These figures will be confirmed with stakeholders at the international stakeholder workshop.
[32] Biotechnology is not a recognised NACE sector, activities generally referred under NACE sector 73, Research and experimental development on natural science and engineering. This NACE sector excludes pharmaceuticals but includes social sciences and humanities which makes statistical analysis rather obscure

Table 3.5 Employment in biotechnology related sector

Sectors	Number of employees	R&D employees
Biotechnology[33]	54,750	NA
Pharmaceutical industry[34]	700,000	116,000
Cosmetics[35]	1,500,000	25,000
Aquaculture[36]	66,905	NA

In addition to the number of employees, the gender distribution of labour force has been estimated using data and figures from Eurostat. Using European data on employment in high-tech sectors for 2012 this shows that 40.8% of all employees are women[37]. Additionally, a 2013 publication from Eurostat[38] on the research, technology and innovation shows that women comprised 32.9% of researchers. It is estimated that the sector of Blue Biotechnology would have similar ranges of gender distribution meaning women are presumed to make up 32-40% of employees.

Employment by age group in science, technology and innovation in the EU27 was as follows, in 2011; the 45–64 years old demographic accounted for the largest share (39%), while the other age groups (25–34 and 35–44 years) each accounted for about 30%. With regards to the education levels in the science and technology sectors in the EU a total of more than 98 million highly qualified knowledge workers were registered in 2011. Almost half of them (42 million people, 42%) were considered highly qualified by both knowledge and education and 73 million (74%) were considered as highly qualified based on education[39]. Unfortunately, no similar statistics were found for the European Biotechnology sector but it is assumed that numbers would be correspondingly similar.

Using the available information on the EUs bioeconomy sector that values the sector at EUR 2 trillion and identifies the sector as supporting 22 million jobs, then a simple estimate is that each job in the sector is worth some EUR 91 000. Beyond these broad-brush estimates, a UK-specific study, in 2005-6 suggested that the UK derived some GBP 46 billion (EUR 55.7 billion) from marine related activities which provided 890 000 jobs at a relative value of GBP 51 685 per job or approximately EUR 62 500 (Pugh, 2008[40]). However, only 1% of these marine activities were ascribed to R&D. Similarly, the economic value derived from living marine resources in the US has been estimated at USD 5.7 billion and involves USD 98 000 per job, or EUR 71 500. Clearly, these are simplistic estimates but they are not totally disparate, including, as they do, the salary and social costs of the employees plus a certain value-added.

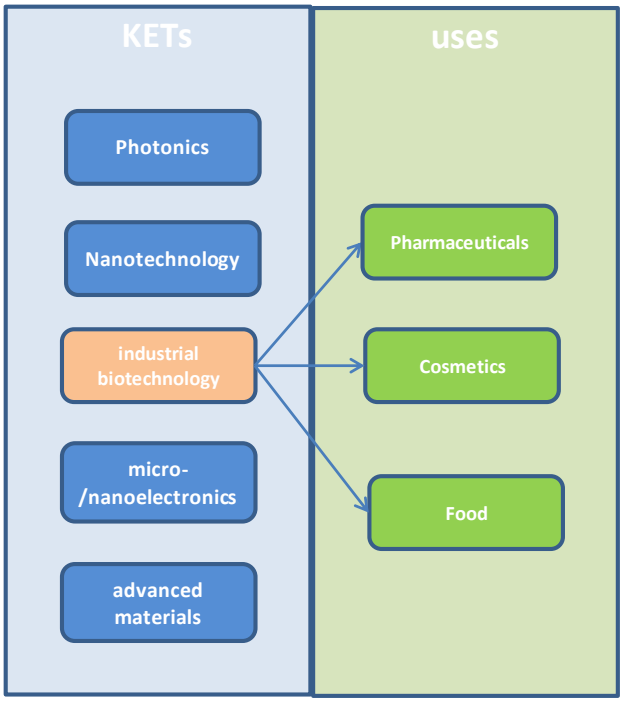
Using information about the global biotechnology industry can provide some insights into the potential of the sector within the EU and the possible proportion of growth and jobs that might be found in the EU? In the absence of clear economic indicators the OECD suggests the use a proxy indicator of market share, the proportion of marine bio patents taken out by stakeholders. Using this approach, on the basis that amongst the major players in marine biotechnology the EU takes out 13% of global patents, the EU Blue Biotechnology sector could sustain 4 800 jobs in 2010 rising to 6 000 by 2018 or in value terms, EUR 364 million rising to EUR 455 million.

[33] Ernst & Young; Biotechnology Industry report 2013
[34] EFPIA (2013): The Pharmaceutical industry in figures, http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf
[35] Cosmetics Europe (201): Activity Report, https://www.cosmeticseurope.eu/about-cosmetics-europe.html
[36] JRC (2013): Summary of the 2013 Economic Performance Report on the EU Aquaculture Sector, http://stecf.jrc.ec.europa.eu/documents/43805/622206/2013-12_STECF+13-30+-+Aquaculture+economics+Summary+report_JRCxxx.pdf
[37] Eurostat (2012): High-tech statistics, http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/High-tech_statistics
[38] Eurostat (2013); Science, technology and innovation in Europe, http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-GN-13-001/EN/KS-GN-13-001-EN.PDF
[39] Ibid.
[40] Pugh, D. (2008) Socio-economic Indicators of Marine-related Activities in the UK economy. The Crown Estate, ISBN: 978-1-906410-01-8.

Key enabling technologies

Key enabling technologies (KETs), are technologies which are of strategic importance to the future competitiveness and prosperity of the EU and its Member States. In a 2009 Communication, preparing for our future: The European Commission identified and highlighted KETs for their potential impact in strengthening Europe's industrial and innovation capacity[41]. These KETs in most cases are not products themselves, but rather inventions that allow further products to be developed. For example, if a new compound is found in crustaceans living at the bottom of the sea which is particularly potent and becomes the basis of a new medicine to cure a type of cancer, it can save millions and create a huge economic effect. It is this potential that relates to why such importance is placed on this frontline research and promoting biotechnology as well as Blue Biotechnology.

Figure 3.4 Uses of KETs



The Action Plan for the EU Integrated Maritime Policy[42] has identified Blue Biotechnology as one of the KETs within the maritime economic sectors. The European Strategy for Marine and Maritime Research[43] prioritises marine biodiversity and biotechnology research, and recognised its potential to contribute to new knowledge on which to base high value products and processes and increase marine resources and biodiversity understanding.

The Horizon 2020 programme that supports frontline research in Europe has recently released its calls for funding of research, several of which are focused on Biotechnology and specifically Blue Biotechnology which indicates the perceived importance of such technology. Table 3.6 gives an indication towards potential applications of new discoveries off the back of possibly Blue Biotechnology KETs.

[41] European Commission (2009). Preparing for our future: Developing a common strategy for key enabling technologies in the EU. Available; http://ec.europa.eu/enterprise/sectors/ict/files/communication_key_enabling_technologies_en.pdf
[42] An Integrated Maritime Policy for the European Union. Available: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52007DC0575:EN:NOT
[43] A European strategy for marine and maritime research : a coherent European research area framework in support of a sustainable use of oceans and seas. Available: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0534:EN:NOT

Table 3.6 Examples of Horizon 2020 calls for funding of research

Call	Description
NMP 10–2014	Biomaterials for the treatment of diabetes mellitus
NMP 12–2015	Biomaterials for treatment and prevention of Alzheimer's disease
BIOTEC 1–2014	Synthetic biology – construction of organisms for new products and processes
BIOTEC 3–2014	Widening industrial application of enzymatic processes
BIOTEC 4–2014	Downstream processes unlocking biotechnological transformations
FoF 12 – 2015	Industrial technologies for advanced joining and assembly processes of multi-materials

It is estimated that for every Euro invested into R&D for industrial biotechnology and biotechnological KETs there will be a tenfold return.[44] The European Competitiveness Report 2010 indicated a global current market volume of KETs to stand at USD 646 billion (EUR 471.6 billion) around 2006/2008, which is projected to grow to over EUR 1 trillion by 2015.

Capital

The growth of the industry has meant an increased demand for investment and the need to raise capital. There have been four main types of acquiring such new capital:

1) IPOs: These "Initial public offerings" are sales of companies (or parts of them) to the public, allowing them to be traded on stock exchanges;
2) Follow-on and other: Follow-on offering are sales of other shares of the company after an IPO has taken place, or raising of additional capital from public investors. There are also several other mechanisms and financial products that facilitate raising capital from private and/or public investors, that are also included in this category;
3) Debt: The most common mechanism is for a business to take credit with a bank (although there are other and more complex debt financial products). The debt has to be repaid in full, plus interest in a given time frame. The inability can result in forced closure of the business and liquidation of assets to pay back the debt. It is therefore different significantly different from the other equity based methods;
4) Venture Capital: Private funds that seek to invest into promising companies (in exchange for equity) with the horizon of enabling the company to grow significantly and then selling their share after only a couple of years.

In terms of raising capital the US is by far the global leader within Blue-Biotech, raising around 80% of all the capital, while Europe represents around 15% of the USD 28.2 billion in 2012. The financing situation in Europe is presented in Table 3.7.

Table 3.7 European Biotechnology financing by year (USD million)[45]

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
IPOs	136	36	454	995	853	1,021	111	143	219	43	40
Follow-on and other	126	1,769	2,196	1,587	3,141	4,600	872	1,892	1,792	1,134	948
Debt	63	39	24	100	279	319	108	654	396	393	1,934
Venture	1,259	1,064	1,860	1,776	1,872	1,821	1,531	1,091	1,371	1,321	1,243
Total	1,585	2,908	4,534	4,459	6,146	7,761	2,622	3,779	3,778	2,891	4,164

Table 3.7 illustrates that the IPO channel has completely collapsed. In fact by 95% compared to pre-crisis levels. In US, by comparison, the IPO levels have recovered quickly to only 35% below the pre-crisis levels.

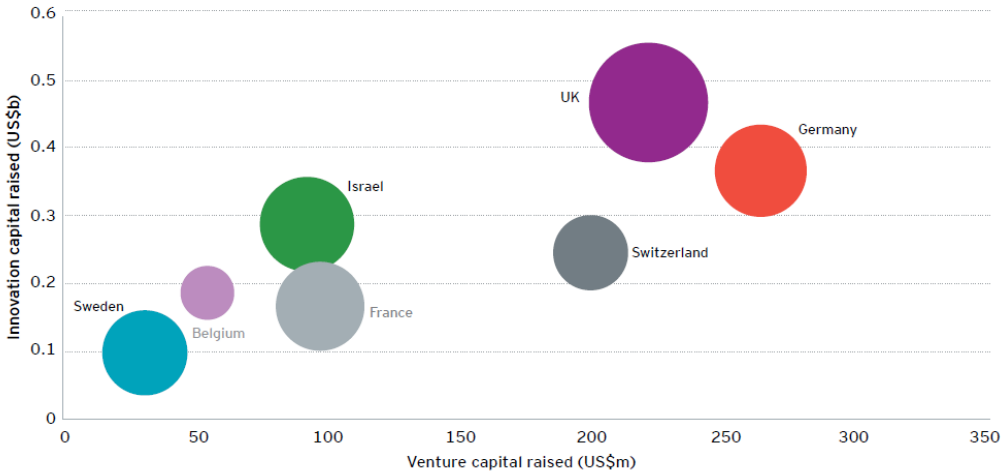
[44] Innovating for Sustainable Growth: A Bioeconomy for Europe, COM(2012) 60
[45] Ernst & Young; Biotechnology Industry report 2013

The virtual closure of the market since the crisis has a serious effect companies by limiting access to finance for not only new companies (by using IPOs), but also companies seeking follow-on offerings. Although follow-ons have been more successful in recovering (due to, amongst others, lower risk levels and more information on the company), they are still at roughly at 50% of their pre-crisis level. Due to several reasons (discussed below), there has been a rise lately of alternative and new financial products as well as financing mechanisms. This has significantly contributed to new capital being raised in the post-crisis world. By comparison in the US, where such products and mechanisms are increasingly the norm, they have contributed significantly in a very swift recovery of this indicator and even exceeding the pre-crisis levels in 2012.

Debt financing has been the largest contributor to new capital raised in 2012. However, this has been dominated by four sector leaders, which took out huge loans - of which: Elan Corp. USD600 million (EUR 438 million) and Jazz Pharmaceuticals USD 575 million (EUR 419.8 million)[46]. When these are taken away the remaining figure is closer to the overall trend of around USD 400 million (EUR 292 million). This suggests a challenging environment for most other smaller R&D-phase companies.

Venture Capital has fallen from an average of USD 1.8 million (EUR 1.31 million) raised in the pre-crisis levels to an average of USD 1.3 million (EUR 0.95 million) in the recent years. This has been largely due to the on-going economic woes in Europe, but also significantly changing market conditions. Using the collapse of the IPO market as an example; IPOs are crucial to Venture Capital as it is an important mechanism to realise their profits, by selling their equity shares of a company that they invested into on the open market. If this option is removed then investing into companies becomes a lot riskier. With young companies, or R&D-phase companies, there are already such significant other risks, so an additional risk such as a more difficult exit strategy can mean that a Venture Capital would rather not invest at all. Furthermore, although the European Venture Capital market is a significant source of capital it is about a quarter of its US counterpart, showing a real potential for expansion. Figure 3.5 presents the major European players.

Figure 3.5 Capital raised by leading European countries in 2012[47]



Particularly striking is that the UK not only shows the largest number of financings (the size of the bubble), but also the highest Innovation capital raised (which calculates direct capital raisings by the majority of the companies, excluding the largest sector leaders). This shows that companies in the UK are overall more successful at raising their own capital compared to other places in Europe.

[46] Ernst & Young; Biotechnology Industry report 2013
[47] Ernst & Young; Biotechnology Industry report 2013

This would suggest a higher entrepreneurial capacity in the UK in finding the finances to run and/or expand business activities. Germany on the other hand led the amount of Venture Capital raised in Europe with USD 263 million (EUR 192 million), pointing towards a particularly developed market in Germany.

3.1.5 The role of SMEs

There is currently no unified directory or inventory of micro- and SMEs in Europe involved in the marine biotechnology and marine bioresources chain. Information is therefore rather incomplete, and the resulting partial view needs to be gained from diverse sources such as lists of attendees or speakers at relevant conferences, e.g. BioMarine[48], participants in national and European RTDI programmes, such as FP6, FP7 or Inter-Reg[49], and association, industry or regional network directories, such as the Bretagne bioservices Directory[50], NetAlgae[51] or the BioMarine Resources Directory[52]. This work remains to be done, but a very preliminary scanning and synthesis of this type of information gives over 140 SMEs involved in different aspects of marine bioresources exploitation and marine biotechnology.

Because the picture is incomplete, it is difficult to map the specialisations of SMEs in this area, especially as there are so many streams of activity, from engineering underwater vehicles and robots, to intelligent and high-density robotic screening for bioactivity of MNPs, and many SMEs are drawn to the marine biotechnology area through EU-funded consortium projects, when their core activity has not been Blue Biotechnology directed to that time. In general, however, apart from the micro- and macro-engineering SMEs, those in biological activities tend to support the concept that SME activity in general stops at the industrial adaptation stage of the value chain.

We can characterise SMEs in a simplified way as initiators, validators or facilitators:

- **Initiators**: typically university spin-outs, scientist-led, and beginning the search for industrial utility of research findings, involved in bioprospecting, collection-building, early genomics and metagenomics;
- **Validators**: typically providing the bioactive screening needed to identify molecules of interest; involved in the stage of industrial adaptation, so demonstrating that the marine-derived products and processes are manufacturable and scaleable;
- **Facilitators**: typically consultancies, creating and analysing opportunities, advising; events organisers, enhancing linkages and networking; project managers; intellectual property advisors.

SMEs tend to be focused at the earlier stages of the value chain, as for them it represents in many cases a cost chain (i.e. the cash-burn stage before income-generation). They will typically be absent from the stage of industrial production of NMPs, largely because of the high capital expenditure that is usually involved in setting up industrial-scale biomass generation for subsequent extraction of materials, up-scaled high-performance purification systems, or large-scale synthesis for production of products. They will also be absent from the commercial-scale or even demonstration-scale levels of energy from algae, for the same reasons of high CapEx.

Their involvement in the earlier stages focuses on identification, validation and de-risking of industrial opportunities from marine bioresources. They may work in collaboration with researchers at universities or institutes, and with larger industrial companies. Universities and research

[48] Final report, 4th BioMarine Business Convention, Halifax, Canada Sept 9-12 2013
[49] See Marine Knowledge Gate http://www.kg.eurocean.org/ and CORDIS http://cordis.europa.eu/projects/home_en.html
[50] http://critt-sante.org/vars/fichiers/Bretagne innovation annuaire.pdf
[51] See http://www.netalgae.eu/industry-directory.php
[52] http://www.biomarine-resources.com/

organisations are typically involved in the stages from bioprospecting to identification and characterisation but may also be involved in industrial adaptation, often as part of contract funding by industry or publicly-funded industry-facing consortia.

Because of the cash-limitations of SMEs and the limited power they have to bring products if marine biotechnology to market, they need downstream linkages to end-users to whom they can sell or licence their innovations, products and processes or who may become their exits through trade sale, and to investors who can help them survive longer while they validate and de-risk their developments.

Opportunities and constraints for SMEs within the European landscape

The analysis also highlighted particular drivers, advantages and opportunities for SMEs. In particular financing is a major issue for SMEs involved in marine biotechnology, as in other sectors. The fate of single-focus marine bioactives companies depends on success stories with a commercial outcome and, in the case of anti-cancer or other products, de-risking them by getting them into clinical trials, either alone or with a strategic partner, before cash-burn drains reserves and saps the patience of investors. In this respect, note the recent failure of the UK company Aquapharm Biodiscovery, devoted to nutraceutical and pharmaceutical molecules from marine organisms. Aquapharm's assets have been acquired by Lallemand Nutrition, the Canadian food and feed additive company, which has not yet announced its intentions for their further development.

The company Nereus Pharmaceuticals, a leading US start-up for NMPs and marine biotechnology, was founded by researchers from the University of California San Diego, with far greater investment than Aquapharm, It had raised over EUR 125 million since 2000, with a long list of investors. In October 2012 it was acquired by Triphase R&D I Corp, a Canadian organisation part-funded by MaRS Innovation, the technology transfer and development arm of the National Research Council's Networks of Centres of Excellence. No further information on the fate of Nereus's assets, including plinabulin, an anti-cancer agent in Phase II trials is available. As the company had undergone a liquidation sale of its physical assets in late 2011, it is likely that only the intellectual assets were acquired.

Start-ups, spin-outs and mid-size companies need to find a mix of funds. As for other biotech and high-tech companies at micro & SME level, Blue Biotechnology SMEs acquire funding through five main routes:

- Start-up, utilising own reserves, university funds if a spin-out;
- Public funding using local economic development agencies and local early-stage funds;
- Strategic links with end-users in collaborations and contract work;
- Public funding from national or European RTDI programmes; and
- Funding from investment organisations.

There are currently no specialised funds available for activities in marine biotechnology in Europe, although there are some that focus on environmental companies, and so include bioremediation, or on alternative energy and so could potentially include marine bioenergy companies as their targets. Private funding of SMEs is dependent more on the attractiveness of the main aim of the SME rather than the source of its innovation. Thus an SME claiming to focus on new products for medicine would approach healthcare-orientated funds and companies. One looking at new materials for cosmetics might seek investors with existing activity in consumer products. Typically, an investment company will have only one marine-orientated or –involved company in its portfolio. In the absence of easy access to investment funding, many SMEs are reliant on public funding for supporting their development projects. This mainly takes place through two routes:

- national, regional or local economic development funding; and
- organised research, development & innovation support programmes, at national level, international level.

National economic support can come from commercialisation-focused public-funded innovation programmes such as the UK Technology Strategy Board's or Norway's Innovasjons Norge (Innovation Norway) or private funding initiatives such as SINTEF's seed-fund for new SMEs developing technology from SINTEF's institutes or NTNU Trondheim, of NOK 209 million (EUR 25 million) established in 2014 and co-funded by the EIB (European Investment Bank) and SpareBank1.

In the European context public funding means programmes such as Framework Programme 7 and Horizon 2020 and related activities, including COST, ERA-NETs and Technology Platforms; and or Inter-Reg activities. NetAlgae, for example, is funded under an Interreg IV action.

SMEs are favoured by public support programmes and there is scope for blue biotech SMEs to take advantage of the EU programme EuroTransBio, which is similar to a Joint Programming Initiative in that it is supported by individual countries pooling their resources in calls of interest. So far, marine biotechnology applications have been in a minority (<1%). A specific public funding opportunity also exists in Horizon 2020 (H2020). This is H2020-SMEINST-1-2014, with a total budget of over EUR 25 million dedicated to SMEs within the Blue Growth activities, including marine biotechnology and aquaculture-related marine technologies and services. The topic within the pillar of Industrial Leadership is "Supporting SMEs efforts for the development - deployment and market replication of innovative solutions for blue growth". For private investors, growth areas are seen as marine ingredients for food, feed and nutraceuticals; bioremediation; and in-sea activities.

Opportunities for SMEs appear to also be affected by local infrastructure. For example, the existence of clusters can help SMEs; strong positive examples include:

- PôleMer France, consisting of the Pôle Mer Méditerranée and the Pôle Mer Bretagne, which has actively involved itself and its SME members in marine biotechnology projects;
- ScanBalt in northern Europe, which is working within the EU Strategy for the Baltic Sea and has established a flagship project SUBMARINER, sustainable uses of Baltic marine resources, with EU region support;
- The German industrial biotechnology cluster CLIB 2021 includes several marine-orientated SMEs amongst its members, including Bitop AG, C-LEcta GmbH, DIREVO Industrial Biotechnology GmbH, Evocatal GmbH and Swissaustral Biotech SA.

The difficulty of SMEs in maintaining momentum through the value chain when marine biotechnology is being applied to biomedical and industrial applications has been recognised by CIESM (the Mediterranean Science Commission), which advocates as a new and innovative policy initiative the bringing of SMEs together with biotechnology associations, venture capitalists, financing bodies and other stakeholders who can help them "weather the economic storm", and tackle financial challenges and constraints.

3.1.6 Products and services already in use

Marine biotechnology is considered a 'young' field of biotechnology and this is demonstrated by the comparative lack of marine biotechnology products on the market. However, Table 3.8 presents examples of some of the products and services currently available.

Table 3.8 Examples of marine biotechnology products and services already in use

Sub-sector	Product area	Product / service	Marine organism	Compound name	Company
Health	Pharmaceutical	Anticancer; anti-tumour agent.	Colonial Tunicate; *Ecteinascidia turbinate*	Trabectedin. Trademark; Yondelis	Pharmamar
	Pharmaceutical	Pain	Cone snail; *Conus magus*	Ziconotide. Trademark; Prialt	Jazz Pharmaceuticals plc (USA)
	Pharmaceutical	Lower Hypertriglyceridemia (fat) levels	Various fish species; Fish oils	Omega-3-acid ethyl esters. Trademark; Lovaza.	GlaxoSmithKline & Pronova BioPharma
	Medical device	Nose spray mediating cold and flu	Red algae	Carragelose®	Marinomed
Cosmetics	Active ingredients	Anti-cellulite	Seaweed	Approximately 120 Seaweed extracts e.g. *Ascophyllum nodosum* extract, *Fucus vesiculosus* extract, *Laminaria saccharina* extract	Multiple
	Viscosity controlling agents	Stabilising formulas	Seaweed	Alginate, carrageenan, agar-agar	Multiple
	Active ingredients	Moisturising products	Jellyfish	Collagen (hydrolysed and/or native)	Multiple
	Active Ingredients	Sun Cream	Red algae; *Porphyra umbilicalis*	*Porphyra umbilicalis* extract	Multiple
	Active Ingredients	Skin lotion	Sea fan; *Pseudopterogorgia elisabethae*	Sea whip extract (INCI)	Estee Lauder
	Final product	Ultra-Matte Moisturising Fluid	Brown Seaweed; *Saccharina* sp.	Algae extract (INCI)	Thalgo
	Final product	Organic Cosmetics Line “Oceanwell”	Brown Seaweed; *Saccharina latissima*	Saccharomyces/*Laminaria saccharina* extract	oceanBASIS

Sub-sector	Product area	Product / service	Marine organism	Compound name	Company
Food	Functional Foods	Antioxidant to help improve gut health.	Various sp. including Bladderwrack; *Fucus vesiculosus*	Fucoidan	Multiple e.g. Doctors Best
	Functional Foods	Weight Loss	Various sp. of Brown Seaweed	Fucoxanthin	Multiple e.g. MD
	Food products and ingredients of marine origin	Food colourant	Phaeophytes	Fucoxanthin	Multiple
	Food products and ingredients of marine origin	Bakery icings	*Laminaria, Macrocystis, Lessonia, Ascophyllum* and other.	Alginate	Multiple
	Food ingredients	E400 to E407	Multiple seaweed species	Alginate, carrageenan, agar	Multiple
	Food products and ingredients of marine origin	Sucrose replacement	Brown seaweed	Mannitol	Multiple
	Functional Foods	Antioxidant	Microalgae; *Haematococcus pluvialis*	Astaxanthin	BioAstin (USA)
Energy	Renewable energy processes	Biofuel	*Sargassum horneri.*	Seaweed bioethanol	Ocean Sunrise Project (Japan)
	Renewable energy processes	Biofuel	Highly productive microalgae e.g. *Euglena gracilis*	Algae Oil	Solazyme (USA), AlgaEnergy (Spain)
Aquaculture	Feed	Fishmeal	Algae oils	ReNew Feed	Cellana
	Feed	Pigment	Microalgae; *Haematococcus pluvialis*	Astaxanthin	Fuji Chemical Ltd (Japan/USA)
	Feed	Marine proteins	Unspecified seaweeds	OceanFeed	OceanHarvest (Ireland)
	Seed	Genetically Improved Salmon Eggs	Salmon	Salmon eggs AquaGen	AquaGen

Sub-sector	Product area	Product / service	Marine organism	Compound name	Company
Marine Environmental Health	Bioremediation	Biosensor	Marine bacterium; *Alcanivorax borkumensis*	Alcanivorax	ATCC (Global|)
	Antifoulant	Antifoulant	Medetomidine**,**	Selektope™	I-Tech AB **(I-Tech),**[53]
	Biosensors	Widespread applications in molecular biology as a reporter protein.	Jellyfish; *Aequorea victoria.* *Allivibrio fischeri*	Green fluorescent protein (GFP); luciferase enzyme of *Allivibrio fischeri*	Various e.g. BioVision Inc
Other	Bio-refineries	Biofuel, chemical building blocks, proteins	Multiple seaweed species	Polysaccharides, proteins	BA Laboratories (US), Statoil (Norway)

[53] Eco-Friendly Biocide Prevents Biofouling on Ships' Hulls. http://shipandbunker.com/news/world/141526-eco-friendly-biocide-prevents-biofouling-on-ships-hulls

3.1.7 Drivers and barriers in the Blue Biotechnology sector

Drivers

The future potential of marine biotechnology's contribution to the key societal challenges of sustainable food security, sustainable energy security, environmental health, human health and wellbeing, and the greening of industrial products and processes provides an overarching driver for the sector. The recent emergence of marine biotechnology as an important field has been the result of advances in science and technology over the last decade or so, and in particular genomic and other 'omic' sciences which have increased our knowledge and understanding of marine resources. Furthermore, the inventory of marine natural products and genes of commercial interest has grown rapidly in recent years as a result of efforts in bioprospecting. The appropriation of marine genetic resources has also grown with over 18 000 natural products and over 4 900 patents associated with the genes of marine organisms[54].

[54] Arrieta J, Arnaud-Haond S and Duarte C., 2010, Marine Reserves Special Feature: What lies underneath: Conserving the oceans' genetic resources. PNAS 2010: 0911897107v1-200911897.

Table 3.9 presents the sub-sector specific drivers.

Table 3.9 Drivers of Blue Biotechnology

Sub-sector	Product area	Type of driver	Reasoning for driver	Stage in value chain
Health	All	Market demand	Increasing ageing population, with age-related conditions including; cancer, neurodegenerative disorders, and osteoporosis. Unsolved indication fields as malaria, dengue etc. Orphan diseases	Marketing & Selling
	All	Financial Incentives	Expanding population and lucrative health business	Marketing & Selling
	Pharmaceuticals	Market opportunities	Multi resistant bacterial threats including remerging pandemics. Growth in resistant strains of bacteria to existing antibiotics.	Marketing & Selling
	All	Innovation	Strong academic field generating a broad supply to the pharmaceutical pipeline and knowledge and for production	Development
Cosmetics	Functional Ingredients	Demand	Strong demand for innovation	Development
	All	Market opportunities	Helpful marketing propositions: grand and mystical connotation of “the ocean”	Marketing & Selling
Food	All	Market demand	The health concerns of aging baby boomers in industrialized countries	Marketing & Selling
	Nutraceuticals	Market demand	A growing desire for alternatives to traditional pharmaceutical products.	Marketing & Selling
	Food products and ingredients of marine origin	Market demand	An increased awareness among consumers of the links between nutrition and health	Marketing & Selling
	Food products and ingredients of	Sustainability	Increased necessity to produce low environmental impact	Marketing & Selling

Sub-sector	Product area	Type of driver	Reasoning for driver	Stage in value chain
	marine origin		feed ingredients.	
	Food ingredients (E400 to 407)	Unique properties	Consumers want smooth products	Manufacture
Energy	Biofuels	Market opportunities	Expected high value in the European market	Marketing & Selling
	Biofuels	Cultivation opportunities	Macroalgae can be produced cheaply and efficiently in conjunction with fish farms.	Manufacture
	Bioplastics	Sustainability	Driven by environmental concerns and public procurement programs.	Manufacture
	Industrial additives	Unique properties	Economic and technical advantages	Manufacture
Aquaculture	All	Sustainability concerns	Pressure on rebuilding fish stocks globally.	Marketing & Selling
	All	Socio-economic development	Seen as a key driver of socio-economic improvements through employment and income in rural areas.	All
	All	Industry Growth	Global industry demand for innovation in this sector due to overcapacity.	Discovery & Research
Marine Environmental Health	Environment sensing	Suitability of product	Cost-effective, compact and portable opportunity in comparison to current ex-situ techniques.	All
	All	Sustainability concerns	Stringent environmental legislation is increasingly widespread and increasing the demand for eco-friendly products and an overarching move towards greening industrial processes and products.	All
All	All	Future potential	Key societal challenges of sustainable food security, sustainable energy security, environmental health, human health and wellbeing, and the greening of industrial products and processes provide an overarching driver for the sector.	All

Barriers

Sub-sector specific barriers (Annex 8) and barriers common to all sub-sectors were identified during the literature review and desk-based research phase of the study. The barriers common to all Blue Biotechnology sub-sectors were presented to stakeholders at the project's Stakeholder Workshop and stakeholders were asked to prioritise them (see Section 3.1.8). In addition, the European Commission's public consultation on Blue Biotechnology (Annex 9) presented a number of perceived barriers relating to bringing marine biotechnology applications into the market and the perceived challenges encountered in research. Stakeholders were asked to rank these barriers. Table 3.10 presents the barriers identified in the literature review and additional barriers identified at the workshop and during the public consultation. Throughout stakeholder discussions it was evident that there is a high degree of interconnectedness between the barriers.

Table 3.10 Barriers to Blue Biotechnology

Type of barrier/bottleneck	Problems identified in desk based research	Problems identified by stakeholders (public consultation and stakeholder workshop)
Coordination	A platform oriented connection of infrastructures is still lacking and only few centres of excellence have been initiated	Collaboration is the real issue. Collaboration between industry, research, SMEs and investors is lacking. Ties in with the need for finance interface and platform.
	Fragmented approach to marine biotechnology research, infrastructures and effort in Europe	Mapping of marine biotechnology activities is lacking – this would inform where collaboration is most needed.
	Lack of coordination between academic and industry partners at the EU level and a lack of common projects.	Communication and knowledge sharing is lacking
		Lack of collaboration including between academic and industrial partners / difficulty in finding partners for collaboration
Finance	Low investment in R&D especially in industry sectors viewed subjectively as un-alluring in comparison to pharmaceuticals industry.	Lack of platform to bring investors and SMEs/projects together
	Access to finance is problematic as few investors are keen to take risks in new technological developments	Lack of interface between investment, industry and research
	Lack of investment in SMEs, SMEs assume risk and often run out of funds before product development is complete	Issues with finance relate to Blue Biotechnology being an 'invisible sector', the sector is not well understood by investors due to lack of expertise, understanding and time to explore possibilities.
		Investors need more predictability and certainty in the product and market
		General lack of funding
Knowledge	Lack of basic research into ecology of marine species and organisms from unusual and extreme environments decreases chances of finding novel bioactive compounds.	Knowledge of Blue Biotechnology sector and its activities is lacking, who is doing what?
	Limited understanding of physiology and ecology of marine species	Knowledge and understanding of Blue Biotechnology in arena outside of Blue Biotechnology is lack, may be deterring investors. Facilitation of knowledge sharing is needed.

Type of barrier/bottleneck	Problems identified in desk based research	Problems identified by stakeholders (public consultation and stakeholder workshop)
	Limited number of marine model organisms	Lack of knowledge (by traditional biotechnology players) about the potential of marine genetic resources for biotechnology applications
	Lack of data about marine organisms which hinders the assessment of the potential of an organism and its genetic diversity	
Regulatory	Access and benefit sharing (high seas) issues	Awareness of regulatory requirements in the sector is lacking
	Intellectual property (IP)	Legal certainty is needed
		Traceability of marine bioresources, proof of legality and consequences later on in life of product.
		Legal framework (e.g. administrative hurdles related to product development, intellectual property rights and ownership barriers)
Policy	There is no Europe wide policy on marine biotechnology.	
	There are varying national policies, strategies, initiatives and programmes.	
Access to resources	Legal access is often only feasible for larger organisations and discoveries are reliant on identification and variability. Discoveries are subject to profit sharing (high seas).	Cost of bioprospecting is high, who will fund this?
	Exploration and sampling in areas of environmental extremes (e.g. high seas) is difficult and expensive	Lack of access to marine genetic resources or sufficient amounts of marine organisms for downstream biotechnology research and development (e.g. sampling, repositories, biobanks)
Supply	Culturing marine microorganisms is problematic as culture techniques are specific for marine organisms. New culture methods and media needed to accommodate the complex and symbiotic nature of marine organisms	
	Productivity of original organisms is often too low to make commercial production possible.	
Infrastructure	Novel data management platforms and information services needed	Lack of research infrastructure
	Lack of analytical platforms by which to process data	

Type of barrier/bottleneck	Problems identified in desk based research	Problems identified by stakeholders (public consultation and stakeholder workshop)
	Lack of storage capacity such as databases to accommodate an increasing production of data	
Technical / equipment	Development and optimisation of appropriate bio-engineering tools	Capacity shortage (e.g. suitably trained personnel, etc.)
	Tools and platforms to facilitate high throughput screening of new 'omics' related information are needed	
	The cultivability of bioactive compounds is constrained by success of microbial and tissue culture, chemical synthesis and biosynthetic engineering.	
	Lack of bio-assays that can accommodate diverse material from marine sources	
	Need to carry out high-content, broad-target screening (screening of active compounds and replication, preventing repeated rediscovery).	
Sustainability / environmental impact	Limitations to harvesting of marine organisms.	
	Harvest of large amounts of marine organisms can cause harm to the marine environment.	
	Separating bioactive compounds/molecules can be time consuming	
Other	Lack of incentives to scientists to fully commit to product development when alternatives exist (i.e. bio-antifoul product).	High risks involved
		Lack of established marine biotechnology value chains or entry points in the already existing ones
		Lack of visibility of the sector

3.1.8 Stakeholder Workshop

A total of 22 stakeholders attended a stakeholder workshop on February 11th 2014. Annex 13 presents the participant selection process and lists the attendees. The purpose of the workshop was to assess the findings from the public consultation, with a focus on the state of play, drivers and barriers, lines of research, main products and services of the Blue Biotechnology sector. The workshop also included discussion on emerging policy recommendations.

The results from the initial desk based research phase and the patent profiling were presented by consortium members, and moderated discussions on the state of play, problems and challenges and drivers and barriers were held. An interactive discussion followed focusing on EU policy options in which stakeholders were asked where they thought the EU could do to address the barriers.

Stakeholders were given a list of barriers to Blue Biotechnology (common to all subsectors) and asked to vote on the top three most important barriers. The results of this prioritisation exercise are presented in Table 3.11.

Table 3.11 Stakeholder prioritisation of barriers

Barrier Type	Number of stakeholder votes
Co-ordination and collaboration	7
Finance	6
Knowledge	6
Regulation	5
Policy	4
Supply / value chains	3
Access to resources	2
Other	2
Infrastructure	1
Technical / equipment	1
Sustainability	0

The top four barriers were explored further and stakeholders were asked to consider the following questions: 1) What is the barrier precisely? 2) How does it impact growth? 3) How can it be overcome? 4) Can you provide good practice examples? The most pertinent points of discussion are noted below. Of particular interest is the interconnectedness of barriers.

Coordination and collaboration

There was a mixed response to the issue of coordination and collaboration. Some stakeholders noted that coordination is not really an issue as research activities are well coordinated in Europe with a number of networks and clusters in existence. The real issue is a lack of collaboration between investors, industry, SMEs and researchers. However, marine biotechnology activities in Europe need to be mapped to inform where collaboration is needed and to provide information to industry and investors to inform them what opportunities exist in Blue Biotechnology. It was noted that there are some examples of productive relationships between industry and research; Unilever and P&G have open innovation approaches and whilst they do not provide direct investment they do look at the different application of marine biotechnology, for example the use of marine proteins in ice cream. The recently launched Blue Biotechnology ERA-NET aims to improve coordination between funding bodies and to enable research.

Finance

Blue Biotechnology is considered to be 'invisible' and as such investment is hard to come by. Blue Biotechnology is complex and there is little understanding of it outside the 'sector' which does make it an unattractive proposition to investors who lack the expertise, understanding and time to fully realise the applications and potential of Blue Biotechnology. An interface or platform which would bring together investors, SMEs and researchers together could facilitate a better understanding and potentially attract more investors to the sector. In Norway, for example, industry is involved at the early stages of research to provoke interest and to provide basic knowledge. However different types of financing and different solutions are needed at the different stages along the value chain. In fact there can be multiple solutions for the same stage: it is a matter of identifying what will work best in a particular situation. Financing of Blue Biotechnology could happen in waves: first an idea is funded, then background research and initial product development is funded, and finally funding is to upscale, commercialise and bring the product to market. Also discussed was investor's preference for predictability and certainty in products and the markets, and this includes a predictable regulatory framework within which to operate. It was difficult to determine for participants if financing barriers were specific to Blue Biotechnology or were in fact common to all biotechnology sectors.

Knowledge

Stakeholders reported that it was not clear what marine biotechnology activities were taking place and who was involved. Mapping the Blue Biotechnology landscape in Europe could be beneficial to financing and collaboration, two issues which are connected. The idea of an interface between industry, research and policy was suggested as a way forward to facilitate knowledge sharing and communication between stakeholder groups. Knowledge is vital in motivating actors to collaborate and informing potential investors. This is an aspect of Blue Biotechnology which is likely to benefit from the recently launched Blue Biotechnology ERA-NET and its coordinating activities.

Regulation

Stakeholders identified the need for legal certainty in Blue Biotechnology. Regulatory issues relating to the traceability of marine resources was noted as a possible barrier to investment. Researchers are not aware of regulatory requirements and nor do they understand how newly drafted regulation will work in practice. There is a lot of uncertainty in the sector.

Policy Options

A number of suggestions were made by stakeholders with regards to possible areas of EU intervention. These are as follows:

- Support bioprospecting activities;
- Facilitate access to samples and data i.e. support biobanks;
- Facilitate industry and research collaboration;
- Clarify regulatory framework in order to create legal certainty;
- Introduce a coherent policy plan which is aligned to Member State policies.

Conclusion: Ten points of interest

The meeting was concluded by a summary of ten points of interest to take forward in the subsequent policy preparation steps:

1. Definition of the Blue Biotechnology sector

There is currently no clear definition of a Blue Biotechnology sector. There are so many Blue Biotechnology activities that it may not be possible to create one generalised sector which encompasses such a complex area. Perhaps the 'sector' is too complex to delineate and to do so would be counterproductive. In fact different definitions are required for different purposes. Thus for instance the sector should be defined in a wider context, if the economic dimension is considered –

whereas when it comes to research questions a narrow definition is more appropriate. The sub-sectors of Blue Biotechnology are at different stages of development and have encountered different stages of growth, therefore to group these together may be limiting. What is clear, however, is that the specific characteristics of Blue Biotechnology are most noteworthy in the early parts of the value chain – most prominently through bioprospecting.

2. Data on the Blue Biotechnology sector is scarce

It is very difficult to collect data on the Blue Biotechnology sector, partly because of a lack of definition but also because of the 'age' of the sector; it is considered to be in its infancy. Therefore there is a lack of statistical information relating to the sector, the ramifications of which are that evaluating the performance of the sector is problematic and not straightforward, and highlighting the importance of the sector to investors is difficult.

3. Public investment in the sector (FP7 & H2020) but not equal access to the funds

Public funding from the EU is available through FP7 and Horizon2020. Funding is accessible to research institutes and SMEs, but access to these varies.

4. Current status of the Blue Biotechnology sector not clear

The current status of the sector is not clear. This is a result of the sector being complex, diverse and without clear definition, being difficult to measure in terms of performance and overlapping with a number of other biotechnology sectors. Whilst patent profiling and output of publications are a measure of the potential of the sector, the commercial success is difficult to determine.

5. Performance in research exceeds that in commercialisation

The EU performs well with regards to publications relating to Blue Biotechnology - 30% of global publications are attributed to the EU - but it appears to be lagging behind in the commercialisation, if one takes patents to be an indicator of commercial activity in an area (e.g. the EU only represents 13% of patents). This suggests that there is a disconnect between research and commercialisation of Blue Biotechnology products and services; but at the same time a more in-depth study with regard to the effectiveness of other commercialisation paths may also be considered (as esp. also SMEs seem not to pursue the patenting path).

6. Health and wellbeing as areas of growth

Health and wellbeing, food and energy appear to be the most important sectors in which Blue Biotechnology is applied in Europe.

7. Access to finance: a main barrier

Access to finance seems to be a main barrier affecting Blue Biotechnology in Europe. The business case of Blue Biotechnology is not communicated to nor well understood by investors. Finance is not a single issue and multiple solutions may be needed to address the specific aspects of finance in the Blue Biotechnology sector, for example at different stages along the value chain, in different sub-sectors and for different stakeholders. There is no 'one-size-fits-all' approach.

8. A lack of collaboration along the value chain

Blue Biotechnology is complex and whilst some aspects (i.e. research) are thought to be well coordinated, there appears to be a lack of collaboration between investors, industry and SME further along the value chain with regards to product development, up-scaling and commercialisation.

9. Regulatory framework: key to future growth

Regulatory issues are key to the future growth of the Blue Biotechnology sector. There is currently a lot of uncertainty which needs to be addressed and it is important to ensure the EU is engaged with the global level discussion that is taking place. The ABS (access and benefit sharing) issue in Blue Biotechnology is unique and requires further clarification and action by the EU.

10. Let's make smart use of the platforms and initiatives that we have

There are a number of platforms and initiatives in Europe which should be utilised, strengthened and supported before new measures are considered.

3.2 Network, cluster and policy analysis

At European level, the importance of exploiting marine bioresources is recognised by its presence in Framework Programme 7 (FP7) and in Horizon 2020, and as one pillar of the Blue Growth strategy. Other documents that have had a strong input into Europe's approach to marine biotechnology or that encapsulate the recent or current status of marine biotechnology include the European Marine Board's Position Paper 15[55] and its more recent paper on Marine Biodiversity[56], the Scoping paper of the KBBE-NET's high-level coordinated working group on marine biotechnology[57], and the outputs of the Coordination and Support Action CSA MarineBiotech[58]. They are part of a continuum of growing interest in the potential of this sector for sustainable growth based on renewable bioresources, and they reinforce the strategic areas that are feasible for SMEs to focus on.

3.2.1 FP6, FP7 and Horizon 2020

The European Union has been and is supporting the improvement of knowledge, human potential and infrastructure for underpinning the development of marine biotechnology throughout Europe and beyond. The EU's actions in the field have a structuring effect and aim at ensuring that Europe remains one of the key players in this rapidly evolving and very promising field of science and technology.

The EU's Framework Programmes for Research FP6 and FP7 have funded key research into marine biotechnology focusing on science policy, coordination, infrastructures and support of marine biotechnology. Due to the complex nature of marine biotechnology and its applications, research funding can be found in a variety of different funding areas and measures. However, our analysis of the dedicated marine biotechnology projects financed by the FP6 and FP7 of the European Union reveal that projects are found only in a small range of funding categories and topics, despite the potential for marine biotechnology to have been included in a much broader range of programmes.

The Sixth Framework Programme (FP6)

Under FP6 nine projects (see Annex 10 for an inventory of FP6 projects) could be specifically affiliated to marine biotechnology representing a funding volume of approximately EUR 40,178,604. These projects comprise specific support actions, SME collaboration projects, one ERA net and one Marie-Curie project and classical research projects; the latter making up EUR 36 million. In

[55] *Marine Biotechnology: a vision and strategy for Europe* Sept 2010 European Marine Board http://www.marineboard.eu/images/publications/Marine%20Biotechnology-37.pdf
[56] *Marine Biodiversity: A Science roadmap for Europe* September 2012 European Marine Board http://www.marineboard.eu/images/publications/Marine%20Biodiversity-122.pdf
[57] *Background and recommendations on future actions for integrated marine biotechnology R&D in Europe* October 2009 CWG-MB http://ec.europa.eu/research/bioeconomy/pdf/cwg-mb_to_kbbenet_report_final.pdf
[58] *Marine Biotechnology R&D in Europe Strategic Analysis* February 2013 http://www.marinebiotech.eu/images/Public_reports/Marine%20Biotechnology%20RTDI%20in%20Europe.pdf

terms of topics the research projects dealt mainly with biodiversity issues (50%), aquaculture and measures to stimulate in a systematic way the sharing of common 'omic' resources. among these research projects, a strong emphasis was put to integrated projects reflected in the much higher funding volume per project (e.g. a total EC contribution of EUR 10 million for “MARINE GENOMICS“). However, all projects were coordinated by universities; industry involvement was on a very low level. Even though not all countries of Europe were involved, the project partnerships reflect a broad network of the academics in the field. France, UK and Germany were the top three proposal partners, which corresponds to the findings from the stakeholder analysis (see Annex 3).

The Seventh Framework Programme (FP7)

Under FP7 new initiatives are continuing and deepening the development of the European Research Area (ERA) in the field of Life Sciences, mainly within the KBBE programme. In FP7, marine related projects are to be found across all themes of the specific programme COOPERATION[59]. Theme 2: “Food, Agriculture and Fisheries, and Biotechnologies” plays a key role to support marine related research projects through three activities. In total 21 projects were funded specifically with marine biotechnology scope[60] with a total volume of EUR 87 million. The EU contribution was devoted to this topic; mainly in 14 research projects which represented EUR 82 million (see Annex 10 for an inventory of FP7 projects). A change in the expected impact of the projects can be observed with the Commission demanding from projects to shape the European Blue Biotechnology landscape, to involve or even be under industry lead and being of direct use for applications. During FP7 25% of funding went to SMEs.

As in FP6, only academic partners were coordinating FP7 projects. Whereas these coordinators originated from eight countries only (Ireland, Germany, Netherlands, Finland, Belgium, Italy, Portugal, UK), in total 24 European countries participated in FP7 marine biotechnology projects, with 18 countries being involved in more than one project. Germany, Italy, UK, France, Belgium and Spain have been most active. With respect to participation, Germany, France and UK were the top 3 proposal partners. The topics of the proposals identified by the mapping exercise largely correspond to the areas of common interest which were (i) marine bioprospecting/biodiscovery (in particular for human health and new industrial compounds); (ii) development of robust, biotechnology-based state of the art R&D tools and infrastructures tailored for marine biotechnology, (iii) molecular aquaculture and (iv) biomass production for bioenergy and fine chemicals.

One additional area that also seems to be re-appearing in many countries is the interest in marine environmental biotechnology applications and bio-sensors, among other in the context of the European Marine Strategy Framework Directive (MSFD).

Horizon2020 (H2020)

The recently established Horizon2020 programme continues to support Blue Biotechnology issues. This time a broad discussion and shaping on policy and stakeholder level fed into the design of the work programme 2014/2015. The strategic approach to research and innovation funding was implemented into the calls. This approach is aiming to provide the scientific and technological

[59] For an overview see: Interim Catalogue of Marine related Projects, EC, 2012, http://ec.europa.eu/research/bioeconomy/pdf/interim_catalogue_of_marine_projects-2012_en.pdf

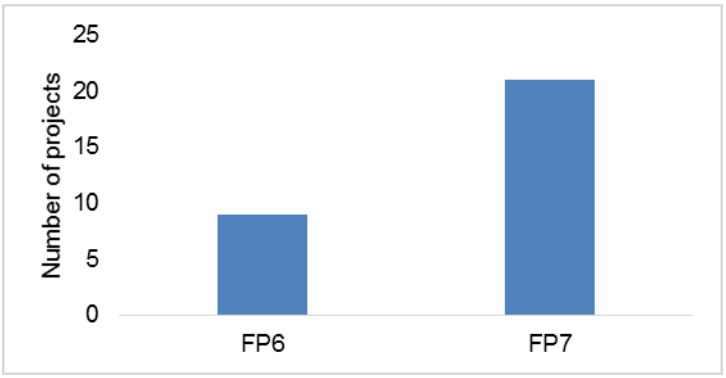
[60] The search was performed according the scoping of this study. However, when searching for ‘marine related projects’, more than 90 projects are found, associated to the KBBE activity 2.1. (Sustainable production and management of biological resources from land, forest and aquatic environments), activity 2.2 (Fork to farm: Food (including seafood), health and well-being) and activity 2.3 (Life sciences, biotechnology and biochemistry for sustainable non-food products and processes). The EU spent more than € 1.9 billion for funding this theme and the knowledge bio-based economy over the duration of FP7 (2007-2013). Each of the three activities comprises marine related areas such as sustainable production and management of fisheries and aquaculture, quality and safety in food products (including seafood) as well as marine biotechnologies. While most projects directly deal with fisheries, aquaculture, seafood safety and quality or marine biotechnologies, some of them are only partially relevant to the marine sector (specific work packages, tasks or experiments). It also includes eight large integrating projects (for a total EU contribution of approximately 60M€) partly funded by Theme 2 under the cross-thematic calls “The Ocean of Tomorrow”.

bases for strategic decisions of emerging industrial sectors[61]. By reducing technical bottlenecks in this area, the whole sector shall become more attractive to investors. It shall also help EU industry to move from the developmental stage to the commercialisation of innovative products. A European approach would raise awareness among policy makers, the private sector and the general public of the potential of marine aquatic products. The most important change is expected to arise from the fact that "Blue Growth" is a focus theme as such in Horizon2020. Therefore marine biotechnology issues will be part of a variety of actions.

So far the "Blue Growth" theme has started very promising with respect to the Blue Biotechnology sector: four calls were published with the start of the work programme (11th Dec 2013) with direct focus to Blue Biotechnology comprising classical research topics, as early discovery of molecules and enzymes as well as societal science related topics and outreach activities, e.g. ocean literacy. The allocated EC contribution for research projects shall be in the range of EUR 82 million in 2014. Having built Horizon2020 around the main societal challenges like an ageing population, food security, energy efficiency, the EU attaches high importance to embed socio-economic sciences and humanities into the work programme[62]. The main scope of the research issues target the technological development rather than supporting discovery or basic research. The European Commission expects that all projects should have a strong impact to the business development of the Blue Biotechnology sector.

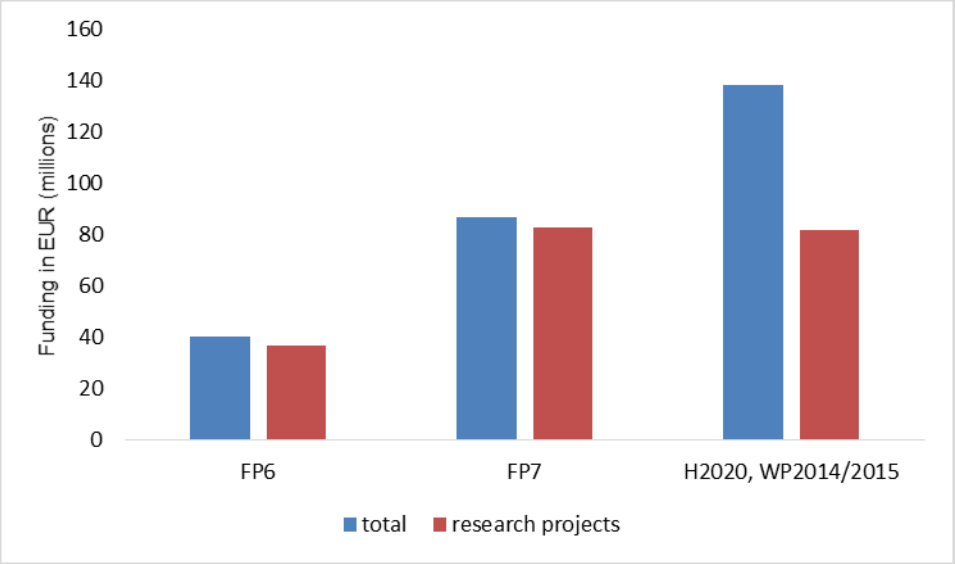
The total funding for marine biotechnology under Horizon2020 may well increase compared to FP7. There will be a share of the EUR 500 for research into marine living resources, probably amounting to around EUR 160million and also a share of a further EUR 500million for biotechnology. Projects under Horizon 2020, however, are to be led by the demands of industry so there may be more opportunities for support to SMEs. This support to Blue Biotechnology may actually be increasing.

Figure 3.6 **Number of projects relating to marine biotechnology under FP6 and FP7**



[61] http://ec.europa.eu/maritimeaffairs/documentation/publications/documents/blue-growth_en.pdf,
[62] http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/index.html

Figure 3.7 **European Commission financial contribution to FP7, FP6 and Horizon2020***



*planned budget

3.2.2 National, regional and European clusters, initiatives and networks

National, regional and Pan-European coordination is essential to provide a coherent framework for marine biotechnology activities. A range of initiatives, networks and clusters relating to marine biotechnology have been established at the national, regional and European level as shown in Annexes 11 and 12. These have implemented approaches to coordinate research and development activities, innovation and infrastructures. Europe wide initiatives and networks can be roughly categorised as those relating to science policy and research coordination and those relating to infrastructure coordination and support; Table 3.12 gives a summary of these.

Table 3.12 **European Union initiatives and networks relating to marine biotechnology**

Science, policy and research coordination	Infrastructure coordination and support
EU Joint Programming Initiative Healthy and Productive Seas and Oceans (JPI-OCEANS)	European Marine Biological Resource Centre (EMBRC)
CSA MarineBiotech	ASSEMBLE (Association of European Marine Biological Laboratories)
European Research Area Network (ERA-NET), a marine biotechnology ERA-NET is in preparation	EUROFLEETS & EUROFLEETS2 (Towards an alliance of European Research fleets)
The Knowledge Based Bio-Economy Network (KBBE-NET)	EC Expert Group on Marine Research Infrastructure (MRI)
European Technology Platforms (ETPs)	ELIXIR
EuroMarine	The European Strategy Forum on Research Infrastructures (ESFRI)
Marine Genomics for Users (MG4U)	
EUR-OCEANS Consortium (EOC)	
MarineKIC Initiative	

During the last ten years, an increase in efforts to develop more focused approaches to stimulate marine biotechnology research and development at the local level was observed. One way this is achieved is through putting in place regional 'bio' and 'marine/maritime' innovation clusters and networks (e.g. ScanBalt, CIESM) which are growing in importance (see Table 3.13). The foundation of these organisations is mainly driven by common interests of stakeholders along specific sea

basins, such as the Baltic. Such development seems likely to expand even more in the future, as the forerunning projects were very successful in their integrative approaches.

Only recently, new forms of networks appeared, were installed or formed (SUBMARINER network, BioMarine) as well as Europe-wide associations of academic stakeholders were re-established (European Society for Marine Biotechnology), indicating rising activity and need for networking within the stakeholder community. Seven regional initiatives and networks have been identified in Europe, three of which have international networks; a summary of these is presented in Table 3.13 below.

Table 3.13 Regional initiatives and networks in Europe

Initiative / Network	Region
Mediterranean Science Commission (CIESM)	Mediterranean
SUBMARINER: Sustainable Uses of Baltic Marine Resources	Baltic Sea Region
Baltic Sea Region	Baltic Sea Region
ScanBalt® fmba	Baltic Sea Region
European Society for Marine Biotechnology	European with international network
BioMarine	International network
BioMarine International Clusters Association	International network

For countries with a federal structure, there appears to be strong engagement to support marine biotech research at the regional level (depending on the available human and infrastructure capacity or potential), because it is seen a key area for new opportunities for sustainable economic growth at local and regional levels. Installing regional bio-innovation and marine/maritime clusters is a strategy employed by several regional governments with relative good results (see Table 3.14).

Some countries focussed on the installation of platforms for certain technologies or applications, reflecting on the need for technological integration. In general, the number of clusters is still small compared to the potential regions that could use marine biotech as a motor for regional development.

Table 3.14 Clusters and other national networks

Country	Initiative / cluster	Description
France	ALLENVI Groupe Mer	Association
	Biogenouest	Platform
	CapBiotek - Regional Cluster in Biotechnologies in Brittany [16]	Regional clusters
	Atlanpole Blue Cluster - Regional Cluster in Biotechnologies in Pays de la Loire[17]	Regional clusters
	Pole Mer Bretagne - Global economic competitiveness cluster in Brittany[18]	Regional clusters
	Pole Mer PACA - Global economic competitiveness cluster in Provence-Alpes-Côte d'Azur[19]	Regional clusters
	Europole Mer "Blue Network" - an informal coordination structure with about 20 members with one of the focal areas (Axe 1) on marine genomics and blue chemistry (related to biotech)	Regional clusters

Country	Initiative / cluster	Description
Norway	Biotech North: BioTech North is the network organisation for the development of biotechnology in the Tromsø region in North Norway.	Regional clusters
	Mabcent-SFI: Center for research based innovation on bioprospecting in Tromsø where academic research groups and SMBs collaborate on defined research topics for innovation.	Regional clusters
	MarBank: A national marine biobank organising the collection, and structuring of the marine biodiversity for research and industrial development.	Regional clusters
Spain	Spanish Biomass Technology Platform One the priorities of the Strategic Plan of this platform is the production of biofuel from microalgae. [13]	Platform
	PTEPA is the Spanish Platform for Fisheries and Aquaculture Research. This platform has develop a SRA [14]	Platform
	Genoma Spain is a government-supported public foundation devoted to promoting technology development, knowledge transfer and innovative practices, chiefly in the biotechnology sector.	Foundation
UK	The European Centre for Marine Biotechnology aims to be the business incubator of choice for new and emerging marine biotechnology companies in the UK. By establishing a growing cluster of activity and international networks it strives to be the premier site for innovative growth and development within this emerging sector.	Regional clusters
	AB SIG, the Algal Bioenergy Special Interest Group	Association
Belgium	Flemish Marine biotechnology Platform Mariene Biotechnologie Platform Vlaanderen	Platform
	The network Aquacultuur Vlaanderen	Platform
Denmark	The Seaweed Network in Denmark (SND)	Association
Germany	Northern network on marine biotechnology	Association
Iceland	Association of Biotech companies defined by the Federations of Icelandic Industries	Association

3.2.3 National policies in Europe

Whilst there is no Europe-wide marine biotechnology policy, European countries do support marine biotechnology in national strategies albeit with varying approaches. The majority of countries do not have specific national marine biotechnology programmes, strategies or policies. Instead marine biotechnology research comes under the remit of general programmes in marine science, biotechnology or other generic sciences, and is supported by overarching policies and strategies in marine sciences and/or biotechnology.

However, a small number of countries have developed specific programmes and strategies, policies or plans for marine biotechnology research. Ireland, Norway and Denmark are three such countries. Ireland adopted its Sea Change: A Marine Knowledge Research and Innovation Strategy[63] in 2007

[63] http://www.marine.ie/home/research/SeaChange/

which presents a national agenda on science, research innovation and management with the aim of transforming the Irish maritime economy. The strategy is being implemented through five programmes, one of which is the Discovery Research Measure Programme whose focus is on marine biodiscovery/biotechnology, marine technology, marine functional foods and renewable ocean energy[64]. In order to deliver on the objectives of the Sea Change a national marine biotechnology programme called Marine Biotechnology Ireland (MBI)[65] was established in order to create and sustain national opportunities for research, development and innovation in marine biotechnology with the goal of becoming an internationally recognised research performer.

Norway published a national whitepaper entitled 'Marine Bioprospecting – a source of new and sustainable wealth growth'[66] in 2009. Norway's strategy is built on marine bioprospecting and the FUGE (functional genomics) programme of 2002-2011 (EUR 190 million), which established a number of important centres with infrastructure and collaborations. The Research Council of Norway, Innovation Norway (focused on industry) and SIVA (the Industrial Development Corporation) work together on the marine biotechnology strategy, so there is always a drive towards embedding research innovation in industry.

Denmark published a report in 2010, 'The Sea – an unexploited resource'[67], which presented all the opportunities in marine biotechnology in Denmark and focused on the use of marine bioresources for biomass, bioprospecting for new biological principles and compounds, and biofilm research.

Other countries do recognise that marine biotechnology is a legitimate topic for research and innovation activity, even if there is no specific national strategy in place. One example is that Norway and the UK have put in place a collaboration on industrial biotechnology and biorefining in 2011, enabled through Innovation Norway and the UK Technology Strategy Board, with support from relevant research councils, to support transnational collaborative projects between companies and researchers equivalent to GBP 2.5 million (EUR 3 million) from each side).

Overall with respect to European countries, four categories[68] of support for marine biotechnology research have been defined as:

1) Countries with a clearly identifiable marine biotechnology focus as developed in dedicated marine biotechnology RTDI plans, strategies and/or funding programmes;
2) Countries with strong marine biotechnology activities in one or more areas, but without dedicated marine biotechnology science and technology plan(s), strategies and/or programmes;
3) Countries with some interest and activities in certain marine biotechnology application areas, but without dedicated marine biotechnology science and technology plan(s), strategies and/or programmes;
4) Countries without dedicated marine biotechnology science and technology plan(s), strategies and/or programmes and where there is only limited marine biotech focus and activities.

Table 3.15 presents an overview of European countries with regards to their support of marine biotechnology activities and illustrates the different ways in which marine biotechnology is being promoted across Europe and the fragmented nature of effort.

[64] http://www.marine.ie/home/research/SeaChange/AboutSeaChange/Discovery.htm
[65] http://www.marine.ie/home/research/SeaChange/NationalMarineBiotechnology/
[66] http://www.regjeringen.no/upload/FKD/Vedlegg/Diverse/2009/Marin_bioprospektering_080909_lavoppl.pdf
[67] http://fvm.dk/fileadmin/user_upload/FVM.dk/Dokumenter/Servicemenu/Publikationer/Havet_-_en_uudnyttet_ressource.pdf
[68] 'Report on strategic analysis of marine biotechnology RTDI in Europe', Marine Board-ESF, 2013: http://www.marinebiotech.eu/images/Public_reports/Marine%20Biotechnology%20RTDI%20in%20Europe.pdf

Table 3.15 Overview of marine biotechnology policy landscape in European countries[69]

Countries with a dedicated plan, programme or strong policy focus on marine biotech	Countries where marine biotech is supported via more wide-scope programmes and/or instruments		
	Considerable interest and/or activities in marine biotechnology R&D*	Some interest and activities in marine biotechnology R&D*	Only limited marine biotech focus and activities*
• Ireland • Denmark • Norway	• Belgium*** • France • Germany*** • The Netherlands • Poland • Portugal • Italy** • Spain • Sweden • UK	• Croatia • Greece • Finland** • Iceland • Romania • Slovenia • Turkey	• Austria** • Bulgaria • Estonia** • Latvia** • Lithuania** • Malta** • Switzerland** • Ukraine**

* Based on the information that could be collected within the scope of the CSA MarineBiotech;

** Countries for which no or only limited information could be collected within the scope of the CSA MarineBiotech;

*** Countries with a federal structure with considerable activities in one or more specific coastal regions.

3.3 Review of patent profiling

A patent profiling sub-study was undertaken as part of the study to provide an overview of pending and approved patents related to Blue Biotechnology in Europe. The setup and validation of the methodology has been completed and is presented in Annex 5 together with the detailed results of the evaluation.

Patents and scientific publications are a measurement of output performance and can be used to assess the relative strengths of a country, region or entity with respect to this specific form of intellectual property protection. However, the analysis of the patent situation does not necessarily reflect the economic power of a given sector, as various other strategies for valorisation exist. Especially in the field of SME, patenting is often avoided due to high costs and efforts. This does, however, not necessarily indicate a lack of commercialisation, but a different method, which requires further study. In terms of showing the relationship and knowledge transfer between academia into larger industry not only the absolute amount of patents filed is interesting, but also the comparison of patent filing versus number of scientific publications.

3.3.1 Positioning of Blue Biotechnology sector vis-à-vis other sectors

Patents and scientific publications are a measurement of output performance and can be used to assess the relative strengths of a country, region or entity with respect to this specific form of intellectual property protection. However, the analysis of the patent situation does not necessarily reflect the economic power of a given sector, as various other strategies for valorisation exist. Especially in the field of SME, patenting is often avoided due to high costs and efforts. This does,

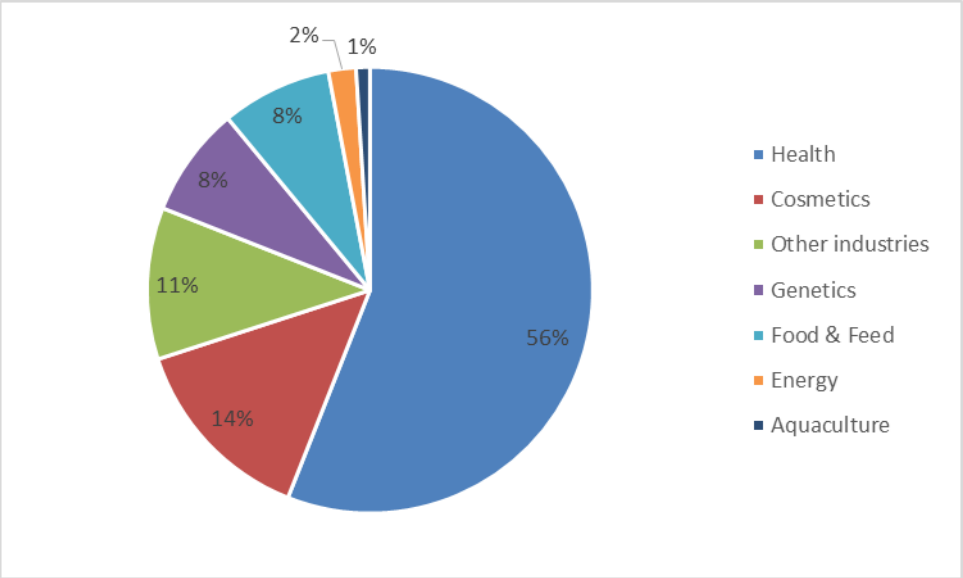
[69] Taken from the 'Report on strategic analysis of marine biotechnology RTDI in Europe', Marine Board-ESF, 2013: http://www.marinebiotech.eu/images/Public_reports/Marine%20Biotechnology%20RTDI%20in%20Europe.pdf

however, not necessarily indicate a lack of commercialisation, but a different method, which requires further study. In terms of showing the relationship and knowledge transfer between academia into larger industry not only the absolute amount of patents filed is interesting, but also the comparison of patent filing versus number of scientific publications.

The number of patent publications has been exponentially increasing over the course of the last 50 years. There was a real hot spot of patenting between 2000 and 2010. A trend analysis undertaken for all sectors until 2020 indicates a stabilisation in the number of patents in most sectors with only cosmetics and energy expected to increase further by 10-20%.

Patents were filed in all subsectors of blue biotech, with a strong focus to health topics covering 56% of all patents (Figure 3.8). As most of the patents deal with compounds or genes with more than one application field rather than with specific production processes, many patents belong to more than one sector. For instance, patents on “natural products” belong in average to three of the subsectors. In some cases patents on genetic material and tools for molecular research and development could not been affiliated to a specific subsector at all, in such case they have been assorted separately.

Figure 3.8 **Patents distribution across Blue Biotechnology sub-sectors**



Most patents belong to the medical or veterinary science and hygiene (International Patent Class, IPC A61). In total only 10 patent classes could be identified with a focus on high value products. This may provide an indication of which sectors are expected to be financially most interesting in the near future as the patent filers have seen them worthwhile to go through the effort and cost of patenting.

The profiling also showed that European inventors file worldwide rather than using the national level: 67 % of all patents in MBT in Europe were filed as world patents especially since 1985.

The detailed analysis of all sectors revealed that the main players in patenting in marine biotechnology in Europe are the two companies Henkel (both in cosmetics and health), Germany, and Pharmamar, Spain (Top2 in Health). The chemical industry company Henkel holds many patents in its portfolio concerning hair care with marine collagen; Pharmamar is a leading pharmaceutical company exclusively working with marine organisms. BASF, which was formerly

identified as one of the main players, does not play a very prominent role anymore[70]. In the energy sector the leading company in patenting is Shell. However, the field of bioenergy is in non-European hands. There are only some minor inventors from European countries, which patent together with big companies in the US or Asia.

In general, companies are the main patent filers, research institutions and universities together represent less than 20% of the total number of patents, indicating a lack in knowledge transfer or alternative valorisation strategies of academic stakeholders. The recently published knowledge transfer report[71] summarised the strong bottlenecks for patenting for academics: costs, knowledge on patenting strategies, to early patenting but as well a lack of interest. For the research community, the pressure of publishing is very high. The benefit of commercialisation (measured in patents) compared to academic success (measured in publications) is mostly perceived to be risky[72]. Vice versa, the big companies do not tend to publicise their results by research communications. When considering the role of SMEs in the patent field, is becomes obvious that many SMEs have other strategies in IP protection but patent filing. Hence, it would be quite interesting to study the commercialisation modes of especially SMEs, as they contribute in a high number to the economic activity of the field.

3.3.2 Global perspectives

The profiling showed the importance of World patents. European inventors file worldwide rather than using the national level: 67% of all patents in marine biotechnology in Europe were filed as world patents. Since the early 1980s worldwide patenting has gained in importance leading to a boost of world patents after 1985. A few patents were filed with specific protection in US (134) or Canada (2). These patents have at least one inventor or applicant from a European country, but the "drivers" of those patents mostly were from non-EU-states.

A recent study[73] compared the European patent situation in the fields of aquatic products (including aquaculture and other industries) and high value products (including health, cosmetic and food) to the world situation: The study indicated a high output of European academia but an overall dominance of Asia in the field of patent filing (main countries: Japan and China), especially in the field of high value products. This is in agreement with the results of the overall Blue Growth study, which stated that scientific publications on the discovery and the usage of new marine molecules have constantly risen. In a global view, Europe generates almost a third of the scientific publications (in particular the United Kingdom, France and Germany) whereas the USA publish approximately a quarter of the scientific papers related to this field. When comparing this scientific activity to the trend in patents publications, the difference is striking: Europe only represents 13% of patents filed in relation to new marine molecules, at the same level than the USA. Japan (28%) and China (13%) seem far more active in patent publications than in scientific publications. Top authors in this field are seldom listed as top patent assignees, regardless of whether this relates to institutions or individual researchers[74]. As discussed, European Academics still seem to prefer publication rather than patent filing or find others way for valorisation.

[70] which is outlined by Arnaud-Haond S, Arrieta J (M, Duarte CM (2011) Marine Biodiversity and Gene Patents. Science 331: 1521-1522; see also presentation Concarneau, 20012): 54 out of 149 German patents in the MBT sectors are from BASF.
[71] DG RES Inn Knowledge Transfer Study 2010-2012
[72] DG RES Inn Knowledge Transfer Study 2010-2012
[73] Thomson Reuter 2011
[74] Data: Aquatic products top 10 priority countries: Japan, USA, patent cooperation treaty, China, Germany, Korea, European patent office, Canada, UK, Australia, with top 5 inventors: Bayer, Mitsubishi, Chugoku Toryo, Chinese Academy of Science, Nippon; EU research top 5: Fraunhofer, Consejo, CNRS, Univ. Madrid, Univ. Hull; World research top 5: all Chinese; in papers: all European; High value products top 10 priority countries: Japan, patent cooperation treaty, China, USA, Russia, Korea, European patent office, Germany, France, UK, with top 5 inventors: Univ. Kangnung Wonju, L'Oreal, Noevir KK, Nestle SA, Dokurit; EU research top 5: CNRS, Univ. Bashkir med, Consejo, Imperial College, Royal Holloway; World research top 5: all Chinese; in papers: USA, France, UK, Germany, Canada.

It would be interesting to assess the economic potential of the individual patents, however this was not possible in the context of this study as: a) economic value is normally generated from a set of patents rather than from individual one's; b) investor decisions often depend on a variety of factors that are kept confidential to third parties; c) economic value from patents may occur only over longer periods of time

3.4 Regulatory Review

Although legal issues clearly emerged from the stakeholder consultation as a barrier for the Blue Biotechnology sector. As described in Annex 14, the legal framework for Blue Biotechnology is complex and multi-layered. The question arises as to the extent to which these issues are susceptible to a specific regulatory response. In general terms there seem to be two main 'problem areas': challenges relating to intellectual property (IP) law and uncertainties with regard to access and benefit sharing (ABS).

IPR are fundamental to the Blue Biotechnology sector just as with other biotechnology sectors. Yet the situation is complex. On the one hand by protecting the interests of those who gather data and patent inventions they reward innovation. At the same time, though, by their nature they also have the potential to hinder or restrict the free flow of knowledge. Moreover there is no doubt that IP law is a complex area of law that requires specialist advice from IP laws and patent advisers. For scientists and SMEs this is an additional source of complexity and cost.

In terms of overall philosophy with regard to IPR in the Blue Biotechnology research sector there are, broadly speaking, two schools of thought: those who believe that scientific knowledge and information should flow freely and should not be subject to effective 'privatisation' (through the acquisition and enforcement of IPRs) and those who consider that IPR are a key means of encouraging development and rewarding investment. Moreover in the case of publicly funded research, including research funded by the EU, the question can legitimately be asked as to who should benefit from the knowledge gained? The funder or the researcher?

In practice institutions will deal with IPR in accordance with the own individual data and IP policies as well as arrangements made on an ad hoc basis with different partners. But even so there are difficult choices to be made. On the one hand as research funding typically depends to a greater or lesser extent on the number of publications there may be pressure to publish. On the other hand publication may not only alert potential competitors but also prejudice subsequent patent applications in terms of harming the novel characteristics of the inventions to which they relate. Consequently it can be better for research institutions, in particular when they collaborate with commercial partners, to keep the data and knowledge confidential prior to applying for a patent. Even here though there are complex considerations to take into account due to the fact that patents are time-limited. Apply for a patent too soon, before a product can be commercialised, and much of the commercial benefit may be lost. Leave it too late and a competitor may get there first.

Of course these are common challenges for technology sectors including other biotech sectors. Although they raise fundamental ethical questions about the nature of knowledge and its relationship to science (is it right that publicly funded data should be privately owned?, are gene patents ethical? and so on) these questions are not restricted to the Blue Biotechnology sector. In other words even if there was an obvious solution to these issues – which there is not – it would clearly not be feasible in to seek to modify IP law just to serve the needs of the Blue Biotechnology sector.

Having said that it must be recognised that IP issues remain a challenge. As noted in section 3.3, European researchers seem to be better at publishing their findings rather than obtaining patents. This may be for a number of reasons but at the end of the day economic growth in the Blue Biotechnology sector is likely to derive primarily from patents and not from published papers (or for that matter the contents of bioinformatics databases). One implication may be that published European research is helping scientists other parts of the world not simply to expand human knowledge about marine biotechnology but to derive commercial advantage through the acquisition of patents. In short there does not seem to a specific regulatory solution to this issue. It does not, though, mean that IPRs are not a barrier for the sector. Possible non-regulatory solutions might include the established of focussed development support system for the Blue Biotechnology sector in connection with IP issues through training and capacity building, networking and information sharing systems and so forth.

As regards the issue of ABS it is necessary to distinguish two sources of marine genetic resources: (1) ABNJ; and (2) areas under national jurisdiction.

Under the first scenario there are two main issues. First of all the manner in which marine genetic resources are obtained is largely unregulated at the level of international law meaning that there may be a risk of irreparable damage to fragile seabed ecosystems. The second issue concerns the whole question of the allocation of benefits derived from such resources. In short can financial benefits be effectively privatised through the grant of patents or, given that ABNJ are un-owned, do they also form part of the common heritage of mankind meaning that they should be shared among the international community (as is the case for deep sea mining in ABNJ)? International consensus on this issue has yet to be reached leading to a high level of uncertainty for the sector, which may deter investment.

As described in Annex 14, this topic is the subject of debate at the international level and is not susceptible of resolution through unilateral EU legislative action. Indeed EU action on this topic might have the risk of destabilising the on-going international discussions. Even attempting to regulate the acquisition of marine genetic resources in ABNJ may have a destabilising effect and in any event there is, as yet, no hard evidence that damage is actually taking place given the (small) size of samples recovered from the seabed (and there is not likely to be any significant impact from collections from the water column). Seeking to regulate this issue at the EU level may also be seen as an additional hurdle for European researchers. On the other hand, though, the patent profiling exercise did not reveal the source of the genetic material used in connection with Blue Biotechnology patents and indeed certain commentators have questioned the extent to which this is really a problem for the sector. The available literature suggests that most marine genetic material connected to patents is sourced from waters under national jurisdiction.

As regards ABS in waters under the national jurisdiction of coastal States the legal framework is at least clearer in terms both of UNCLOS and the Nagoya Protocol which will be implemented in the EU through the ABS Regulation. Pending the entry into force of the Nagoya Protocol it is of course premature to assess how effective this framework will be. In terms of marine research it seems relatively clear, however, that the regime may be challenging to implement at a practical level in terms of coordinating coastal permission for research cruises with the need to conclude specific ABS agreements in part due to the specific nature of Blue Biotechnology. Given that this topic has only recently been legislated by the European Parliament, there is no question of a specific regulatory response to the legal challenges faced by the Blue Biotechnology sector in terms of the implementation of the Nagoya Protocol. Nevertheless as with IP issues there is clearly a need for continued EU support as regards legal issues including with respect to the development of model ABS agreements, training and capacity building. This could in particular be provided through the

development of detailed guidelines on the implementation of the Nagoya Protocol in maritime areas under coastal State jurisdiction taking into account the relevant provisions of UNCLOS.

3.5 Conclusions

The sub-sectors of Blue Biotechnology (health, cosmetics, food, energy, aquaculture and marine environmental services) are diverse and dynamic. They are at different stages of development and have encountered different stages of growth. There is a huge array of potential products and services across all of the sub-sectors - which demonstrate the potential of the Blue Biotechnology sector. With regards to actual products and services currently on the market the selection is much less clear. This is illustrative of the view that Blue Biotechnology sector is considered a 'young' field of biotechnology. Furthermore, the health, cosmetics and food sectors are the largest 'users' of Blue Biotechnology and their products usually have to go through numerous trials and testing.

Marine research infrastructures (MRIs) support marine biotechnology by improving knowledge, giving access to new resources and decreasing the risk of operations, thereby supporting the maritime economy and blue growth. Europe has an array of marine research infrastructures and there are a number of initiatives and networks in place which aim to coordinate their efforts and facilitate access to them. However, there it is still reported by stakeholders that Blue Biotechnology infrastructure is lacking.

One conclusion is that Blue Biotechnology will not provide mass employment in Europe – at least not in the short- or medium future. However, the key people involved in Blue Biotechnology are groups of specialised, highly trained, researchers, innovators and entrepreneurs. The jobs are high end staffed by people who were expensive to train. The main economic contribution is likely to be from the value added derived from these attributes and intellectual property rights. Yet broader and potentially far- reaching socio-economic benefits could be derived from Blue Biotech applications and products in the fields of pharma, health, food, cosmetics and energy.

SMEs are an important aspect of the Blue Biotechnology sector as they play a key role bridging the gap between research activities and commercialisation of products. SMEs tend to be focused at the earlier stages of the value chain, as for them it represents in many cases a cost chain (i.e. the cash-burn stage before income-generation). They will typically be absent from the stage of industrial production of natural marine products, largely because of the high capital expenditure that is usually involved. Their involvement in the earlier stages focuses on identification, validation and de-risking of industrial opportunities from marine bioresources. They may work in collaboration with researchers at universities or institutes, and with larger industrial companies. Financing is a major issue for SMEs involved in marine biotechnology, as in other sectors. The fate of single-focus marine bioactives companies depends on success stories with a commercial outcome and, in the case of anti-cancer or other products, de-risking them by getting them into clinical trials, either alone or with a strategic partner, before cash-burn drains reserves and saps the patience of investors.

Each sub-sector faces is own specific challenges and barriers. However, the study has focused above all on barriers common to all sub-sectors and unique to Blue Biotechnology. Barriers were identified through the research and prioritised through two stakeholder processes. The general barriers perceived to be the most important in Blue Biotechnology are a lack of coordination and collaboration along the value chain, lack of access to finance, lack of knowledge and issues regarding access to resources.

More specifically, it appears that Europe is strong in coordinating research activities in the early stages of the value chain but there is a lack of collaboration further along the value chain between those doing the research and initial product development (mainly research institutes and SMEs) and investors, larger companies with the resources to up-scale and commercialise a product and the industry within which the marine biotechnology application will be used.

Access to finance is a key issue as well. Whilst there is funding available to Blue Biotechnology related research under the EU's FP7 and Horizon2020 programmes there is a lack of funding further along the value chain. SMEs involved in product development are reliant on reliable long term funding and the Blue Biotechnology sector is reliant on SMEs de-risking the value chain.

Knowledge refers to a number of different issues; knowledge of marine organisms and the 'uses' in Blue Biotechnology; lack of knowledge about the Blue Biotechnology sector and its potential among those outside of the field, i.e. the invisibility of the sector – this can affect investment in the sector as there is a lack of understanding of Blue Biotechnology which can act as a deterrent; knowledge of who is doing what within Blue Biotechnology in Europe, what products are SMEs working on and what research projects are taking place – mapping out Blue Biotechnology activities in Europe will help with collaboration and possibly investment.

Access to resources also contains a number of specific aspects: regulatory issues such as Access and Benefit Sharing (ABS) in Areas Beyond National Jurisdiction (ABNJ) are unclear and create uncertainty; there is legal uncertainty regarding the source and traceability of marine resources used in Blue Biotechnology products; physical access to marine resources for the purposes of bioprospecting and collection can be difficult and costly.

The EU recognises the importance of Blue Biotechnology as is demonstrated by the funding of marine biosciences, and marine biotechnology in particular, under the EU Research Framework programmes and specifically through Horizon2020 – which recognises Blue Growth as a focus theme. A range of initiatives, networks and clusters relating to marine biotechnology have been established at the national, regional and European level whose objectives have been to coordinate research and development activities, innovation and infrastructure. The recently launched Marine Biotechnology ERA-NET is one such initiative which will promote and coordinate collaboration between national and regional research funding organisations and programme administrators with the goal of establishing a long-term European Research Agenda and facilitating information exchange. There is no overarching Blue Biotechnology policy in Europe and the approach of Member States towards national policies is disparate.

Europe appears to be very active within the R&D stage of the Blue Biotechnology value chain. Europe generates almost a third of the scientific publications in this field. However, comparing this scientific activity to the trend in patents publications, a striking difference emerges that suggests that there is less success in developing products from promising discoveries. For example, while strong in publishing new research, Europe only represents 13% of patents filed in relation to new marine molecules. In contrast, Japan and China seem far more active in patent publications than in scientific publications.

The distinctiveness of Blue Biotechnology is shown to be largely defined by the medium itself. The main characteristics which emerge include:

- Difficulty in sampling the huge diversity of resources;
- Potential high cost of sampling some of these;
- The consequent preponderance of public funding for Research and Development;
- The complexity of property rights under marine governance mediated by UNCLOS;

- The lack of clarity on the mechanism for benefit sharing particularly in marine systems re Nagoya;
- The uncertainty of the status of genetic resources in Areas Beyond National Jurisdiction;
- The dependence upon SMEs to translate R&D results into a marketable product for commercialisation;
- The high risk and vulnerability of SMEs; and
- Problems of economic data availability within a poorly defined sector.

4 Objectives and policy options

This section will make a bridge between the EU-level problem analysis and the policy actions that can be envisaged by the EU. In making this bridge, we will follow the step-by-step approach as indicated in the EU Impact Assessment Guidelines[75]. We will revisit the barriers and problems, with the aim to prioritise and structure these, allowing for a distinction between general and specific problems (Section 4.1). Subsequently, we will provide an overview of objectives that can be considered suitable for further scrutiny (Section 4.2) A preliminary analysis of the specific objectives is presented in the following sections, each including a number of operational objectives/policy actions (Sections 4.3- 4.6). Building on the options proposed in the Terms of Reference, we then elaborate 4 policy options, each including a number of the above policy actions (Section 4.7).

4.1 Revisiting the barriers and problems

Within the context of the project three fundamental sources are being used to identify objectives and the underlying problems and barriers, these are:

- Literature review and desk-based research;
- Stakeholder information provided via the international workshop; and
- Stakeholder information provided via the public consultation.

In Section 0 an overview of barriers relevant for the future development of Blue Biotechnology common to all sub-sectors is presented. Additional considerations are 1) whether these problems considered important by stakeholders, either via the international workshop or through the consultation? And 2) whether the EU is positioned to address these barriers? This leads to Table 4.1, which includes minor reformulation of specific problems to better fit the evolving insights.

Table 4.1 Review of barriers and problems to marine biotechnology common to all sub-sectors

Type of barrier	Specific problems	Important for stakeholders? (1 = none, 5 = very)	Scope for EU action? (1 = none, 5 = yes)
Coordination / collaboration / cooperation	*A platform oriented connection of infrastructures is still lacking and only few centres of excellence have been initiated*	*5*	*5*
	Fragmented approach to marine biotechnology research, infrastructures and effort in Europe	*5*	*5*
	Lack of cooperation between research, SMEs and upscale businesses	*5*	*5*
	Lack of common projects	*4*	*4*
Finance	*Low investment in R&D especially in industry sectors viewed subjectively as un-alluring in comparison to pharmaceuticals industry.*	*4*	*4*
	Access to finance is problematic as few investors are keen to take risks in new technological	*5*	*4*

[75] European Commission, 2009, Impact Assessment Guidelines http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf

Type of barrier	Specific problems	Important for stakeholders? (1 = none, 5 = very)	Scope for EU action? (1 = none, 5 = yes)
	developments		
	Lack of investment in SMEs, SMEs assume risk and often run out of funds before product development is complete (especially for second and third rounds of product development)	*5*	*4*
Knowledge	*Lack of basic research into ecology of marine species and organisms from unusual and extreme environments decreases chances of finding novel bioactive compounds.*	*4*	*3*
	Limited understanding of physiology and ecology of marine species	*4*	*2*
	Lack of data about marine model organisms	*4*	*2*
	Difficult for SMES to access knowledge infrastructure such as research vessels and underwater vehicles	*4*	*4*
Access to resources	*Discoveries are not subject to benefit sharing (high seas).*	*4*	*3*
	Unclear and incomplete legal framework	*4*	*4*
	Exploration and sampling in areas of environmental extremes (e.g. high seas) is difficult and expensive	*4*	*1*
Policy	There is no Europe wide policy on marine biotechnology.	3	5
	There are varying national policies, strategies, initiatives and programmes.	3	3
Supply	Culturing marine microorganisms is problematic as culture techniques are specific for marine organisms. New culture methods and media needed to accommodate the complex and symbiotic nature of marine organisms	2	2
	Productivity of original organisms is often too low to make commercial production possible.	2	2
Other	Lack of incentives to scientists to fully commit to product development when alternatives exist (i.e. bio-antifoul product).	2	2
Technical / equipment	Development and optimisation of appropriate bio-engineering tools	1	1
	Tools and platforms to facilitate high throughput screening of new 'omics' related information are needed	1	1
	The cultivability of bioactive compounds is constrained by success of microbial and tissue culture, chemical synthesis and biosynthetic engineering.	1	1
	Lack of bio-assays that can accommodate diverse material from marine sources	1	1

Type of barrier	Specific problems	Important for stakeholders? (1 = none, 5 = very)	Scope for EU action? (1 = none, 5 = yes)
	Need to carry out high-content, broad-target screening (of active compounds and replication, preventing repeated rediscovery).	1	1
	Separating bioactive compounds/molecules can be time consuming	1	1
Infrastructure	Novel data management platforms and information services needed	1	3
	Lack of analytical platforms by which to process data	1	3
	Lack of storage capacity such as databases to accommodate an increasing production of data	1	3
Sustainability / environmental impact	Limitations to harvesting of marine organisms.	1	3
	Harvest of large amounts of marine organisms can cause harm to the marine environment.	1	3

Note: Types of barriers in italics will be taken forward in the subsequent stages

In addition, some stakeholders have pointed to various other problems such as:

- Limited visibility of the sector;
- Capacity shortage including suitably trained personnel;
- Lack of established blue biotech value chains.

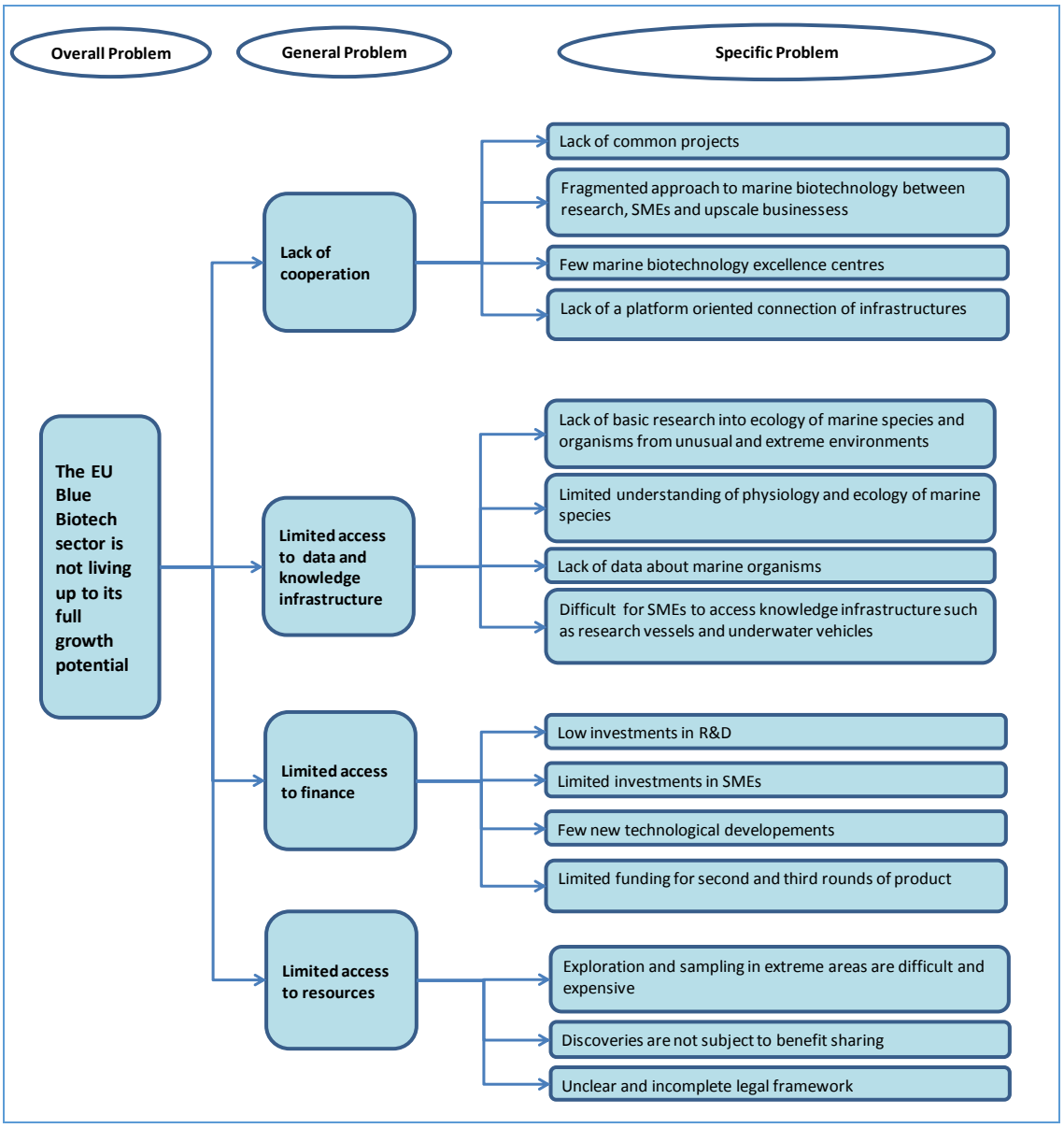
Although we acknowledge these additional problems, our judgment is that these are mostly interlinked with existing problems. An example for this would be the perceived limited visibility of the sector which can be related partly to the lack of cooperation and lack of a common platform for exchange.

We have identified the overall problem as being the fact that the EU Blue Biotechnology sector is not living up to its full growth potential. This limited potential is considered due above all to four general problems and barriers that are particular to the EU Blue Biotechnology sector;

1) Lack of cooperation along the value chain;
2) Limited access to data & knowledge infrastructure;
3) Limited access to finance and;
4) Limited access to resources.

Figure 4.1 presents the four general problem areas which have been further specified – at the level of specific problems.

Figure 4.1 Problem tree



4.2 Overview of objectives

The above structuring of overall, general and specific problems now allows for a transposition into overall, general and specific objectives for possible EU action.

It is essential that the formulation of the objectives is aligned with a wider policy agenda – such as the EU 2020 initiative[76] calling for smart growth and the creation of new products/services that generate growth and jobs and help address social challenges. It is also important to see these fit within the overall Blue Growth Agenda, as outlined in the Blue Growth communication[77]. Based on these, the *overall objective* of such policy actions is that the EU Blue Biotechnology sector is living up to its full growth potential.

[76] http://ec.europa.eu/europe2020/europe-2020-in-a-nutshell/priorities/smart-growth/index_en.htm
[77] COM (2012) 494 final

Based on the general problems as identified above, the following *general objectives* have been identified. These are objectives that the policy aims contribute to:

1. Enhance cooperation across the value chain;
2. Facilitate access to knowledge and exploratory infrastructure;
3. Facilitate access to finance across the value chain; and
4. Facilitate access to resources.

A closer analysis of the general objectives, a larger number of possible *specific objectives* can be identified. These specific objectives are crucial as they set out what the policy interventions are expected to concretely achieve. Figure 4-2 overleaf shows that a large number (15) of specific objectives can be generated.

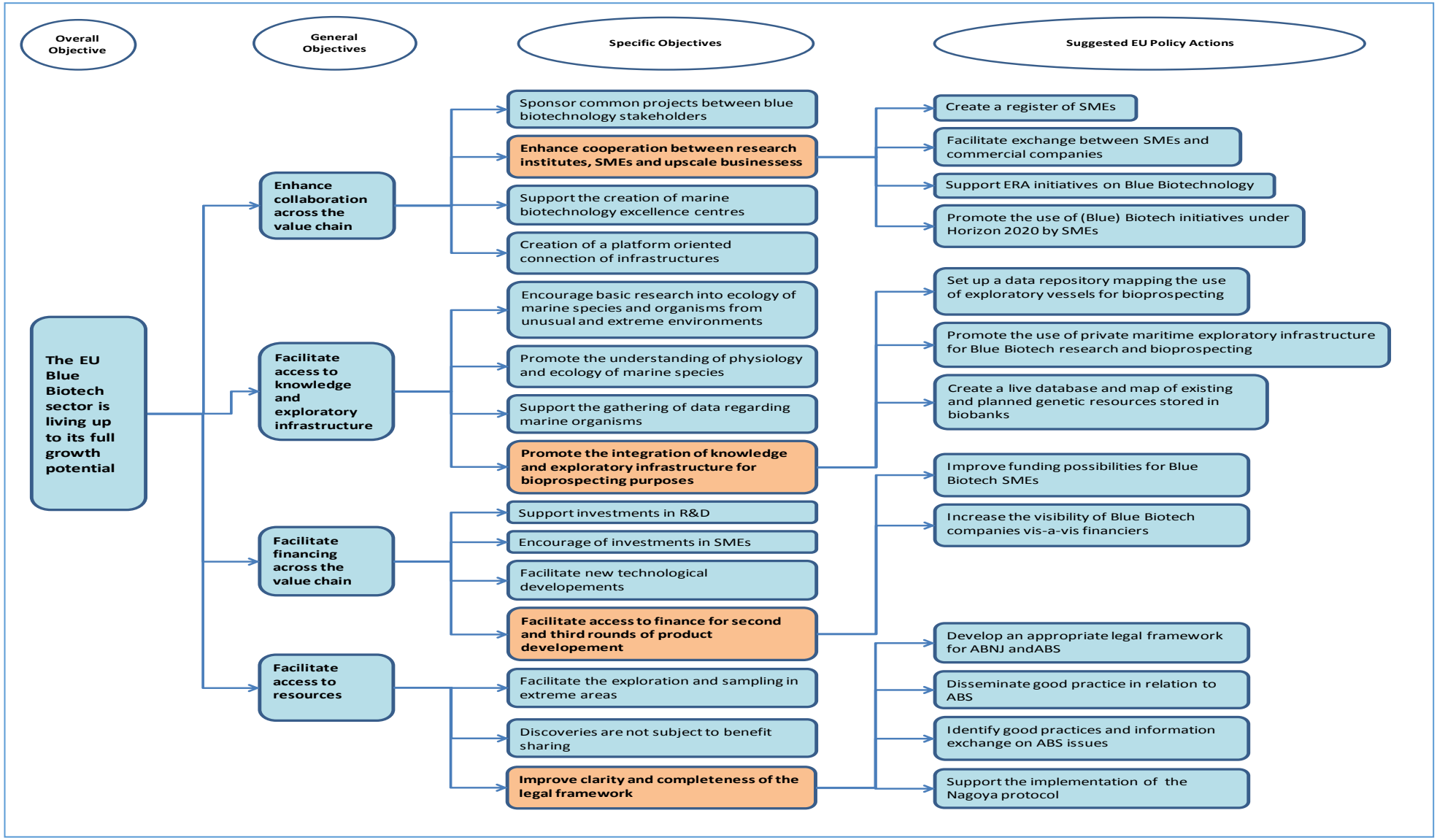
On the basis of the findings of the desk-based research and the preliminary findings of the stakeholder consultation (Table 4.1), four specific objectives have been selected on the basis of the importance considered by stakeholders and the scope for EU action. The following specific objectives have been retained for subsequent scrutiny:

1. Enhance cooperation between research institutes, SMEs and businesses involved in up-scaling;
2. Promote integration of exploratory infrastructure for bioprospecting purposes;
3. Facilitate access to finance for second and third round product development stages; and
4. Improve clarity and completeness of legal framework.

For each of these specific objectives, a number of *operational objectives* have been defined, which are then translated into policy actions.

Figure 4.2 illustrates the structure and development of the general, specific and operational objectives.

Figure 4.2 Objective tree



4.3 Specific objective 1: Enhance cooperation between research, SMEs and upscale businesses at an EU level

4.3.1 Preliminary analysis of objective 1

Research institutes, private enterprises and businesses in charge of up-scaling play an equally important role in the sector. The enterprises incorporate both the multinational actors under the pharma, cosmetic, food and energy sectors as well as SMEs. The latter are to a large extent focused on the earlier stages of the value chain and may be absent from industrial production due to the high capital expenditure.

Research and academia tend to be involved mostly in the first stages of the value chain and are likely to have – through public and private financing – access to state of the art infrastructure including laboratories and research vessels.

The successful commercialisation of a product or an idea requires scientists and SMEs to differentiate their products from the competition and to understand the strength and weaknesses of their products as well as the development process. Information on the value chain and the product development process are crucial in attracting upscale businesses investors who are willing to follow a longer commercialisation process.

It is essential that the key stakeholder groups interact and collaborate with each other and at the same time encourage and facilitate the involvement of new SMEs thereby ensuring that new initiatives, ideas and start-up potential is utilised and supported to its full extent.

Literature review and stakeholder consultation both indicate that there is a significant amount of coordination and connection at the research stage of the value chain (through various networks and clusters as presented in Section 3.1.8) but this tends to decrease as one moves along the value chain and there appears to be a lack of collaboration between the research and private sectors (particularly SMEs) through the various network and initiatives.

4.3.2 Overview of possible policy actions

The key linkages which would require further strengthening are between the SMEs and the businesses that facilitate the commercial up-scaling of products. An example is referred to under Section 3.2.2: CIESM now have initiatives between SMEs, venture and related capital funds and commercial up-scalers. Similar initiatives promoting information exchange and workshops between the stakeholder groups with particular attention to start-ups could be facilitated using the financial instruments of the European Commission including Horizon 2020.

Furthermore, the promotion of a live register recording companies active in Blue Biotechnology including start-ups and SMEs and their lines of products could further facilitate collaboration not only between research enterprises but also with potential commercial partners. Such live register and connecting promotional campaigns and workshops could be commissioned by the European Commission using the existing financial support schemes.

The following possible policy actions are foreseen under objective 1:

1. Create a register of SMEs active in Blue Biotechnology and their products;
2. Facilitate events such as exchange programmes, workshops, seminars between SMEs, investors and commercial companies;
3. Promote the use of Blue Initiatives under Horizon 2020 by SMEs, and address barriers that prevent the uptake;

4. Support the ERA initiative on Blue Biotechnology and encourage the links with SMEs.

4.4 Objective 2: Promote integration of knowledge and exploratory infrastructure

4.4.1 Preliminary analysis of objective 2

As noted earlier in the report, marine biotechnology is reliant upon scientific knowledge and technological innovation. A significant share of this scientific and technological potential lies with research infrastructures (RIs) that range from databases and libraries through large and small-scale research facilities (e.g. laboratories) to research vessels, communication networks, and computing facilities. While some of these facilities are accessible to research centres and large enterprises, SMEs often rely upon involvement with large publicly financed consortia to gain access to such infrastructure.

SMEs are highly cost-sensitive and are mostly involved in the earlier phase of the supply chain. Therefore for them access to infrastructure – e.g. research vessels and underwater vehicles mostly owned by public operators - is a crucial element of product development.

Currently there is limited knowledge regarding the extent to which these vessels (including those that are owned by private enterprises) are being used for bioprospecting purposes. Therefore a common platform with information regarding the availability and accessibility of these vessels could further contribute to facilitating research.

An important element within this objective would be the promotion of an integrated database with information regarding samples and data that have been collected by the research vessels and stored at biobanks. Improving transparency regarding the types of samples and biospecimen collected through bioprospecting could support SMEs and facilitate access to information.

4.4.2 Overview of possible policy actions

A number of EU level policy actions are envisaged to support the integration of knowledge and exploratory infrastructure. These include:

1. Setting up a data repository mapping the use of exploratory vessels for bioprospecting purposes;
2. Explore the possible ways and the extent to which private maritime exploratory infrastructure can be used to support public research and bioprospecting; and
3. Create a live database and map of existing and planned genetic resources stored in biobanks, (including information on the composition of the biomaterials, their source of origin, the users and the depositors).

4.5 Specific objective 3: Facilitate access to finance for second and third rounds of product development

4.5.1 Preliminary analysis of objective 3

As start-ups, spin-outs and mid-size companies rely strongly on external financing across the value chain. It is therefore essential that information and access to public and private financing initiatives remains available throughout the product development process.

Enterprises in the sector are especially vulnerable to running out of funds between the stages of development and full implementation. In some cases financial resources are limited to the first phases of research and no money is being raised for product development. Additionally, investors often would like to see some progress in product development before offering funds. As fast-tracking commercialisation in many cases may not be possible due to strict controls over clinical trials more emphasis is placed onto consistency in the availability of funds.

There are currently no specialised funds available for activities in marine biotechnology in Europe. Therefore marine biotechnology companies rely on more generally targeted public and mixed financing. While some financial instruments focus on SMEs and start-ups in general, other are targeting specific subsectors e.g. pharma or have a wider scientific or technology approach e.g. renewable energy. Public financing, on both the national as well as the EU level, is particularly important as private financiers have been noted to be somewhat reluctant to join in the earlier and mid-range phases of the value chain due to the long development and commercialisation process.

4.5.2 Overview of possible policy actions

Possible policy actions include:

1. Establish a Blue Growth fund for Blue Biotech SMEs, to be constructed from existing financing instruments e.g. JEREMIE[78], the European Investment Bank[79] and the European Investment Fund`s Progress microfinance facility[80] that could support this fund using streamlined mechanisms such as bridging loans;
2. Promote Blue Biotech financing through existing financing instruments e.g. JEREMIE[81], the European Investment Bank[82] and the European Investment Fund`s Progress microfinance facility[83] that could support this fund using streamlined mechanisms such as bridging loans;
3. Facilitate a series of events and programmes between SMEs and financers using specialised technology transfer services and mediators;
4. Continue to develop and promote the mapping of Blue Biotech investors;
5. Map Blue Biotech products by SMEs that require financing.

4.6 Specific objective 4: Improve clarity and completeness of legal framework

4.6.1 Preliminary analysis of objective 4

Uncertainty regarding the legal aspects of the Blue Biotechnology sector is seen as a major constraint to growth. This uncertainty derives from a number of different elements including the impacts of intellectual property (IP) law, the sheer complexity of the legal aspects of the acquisition of marine genetic material, the development and commercialisation of products and the sharing of benefits.

[78] European Commission (2013): Special support instruments, http://ec.europa.eu/regional_policy/thefunds/instruments/jeremie_en.cfm#2
[79] European Investment Bank (nd): Sharing risk in research, development & innovation (RSFF), http://www.eib.europa.eu/products/rsff/index.htm
[80] European Investment Fund (2013): Progress Microfinance Funded Instruments, http://www.eif.europa.eu/what_we_do/microfinance/progress/funded_instruments/index.htm
[81] European Commission (2013): Special support instruments, http://ec.europa.eu/regional_policy/thefunds/instruments/jeremie_en.cfm#2
[82] European Investment Bank (nd): Sharing risk in research, development & innovation (RSFF), http://www.eib.europa.eu/products/rsff/index.htm
[83] European Investment Fund (2013): Progress Microfinance Funded Instruments, http://www.eif.europa.eu/what_we_do/microfinance/progress/funded_instruments/index.htm

Industry has in particular expressed concern about the complexity of implementing the access and benefit sharing (ABS) regime foreseen by the Nagoya Protocol and the practical challenges that this might bring about. Concerns are also raised as to how marine genetic material may be responsibly acquired from areas under national jurisdiction.

With regard to ABNJ the legal framework for ABS in terms of marine genetic resources is essentially incomplete with neither UNCLOS nor the legal regime created under the Convention on Biological Diversity (CBD) providing much in the way of substantive regulation of this topic. Different arguments are advanced as to whether such resources form the common benefit of mankind or whether they may be freely acquired pursuant to the freedom of the high seas. The underlying issue in benefit sharing is whether the benefits from exploiting these resources should be shared by the entire international community or only by the States or individual corporations with the capacity to exploit them[84]. The lack of legal certainty is in turn a potential deterrent for potential investors in the Blue Biotechnology sector. At the same time there is minimal control over how marine genetic resources are acquired within ABNJ with consequent risks for what are frequently fragile marine environments.

4.6.2 Overview of possible policy actions

From the perspective of the EU, possible policy interventions under this objective could include:

1. Provide on-going support for the development of an appropriate legal framework at the international level for the protection of marine biodiversity in ABNJ;
2. Disseminate good practice in connection with ABS issues relating to marine genetic resources;
3. Facilitate cooperation between Member States (identify good practices and information exchange);
4. Develop detailed guidelines for the implementation of the Nagoya Protocol in maritime areas under coastal state jurisdiction;
5. Support the implementation of the Nagoya protocol through the continued development of model ABS agreements and appropriate support mechanisms.

4.7 Development of policy options

A number of areas of potential EU approaches have been put forward by the European Commission to guide sector development towards meeting the above detailed specific objectives. These include a baseline scenario, a soft option and finally a more stringent approach. These three options have been assessed in light of the problem areas and the specific objectives and have been amended with an additional option which promotes the mainstreaming and integration of Blue Biotechnology into the currently existing policy framework relevant for biotechnology.

The four broad policy options are as follows:

- Option 1: Baseline scenario/no additional action option;
- Option 2: Facilitation and promotion/soft measure;
- Option 3: Mainstreaming Blue Biotechnology; and
- Option 4: Formal policy measures.

The relation between the policy options and the specific objectives as well as policy actions is illustrated by the following table.

[84] Global Ocean Commission (2013): Bioprospecting and marine genetic resources in the high seas, http://www.globaloceancommission.org/wp-content/uploads/GOC-paper04-bioprospecting.pdf

Table 4.2 Policy options and their composition

General objective	Specific objective	Policy actions	Option 1	Option 2	Option 3	Option 4
Improve collaboration across the value chain	Enhance cooperation between research institutes, SMEs and businesses involved in up-scaling	Create a register of SMEs		X		X
		Facilitate exchange programmes between SMEs and companies		X	X	
		Support ERA initiative on BB		X		
		Promote the use of (Blue) Biotech Initiatives under Horizon 2020 by SMEs		X	X	
Improve access to infrastructure across the value chain	Promote integration of exploratory infrastructure for bioprospecting	Set up a data repository mapping the use of exploratory vessels for bioprospecting purposes		X		
		Promote the use of private maritime exploratory infrastructure for BB research and bioprospecting		X		
		Create a live database and map of existing and planned genetic resources stored in biobanks		X		
Facilitate financing across the value chain	Facilitate access to finance for second and third round product development stages	Establish a Blue Biotech fund		X		X
		Promote use of existing financial instruments for Blue Biotech			X	
		Facilitate a series of events and programmes between (Blue) Biotech SMEs and financers		X	X	
		Continue to develop and promote the mapping of (Blue) Biotech investors		X	X	
		Map (Blue) Biotech products by SMEs that require financing.		X	X	
Ease access to resources	Improve clarity and completeness of legal framework	Adoption of a communication supporting the development of an appropriate legal framework		X	X	
		Adoption of a regulation on the acquisition of marine genetic resources in ABNJ				X

General objective	Specific objective	Policy actions	Option 1	Option 2	Option 3	Option 4
		Setting out best practice guidance on ABS issues at Member State level		X		
		Identify good practices and information exchange		X	X	
		Supporting the implementation of Nagoya protocol through the continued development of model ABS agreements and appropriate support mechanisms.		X		X

Below we describe the policy options as well as the policy actions which can be connected according to the table above. We have bundled some policy actions in anticipation of the assessments of their impacts in the subsequent stage of the project.

4.7.1 Policy option 1: No additional action

Option 1 is the baseline scenario and involves making no changes to the existing situation, in particular:

- the existing definition of the Blue Biotechnology sector will remain as per the recommendation from the OECD[85] and there will be no clarification with regard to the specific applications and processes that are characteristic of the sector;
- there will be no further guidance regarding the scope of the sector;
- there will be no further clarification of the distinction between industrial biotechnology and Blue Biotechnology; and
- current financing instruments such as Horizon 2020 will continue to be used to support (Blue) Biotechnology industry; and
- no financing and regulative instrument (directive, regulation etc.) specific to Blue Biotechnology will be introduced.

4.7.2 Policy option 2: Facilitating and promoting (soft policy measure)

Option 2 involves facilitating and promoting a number of key issues with regard to the Blue Biotechnology sector and may include the following policy actions in line with the above specific objectives (SO = Specific objective referred to):

A. Support the development of the Marine Biotech ERA-NET (ERA-MBT) (SO1);
B. Promote collaboration between stakeholders via EU level and international workshops and other events (SO1);
C. Mapping of Blue Biotech SMEs (in order to increase visibility - passively) (SO1 + SO3);
D. Organise Blue Biotech matchmaking events bringing SMEs and investors together (in order to increase visibility – actively) (SO1 + SO3);
E. Support the mapping of genetic resources stored in biobanks (SO2);
F. Support the mapping of available infrastructure (particularly those used for bioprospecting) (SO2);
G. Continue to develop and promote the mapping of Blue Biotechnology investors (SO3);

[85] http://stats.oecd.org/glossary/detail.asp?ID=219

H. Establish a Blue Growth fund for Blue Biotech SMEs, to be constructed from existing financing instruments e.g. JEREMIE[86], the European Investment Bank[87] and the European Investment Fund`s Progress microfinance facility[88] that could support this fund using streamlined mechanisms such as bridging loans (SO3);
I. Disseminate information on the available financial instruments for SMEs (e.g. Horizon 2020) and raise awareness about the various financial mechanisms among Blue Biotechnology stakeholders (SO3);
J. Identify and disseminate best practices related to ABS and related to marine genetic resources (SO4);
K. Develop and promulgate guidelines for the implementation of the Nagoya Protocol and ABS of marine genetic resources (SO4).

4.7.3 Policy option 3: Mainstreaming Blue Biotechnology

Option 3 entails making full use of the current policy initiatives favouring biotechnology, and promotes their blue components. Mainstreaming Blue Biotechnology with biotechnology would mean that measures and strategies aiming at biotechnology in general would be assessed to identify to what extent they could be utilised to attain specific Blue Biotechnology development goals This option will be developed by assessing and promoting the Blue Biotech component of cross-sectoral policies supporting economic, research development and job growth such as:

- European Research Infrastructure Consortium[89];
- European strategy for Key Enabling Technologies[90];
- European Commission Communication on A European Strategy for Marine and Maritime Research: A coherent European Research Area framework in support of a sustainable use of oceans and seas[91] etc.

Policy actions would include:

A. Promote the inclusion of Blue Biotechnology research activities in existing ERA's (e.g. ERA Industrial Biotechnology (SO1);
B. Identify good practices and benchmarks for the Blue Biotechnology sector, by building on existing biotechnology practices (SO1);
C. Facilitate programmes, matchmaking events and roadshows for Blue Biotech SMEs as part of broader initiatives for biotechnology and emerging sectors (in order to increase visibility) (SO1 + SO3);
D. Provide extensive guidance to stakeholders on how existing provisions related to biotechnology[92] can be implemented and utilised within the context of Blue Biotechnology (SO2);
E. Promote the use of support mechanisms for start-ups and SMEs that collaborate with research centres and private investors at an early stage of the product development process (SO2);

[86] European Commission (2013): Special support instruments, http://ec.europa.eu/regional_policy/thefunds/instruments/jeremie_en.cfm#2
[87] European Investment Bank (nd): Sharing risk in research, development & innovation (RSFF), http://www.eib.europa.eu/products/rsff/index.htm
[88] European Investment Fund (2013): Progress Microfinance Funded Instruments, http://www.eif.europa.eu/what_we_do/microfinance/progress/funded_instruments/index.htm
[89] COUNCIL REGULATION (EU) No 1261/2013 of 2 December 2013 amending Regulation (EC) No 723/2009 concerning the Community legal framework for a European Research Infrastructures Consortium (ERIC), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:326:0001:0002:EN:PDF
[90] European Commission (2012): A European strategy for Key Enabling Technologies - A bridge to growth and jobs", http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0341:EN:NOT
[91] European Commission (2008): European Commission Communication on A European Strategy for Marine and Maritime Research: A coherent European Research Area framework in support of a sustainable use of oceans and seas, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0534:EN:NOT
[92] Including but not limited to the European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions and the 2002 EC Communication on Life sciences and biotechnology – A Strategy for Europe

F. Foster the development of a live database of biotechnology SMEs and products, and include Blue Biotechnology as a category (SO2);
G. Promote Blue Biotech financing through existing financing instruments e.g. JEREMIE[93], the European Investment Bank[94] and the European Investment Fund`s Progress microfinance facility[95] that could support this fund using streamlined mechanisms such as bridging loans (SO3);
H. Assess and promote the blue component of financial mechanisms such as the EU Structural Funds or Horizon 2020 and set targets for several sectors (earmarking) (SO3);

4.7.4 Policy option 4: Formal policy measures

Option 4 involves more stringent policy measures aimed at developing specific Blue Biotechnology targets and initiatives. It can include:

A. Increase the visibility of the Blue Biotechnology sector by proposing a specific NACE code for (Blue) Biotechnology (allowing for increased visibility by defining the sector) (SO1);
B. Create a register for Blue Biotech firms (SO1);
C. Establish a (stand-alone) Blue Biotechnology fund through a joint initiative of EC DG MARE and the EIB (similar to JESSICA, JEREMIE, JASPERS) (SO3);
D. Promote legal measures to establish a licensing and environmental impact assessment framework within UNCLOS as well as a common benefit mechanism and sharing fund (SO4);

[93] European Commission (2013): Special support instruments, http://ec.europa.eu/regional_policy/thefunds/instruments/jeremie_en.cfm#2
[94] European Investment Bank (nd): Sharing risk in research, development & innovation (RSFF), http://www.eib.europa.eu/products/rsff/index.htm
[95] European Investment Fund (2013): Progress Microfinance Funded Instruments, http://www.eif.europa.eu/what_we_do/microfinance/progress/funded_instruments/index.htm

5 Impact Assessment

In this chapter, we review the impacts of the policy actions as proposed. We do so by identifying the relevant economic, social and environmental impacts (5.1), followed by an assessment at the level of measures (5.2), and based on the (often limited) information available about these policy actions. Those more substantial impacts will then be assessed in more detail (5.3). This will culminate in a comparison of options (5.4).

5.1 Inventory of relevant economic, social and environmental impacts

The Impact Assessment Guidelines[96] provide a long-list of potential impacts, of which a selection has been made limiting the analysis here to those impacts that are applicable to the policy packages defined. An explanation is given in the below table, where also the relevance to the three policy packages defined in Ch.4 is indicated. These impacts will be assessed in more detail in the remaining sections.

Table 5.1 Main impacts and relevance to the defined policy packages

Impact	Relevant to policy packages			Explanation
	A	B	C	
Economic				
Competitiveness, trade and investment flows	√	√	√	Impact on the position of EU Blue Biotech firms in a global setting would be strengthened.
Operating costs and conduct of business/Small and Medium Enterprises	√	√	√	Finance actions in particular would contribute to continuity and development of BB SMEs; bioprospecting actions would reduce transaction costs.
Property rights			√	UNCLOS provisions on benefit sharing would help to ensure that bioprospecting results are clearly shared
Innovation and research	√	√	√	No particular actions in A and C in this area; supportive measure in B.
Specific regions or sectors	√	√	√	Those regions where Blue biotech is most present; longer term impacts on food, cosmetics, health and energy sectors
Consumers and households	√	√	√	Actions proposed would ultimately benefit consumers in areas of food, cosmetics, health and energy
Third countries and international relations			√	UNCLOS provisions on benefit sharing and environmental impact assessment
Social				
Employment and labour markets	√	√	√	Job creation expected as part of growth in SMEs
Individuals, private and family life, personal data			√	Creation of BB SME database would require disclosure of personal data
Public health and safety	√	√	√	A thriving BB sector would increase the chance of bringing to market products that treat diseases.

[96] Based on the full list of Impacts and Key Questions available in the EU Impact Assessment Guidelines (2009), p. 32-38

Impact	Relevant to policy packages			Explanation
	A	B	C	
Social impacts in third countries			√	UNCLOS provisions on benefit sharing would help development of third countries involved
Environmental				
Water quality and resources	√	√	√	A regulated development of the BB sector would mitigate environmental impacts related to bioprospecting.
Renewable or non-renewable resources		√		A regulated development of the BB sector would mitigate the impacts of bioprospecting on renewable sources.
The environmental consequences of firms and consumers	√	√	√	Large scale BB applications could replace existing chemically based production chains and increase sustainability (e.g. in pharmaceuticals, food).
Animal welfare			√	A regulated development of the BB sector would mitigate environmental impacts related to bioprospecting (dee-sea creatures)
International environmental impacts			√	UNCLOS provisions on environmental impact assessments would benefit the international environment

5.2 Assessment of impacts by measure

All measures identified in Ch.4 have been qualified in terms of their economic, social and environmental impact. For each impact category (economic, social, environmental), a qualitative score is given from "-" (poor) to "0" (neutral) to "+" (minor positive impact) to "++" (substantial positive impact) to "+++" (major positive impact).

It is noted that for a number of actions, the direct impact will be limited (e.g. when the action concerns the execution of a study on a particular topic), but the relevance may still be high as such actions be set the ground work needed for any further implementation activities.

Table 5.2 **Economic, social and environmental impacts of policy actions by policy option (compared to baseline option 1)**

Policy options- Full list of actions		Assessment of Impacts		
		Economic	Social	Environ-mental
2	**Facilitating and promoting Blue Biotechnology (soft policy actions)**			
2A	Support the development of the Marine Biotech ERA-NET (ERA-MBT) (SO1)	++	+	
2B	Promote collaboration between stakeholders via EU level and international workshops and other events (SO1)	+	+	
2C	Mapping of Blue Biotech SMEs (in order to increase visibility - passively) (SO1 + SO3)	+	+	
2D	Organise Blue Biotech matchmaking events bringing SMEs and investors together (in order to increase visibility – actively) (SO1 + SO3)	+	+	
2E	Support the mapping of genetic resources stored in biobanks (SO2)	+	+	
2F	Support the mapping of available infrastructure (particularly those used for bioprospecting) (SO2)	+	+	
2G	Continue to develop and promote the mapping of Blue Biotechnology investors (SO3);	+	+	
2H	Establish a Blue Growth fund for Blue Biotech SMEs, to be constructed from existing financing instruments - using streamlined mechanisms such as bridging loans (SO3)	++	+	
2I	Disseminate information on the available financial instruments for SMEs (e.g. Horizon 2020) and raise awareness about the various financial mechanisms among Blue Biotechnology stakeholders (SO3)	+		
2J	Identify and disseminate best practices related to ABS and related to marine genetic resources (SO4)	+		+
2K	Develop and promulgate guidelines for the implementation of the Nagoya Protocol and ABS of marine genetic resources (SO4).	+++	+	+++
	Total scores policy option 2 *Average score per individual policy action*	*15* *1.4*	*9* *0.8*	*4* *0.4*
3.	**Mainstreaming Blue Biotechnology**			
3A	Promote the inclusion of Blue Biotechnology research activities in existing ERA's (e.g. ERA Industrial Biotechnology (SO1)	+	+	

Policy options- Full list of actions		Assessment of Impacts		
		Economic	Social	Environ-mental
3B	Identify good practices and benchmarks for the Blue Biotechnology sector, by building on existing biotechnology practices (SO1)	+		
3C	Facilitate programmes, matchmaking events and roadshows for Blue Biotech SMEs as part of broader initiatives for biotechnology and emerging sectors (in order to increase visibility) (SO1 + SO3)	+		
3D	Provide extensive guidance to stakeholders on how existing provisions related to biotechnology can be implemented and utilised within the context of Blue Biotechnology (SO2)	+		
3E	Promote the use of support mechanisms for start-ups and SMEs that collaborate with research centres and private investors at an early stage of the product development process (SO2)	+		
3F	Foster the development of a live database of biotechnology SMEs and products, and include Blue Biotechnology as a category (SO2)	+		
3G	Promote Blue Biotech financing through existing financing instruments	++		
3H	Assess and promote the blue component of financial mechanisms such as the EU Structural Funds or Horizon 2020 and set targets for several sectors (earmarking) (SO3)	+		
	Total scores policy option 3 *Average score per individual policy action*	*9* *1.1*	*1* *0.1*	*0*
4	**Formal policy measures**			
4A	Increase the visibility of the Blue Biotechnology sector by proposing a specific NACE code for (Blue) Biotechnology (allowing for increased visibility by defining the sector) (SO1)	++	+	
4B	Create a register for Blue Biotech firms (SO1);	++	-	
4C	Establish a (stand-alone) Blue Biotechnology fund through a joint initiative of EC DG MARE and the EIB (similar to JESSICA, JEREMIE, JASPERS) (SO3);	+++	+	
4D	Promote legal measures to establish a licensing and environmental impact assessment framework within UNCLOS as well as a common benefit mechanism and sharing fund (SO4).	+++		+++
	Total scores policy option 4 *Average score per individual policy action*	*10* *2.5*	*1* *0.2*	*3* *0.8*

As can be seen from the above table, *policy option 2 (soft measures)* generates the largest number of policy actions (11), most of which having minor economic and social (employment) impacts. However the overall economic and social impacts can be moderate in case these actions would reinforce each other. Environmental impacts are expected to be negligible.

Policy option 3 (mainstreaming) would generate 8 actions, most of which having a minor economic impact. Less certain is whether these economic impacts would be sufficiently strong to generate employment (social) impacts. Much will depend on the packaging and precise implementation of these actions. Environmental impacts are expected to be negligible as well.

The number of actions under *Policy option 4 (Formal policy measures)* would be limited to 4, however the impacts of these individual measures could be substantial, both in economic as well as environmental terms.

5.3 Substantiation of impacts by policy option

As part of the substantiation of the most relevant impacts for the policy options, this section provides a qualitative assessment of those measures that are expected to have a more significant impact (score '++' or '+++' in section 5.2 above). The assessment also indicates the most relevant impact areas for each measure, amongst those presented in the section above, as well as the causal logic which justifies the qualitative assessment of potential impact of the measure.

5.3.1 Impacts of policy option 2

Most substantial impacts are expected from two measures, 2A. and 2H.

2A. Support the development of the Marine Biotech ERA-NET

Expected results

The result would include further promotion of the Marine Biotech ERA-NET and consequently a more streamlined communication supporting networking and cooperation projects within the scheme. Moreover, the measure could potentially contribute to promoting synergies between the subsectors within Blue Biotechnology, namely pharmaceuticals, cosmetics, energy, food etc.

Specific impacts

Specific impacts would translate into an increased number of Blue Biotechnology projects launched in cooperation with academics and SMEs on the national or European level. Consequently, the measure would contribute to the emergence of new products and marketable prototypes.

Wider impacts

The creation of a European platform could contribute to increased visibility of the sector at the European as well as the international level. Additionally the overarching research potential of the wider biotechnology industry could be strengthened by the increased numbers of joint initiatives between researchers and private enterprises. Moreover, the increased and wider collaborations could lead to a better and more efficient use of available infrastructure – including those exploratory vessels that are in private ownership.

2H. Establish a Blue Growth bridging fund

One of the main challenges that Blue Biotech companies experience is to move from Discovery into Product Development. Investors often require additional evidence that the product is feasible to

even be developed (Patent approval, clinical trials, prototype etc.) before committing finances. At this stage short term financing is often missing to allow the company to progress.

Expected results

The bridging fund aims to address this gap between research financing (e.g. Horizon 2020) and mid to long term product financing (e.g. EIB, Venture Capital, private investments). The difference to other financial products on offer will be its:

- Duration – it should be flexible depending on the specific project and the time required for the proceeding;
- Adaptability – the needs of the companies to sometimes prepare the product can at times be also related to simple cash-flow issues and therefore restrictions on the use of the financing should be adaptable to the immediate needs of the company.

Given that we estimate that there are between 80-130 companies focused on Blue Biotech and that the average amount needed would most likely range between € 40k - € 250k[97] we propose a fund between € 8m - € 32.5m. It would most likely be administered under a current framework such as the guarantee scheme of the EIB.

Specific impacts

The bridging finances will allow the company/spin-off to present a much more complete and clear vision of its product as well as its IPR protected. This will have two main specific impacts:

- Stimulate investment – this is largely due to the fact that the products will be a lot less risky, since many of the commercial risks have been addressed by the activities facilitated by this bridging financing. Given that risk is one of the main factors in investment decisions and given that high risk perception is one of the main reasons for not investing into new sectors, this will encourage investments.
- Higher company return – due to the fact that the development of the product has been progressed and that the risks have been decreased the company can demand a higher return if selling their product, or give up less equity in return for investments. Therefore benefitting financially from their activity.

Wider impacts

The ability to complete the process of product development would encourage entrepreneurship as it more likely that the right investors/buyers would be found to fully develop the product. Furthermore, additional activities or risks would be financially rewarding.

2K. Develop guidelines for the implementation of the Nagoya Protocol in maritime zones under coastal State jurisdiction

Expected results

The expected result of this measure would be an increased awareness and improved practical understanding of the legal requirements relating to access and benefit sharing in maritime zones under coastal State jurisdiction thereby encouraging bio-prospecting and cooperation with third countries.

Specific impacts

The specific impacts brought along by increased legal clarity would include an increased collaboration potential from investors who would see lower risks as well as a reduced burden on research organisations interested in bioprospecting in maritime areas under coastal State jurisdiction.

[97] This is the financing gap between micro-loans and larger loans

Wider impacts

Among the wider impacts could be improved collaboration with and support to research programmes in third countries thereby contributing to an increase in the number of marketable products and increased protection of biodiversity.

5.3.2 Impacts of policy option 3

Most substantial impact is expected from only one measure, 3G.

3G- Promote Blue Biotech funding through existing financing instruments

Expected results

There are already several financing instruments that focus on innovative industries as well as SMEs in general.[98] Missing however, is a focus on new industries such as Blue Biotech and actively supporting them. Start ups and R&D is of course present, but new industries experience the issue of lack of focus and comprehension on the side of financial institutions to a much greater level. This could be altered by:

- Earmark certain financial instruments/ budgets targeted at Blue Biotech companies;
- Market and financial research to be conducted on the sector to gain a better understanding of the sector and the risks to facilitate future investment decisions using the existing financial instruments;
- The providing institutions and funds (ERDF, EMFF, ESF, EIB) make a greater effort to reach out to the Blue Biotech sector with the financial instruments already available.
- Provide help in completing applications for finances & business plans to companies emerging from pure frontline research to a more commercial world.

Specific impacts

The greater availability of finances (e.g. from mainstream Structural Funds, Horizon 2020 and EIB facilities) would give more Blue Biotech the opportunity to develop their products or find the right investors that would be of interest. The help and focus provided by the institution to the companies would allow them to be more sustainable over the long run as crucial business and financial skills would be gained. Lastly the knowledge about the sector would help to make better informed investment decisions by companies as well as investors, thus stimulating the most efficient system (by either increasing the amount of finances available and/or the cost of acquiring finances).

Wider impacts

Greater knowledge about the sector would encourage investors to invest and greater availability of finances would encourage more companies to start their operations in the sector. In this way the growth of the sector would be encouraged to closer meet its growth potential.

5.3.3 Impacts of policy option 4

All five actions proposed under this policy package are expected to have substantial impacts.

4A Increase visibility by proposing a specific NACE code

Expected results

The aim is to establish a new 3 digit NACE code for Biotechnology and a 4 digit NACE code for Blue Biotech. This could be conducted by either adding an additional code to the current dataset, or conducting a 3rd Revision of the NACE code system.

[98] http://europa.eu/youreurope/business/funding-grants/access-to-finance/

Having said this, such change of NACE codes is operationally very complicated as not only does it involve Eurostat's internal processes, but it also needs to be approved and implemented by all National Statistics Offices.

Specific impacts

The impact would be that the sector would be comprehensively defined, thus rendering sector analysis much more feasible and accurate. This in turn would significantly aid investors in understanding the sector and thus making better informed analysis about the future trends and the risk levels. Given that risk is often the main obstacle to investing or providing finances, this would significantly improve the access to finance for Blue Biotech companies.

Wider impacts

By carving out Blue Biotechnology at the 4-digit NACE code (building on a 3-digit NACE code for Biotechnology, the precedence could be set to establish a Maritime wide distinction of other activities. Such maritime specific data would enable a much more accurate analysis of the maritime economy and contribute significantly to policy actions.

4B Create a register for Blue Biotech firms

Expected results

The expected result of this measure would translate into improved transparency of the sector and improved access to information to all interested parties. Moreover, it would contribute to a better understanding of the size of the industry and the related activities – including research and product formulation - carried out by the companies. Furthermore, the measure could contribute to a strengthening of relations between the stakeholders including investors.

Specific impacts

The specific impact of the measure would include an increase in the number of collaborations between academia, private enterprises and investors. Additionally the measure can increase the number of partnerships currently engaged in research and thereby contribute to result including a better understanding of the ecology of marine species, collection of data on marine organisms etc. Furthermore the measure could facilitate the commercial uptake of products in development as investors would have access to a database by which they could gain an overview and understanding of the research and product development potential in Europe (better decision making based on more accurate information).

Wider impacts

A wider impact of the measure would be the increase in awareness of the wider scientific community with regard to the research and product development activities that takes place within Blue Biotechnology. This could potentially result in new applications for the products and encourage investments. Furthermore, results could include an overall growth for the sector and an increased number of jobs for skilled personnel.

4C Establish a (stand-alone) Blue Biotech fund

Expected results

The stand-alone Blue Biotech fund would focus on funding a combination of research in the sector as well as the roll-out stage in the industry. The aim would be clearly identified and would focus on actively supporting the sector.

However, such funds are very costly to run and monitor given the small size of the industry. Furthermore, actions are being taken to prevent fragmentation of funding and funds and instruments are being concentrated into efficient hubs - such as Horizon 2020 for R&D or the EIB's financial instruments.. The stand-alone fund could therefore clash and overlap with some of these other funding streams.

Specific impacts

Blue Biotech companies would have an additional stream of finances to either fund their research, or their roll-out phase. Given that at times it is the running out of other funds that stop the development of products this stand-alone fund could bridge that as well as further encourage the sectoral growth.

Wider impacts

A growing sector with extra funding would not only attract more companies and research institutes to participate, but also of investors and buyers looking into new booming sectors.

However, such a stand-alone fund could also have a negative impact due to fragmentation of the funding streams and encouraging other sectors to also set up their specific funds. This could be seen as 'winding back the clock' on the progress that has occurred in bringing a more streamlined approach and increased efficiency in EU funding.

4D Promote legal measures in the context of UNCLOS

Expected results

The expected result of this measure would be an increased awareness and improved understanding of the legal conditions that can be relevant for access and benefit sharing which could translate into a wider collaboration of stakeholders on international waters.

Specific impacts

The specific impacts brought along by increased legal clarity would include an increased collaboration potential from investors who would see lower risks. Additional specific impacts would be an increase in the number of marketable product as a result of the increased inflow of investments.

Wider impacts

Among the wider impacts could be the identification and the dissemination of good practices in relation to access and benefit sharing among stakeholders, reduced risk profiles and consequently an increased number of bioprospecting activities on international waters.

5.4 Comparison of options

The four policy options detailed in the previous sections are aimed at strengthening the EU Blue Biotechnology industry in order to provide support for the future growth and development of the sector. This section contains the comparison of the four policy options based upon the perceived benefits which they are expected to bring forth.

The following table provides an overview on the policy options as they are measured against the three key criteria of effectiveness, efficiency and coherence:

- Effectiveness in terms of addressing the problems, achieving objectives and/or enhancing the sector's performance;

- Efficiency in terms of the impacts achieved and results emerged by way of implementing the relevant measures;
- Coherence of the policy options, in terms of the extent to which the proposed intervention contributes to and/or mutually reinforces the current policy actions, rather than duplicating or conflicting with them.

Table 5.3 Comparing the policy options (option 1 being the baseline)

Policy option	Effectiveness	Efficiency	Coherence	Total
2 Soft measures	+++	+	+	+++++
3 Mainstreaming	+	++	+	++++
4 Formal measures	++	-	-	0
Grading Scale: Highly Positive (++), Positive (+), Neutral (0), Somewhat negative (-), Highly negative (--)				

As it is illustrated by the table above, each of the options scores differently against the criteria. Option 1 describes a scenario in which the current status quo would continue to apply in the future with regard to European policy measures which would result in a continuation of the situation whereby the EU Blue Biotechnology sector would not live up to its potential.

Option 2 Soft Measures has the highest overall score in terms of effectiveness, efficiency and coherence as it would contribute positively to all three main criteria and enhance the sector performance via both financial support and a facilitation of research collaboration. Option 2 could effectively stimulate collaboration between stakeholders via providing further support to the Blue Biotech ERA-NET. Furthermore, it could facilitate the involvement of investors by lowering the risks and providing businesses with a bridging loan supporting the product development process. However the overall assessment of the effectiveness, efficiency and coherence of these actions would much depend on the details of the policy implementation.

Option 3 Mainstreaming would be ranked second, however based more on efficiency and coherence than on effectiveness. One of the aspects Option 3 would omit is providing support for a better integration of potential investors into the value chain including bioprospecting, as this aspect (particular to Blue Biotechnology) would not receive specific attention. The overall assessment of the effectiveness, efficiency and coherence of these actions would much depend on the details of the policy implementation, including the use that can be made of existing initiatives.

Option 4 Formal measures contains a number of potentially powerful actions which could render this option quite effective. However, it would score rather negative on efficiency and coherence considerations, thus making it the least preferred option. With regard to efficiency, it would require substantial efforts, wider and longer term European and potentially international efforts to implement its measures. Furthermore, its coherence would be compromised by the fact that it could contradict current European strategies and policy frameworks. For example the specific Blue Biotechnology fund would not be much aligned with current horizontal EU financial instruments for growth and development. Consequently, in order to further evaluate whether one or more initiatives under Option 4 would have a future potential it would be necessary to identify the ambitions of the European Union for the sector of Blue Biotechnology as a whole.

Given the complementary nature of the policy options and the closely connected problem areas, the analysis has found that a combination of policy options 2 and 3 is likely to be the most effective in addressing the overall problem of the sector.

Option 2 with a number of supplementary policy actions from Option 3 could effectively:

- increase collaboration across the value chain, including those parts which are specific to Blue Biotechnology (e.g. bioprospecting);
- increase funding available across the value chain;
- encourage better understanding of the sector by the investors thereby lowering risks and encouraging investments;
- bridge the so-called *valley of death* for product development.
- improved collaboration with and support to research programmes in third countries thereby contributing to an increase in the number of marketable products and increased protection of biodiversity.

The combination of the measures within Options 2 and 3 would ensure wide ranging and effective collaborations between the different groups of stakeholders throughout the value chain. Thereby it would facilitate commercialisation and product development for researchers and private enterprises (particularly SMEs).

Furthermore, measures aimed at providing increased financial support would allow for a smooth transition between the research, the product development and the marketing stages and could create a long-term perspective for the private enterprises. The promotion of collaboration could drive numerous research activities and could potentially have spill-over impacts in other areas of biotechnology.

6 Conclusions

6.1 Conclusions

The general objective of the study and of this report is to support the impact assessment process of the European Commission by providing information, data and specific analysis with the ultimate aim of deepening and further analysing the growth potential of the Blue Biotechnology sector. Information collection has been carried out using various means including desk-based research, analysis of public consultation (survey results) and interactive discussions with stakeholders (international workshop).

Data and information gathered through these channels have been used to identify the:

- overall and specific problems of the sector;
- overall and specific objectives of the sector; and
- the key measures and initiatives that are relevant at the European level and could be carried out within the policy options to respond to the key problems of the sector.

In order to respond to the overall problem of facilitating the development of the sector and allowing Blue Biotechnology to live up to its growth potential a number of individual policy measures have been identified and analysed in terms of their specific and overarching impacts and potential results. The assessment concluded that a combination of two policy options – namely Option 2 (soft policy option) and Option 3 (streamlining option) – would be the most effective and relevant to pursue in order to respond to the key problems of the sector.

The two policy options contain effective measures addressing the researchers, private enterprises and the financial investors thereby facilitating and increasing collaborations as well as improving the potential of enterprises to develop and market commercially viable products.

The combined impact of the proposed policy actions would – if well-designed and implemented - address the barriers specific to Blue Biotechnology in the EU. Opportunities provided by the financial instruments specifically targeting the growth of SMEs and the support of start-up companies in the field could contribute to a reduction of the brain-drain, especially so from the United States. The opportunities provided by bridging funds can effectively and directly support investment and aid private enterprises.

Taken together, these actions would eliminate or at least address the reasons why the annual compound growth rate of Blue Biotechnology (currently 4-5%[99]) is less than that of biotechnology as a whole – currently up to 6-8%. Currently the European Biotechnology industry has an estimated annual revenue of € 15 billion[100] while the Blue Biotechnology sector`s higher-end revenue generation is estimated to be around € 754 million. An estimated annual compound growth rate of Blue Biotechnology of 6-8% in 5 years could lead to an annual revenue generation of up to € 1 billion. This growth rate could effectively result in an increase in demand of high-end jobs as well as an increase of end-products. The employment increase in the Blue Biotechnology sector, given the ambitious overall growth rate, could amount to up to 10,000 additional work places in 5 years time. It would also help to boost the return on investment from previous, current and

[99] Global Industry Analysts Inc. “Marine Biotechnology: A Global Strategic Business Report” 2011
[100] Ernst & Young; Biotechnology Industry report 2013

future R&D funding programmes already implemented or committed, especially so through the Horizon 2020 programme.

Most importantly, the wider impacts of the sector`s development can result in numerous inventions benefiting the wider society – including those in the areas of health, food, pharmaceuticals and energy.

6.2 Monitoring and evaluation

In order to assess and monitor whether the selected policies have delivered the expected results a list of specific indicators need to compiled (Table 6.1) that correlate with the individual initiatives.

The assessment of these indicators can be both qualitative and quantitative. As the selected policy options (Options 2 and 3) contain initiatives that could be assessed in both qualitative abd quantitative terms it is suggested that both types of assessments are carried out. The following table gives an overview of the possible indicators to follow for the future evaluation of initiatives under Options 2 and 3.

Table 6.1 Monitoring indicators

Initiative	Indicator
Option 2	
2A. Support the development of the Marine Biotech ERA-NET	Number of new research and product development collaborations
	Number of new enterprises (special focus on SMEs) that have previously have not been involved in consortiums under ERA-NET
	Number of new products marketable prototypes entering the market as a result of collaboration within ERA-NET projects
	Utilisation (% share) of EU biotechnology infrastructure (including biobanks and research vessels) in ERA-NET projects
2H. Establish a Blue Growth bridging fund	Number and value of applications for financial support from the bridging fund
	Number and value of financial loans approved from the bridging funds
	Commercial value of products developed using the bridging loan
	Share of venture capital investment in the Blue Biotechnology sector
Option 3	
3G- Promote Blue Biotech funding through existing financing instruments	Number of companies active in the sector
	Number of Blue Biotechnology projects/consortiums seeking financial support
	Number of new technologies, processes and products in Blue Biotechnology realised through the project supported
	Spin-off projects and marketable products realised as a follow-up of the support

Annexes: Supporting Information

Annex 1: Events and policy documents

Table 0.1 Chronology of important events and policy documents relating to marine biotechnology in Europe

Year	Document / Activity	Description
2001	ESF Marine Board Position Paper 4: A European Strategy for Marine Biotechnology	Identification of benefits that marine biotechnology could offer Europe if its development was sufficiently supported, and identification of four key objectives.
2002	US National Academy of Sciences: Marine Biotechnology in the 21st Century Problems, Promise and Products	Highlighted the need to develop new advanced techniques for detection and screening of potentially valuable marine natural products and biomaterials.
2005	The CIRCA Report on Marine Biotechnology	This MI funded study provides an overview of marine biotechnology and makes recommendations about how Ireland could develop capabilities in marine biotechnology
2006	European Commission Green Paper - Towards a future Maritime Policy for the Union: a European vision for the oceans and seas (COM (2006) 275).	Identifies Blue Biotechnology as one of the key enabling technologies and maritime economic sectors
2006	European Commission background paper no.10 on Marine Biotechnology	Document to provide background material and information on marine biotechnology in support of the Green Paper on Maritime Policy (COM (2006) 275).
2007	European Commission accompanying document to the Communication on An Integrated Maritime Policy for the European Union	Identifies Blue Biotechnology as an area of particular interest in terms of turnover, growth and employment.
2007	The Bremen Marine Biotechnology Meeting	Led by the European Commission and attended by representatives from industry and Europe's marine biotechnology research community, this meeting highlighted the importance of the EU Framework Programme in supporting marine biotechnology research and called for the development of a European marine biotechnology research strategy.
2008	Joint EC-US CIESM Workshop on Marine Genomics: At the Interface of Marine Microbial Ecology and Biotechnological Applications	From the EC-US Task Force on Biotechnology Research.
2008	European Commission Communication on A European Strategy for Marine and Maritime Research: A coherent European Research Area framework in support of a sustainable use of oceans and seas	Prioritises marine biodiversity and biotechnology research, and recognised its potential to contribute to new knowledge on which to base high value products and processes and increase marine resources and biodiversity understanding.
2009	EU KBBE-NET Coordinated Working Group on Marine Biotechnology (CWG-MB)	Set up to stimulate the development of marine biotechnology in Europe, to identify priority actions and desired impacts/objectives of

Year	Document / Activity	Description
		common interest. Scoping report produced which identified research priorities and made recommendations for future actions.
2010	Marine Board-ESF Position Paper 15: Marine Biotechnology: a New Vision and Strategy for Europe	Provides an updated view of marine biotechnology for policy makers and others involved in marine biotechnology at the EU and national level. Presents a common vision and strategy for European Marine Biotechnology research.
2012	European Commission, A Marine and Maritime Agenda for Growth and Jobs: "The Limassol Declaration"	Calls for the development of the Blue Biotechnology sector to be sustained and to promote the access and fair and equitable benefit sharing arising from the use of genetic resources.
2012	European Commission Communication on Blue Growth: Opportunities for marine and maritime sustainable growth (COM(2012) 494 final)	Presents a long-term strategy to support growth in the maritime sector as a whole. Blue Biotechnology is highlighted as a focus area.
2012	European Commission adopted a strategy for "Innovating for Sustainable Growth: A Bioeconomy for Europe (COM(2012) 60 final)	This strategy proposes a comprehensive approach to address the ecological, environmental, energy, food supply and natural resource challenges that Europe and indeed the world are facing already today.
2012	OECD – Global Forum on Biotechnology entitled Marine Biotechnology: Enabling solutions for ocean productivity and sustainability	Brought together a range of stakeholders from 34 countries to discuss the opportunities and challenges of marine biotechnology.
2013	OECD - Marine Biotechnology: Enabling solutions for ocean productivity and sustainability	Synthesis of information presented at the Global Forum on Biotechnology and background research conducted by the OECD's Working Party on Biotechnology.
2013	European Union Research and Innovation programmed: Horizon 2020. 2014 – 2015 Work Programme for Societal Challenge 9: Food Security, Sustainable Agriculture and Forestry, Marine, Maritime and Inland Water Research and the Bioeconomy	Calls on Blue Growth (to which other parts of Horizon 2020 contribute directly and indirectly).
2013 - 2014	ERA-NET Marine Biotechnology	

Annex 2: Towards a value of the Blue Biotechnology sector

Biotechnology has been identified as a promising sector of the marine economy within the EU and a feature of the Blue Growth initiative[101]. Despite the challenges identified in Section 1.2, given the potential contribution to jobs and growth in Europe, it is worth trying to look at orders of magnitude of value of Blue Biotechnology as a guide to prioritising future investments and policy initiatives.

Value estimation for European marine biotechnology can begin by looking at the scale and estimates available for the bioeconomy in general. In total, the EU's bioeconomy sector represents close to EUR 2 trillion in annual turnover, which accounts for 22 million jobs and 9% of the total workforce[102]. However, the definition of bioeconomy is too broad, as it encompasses food production, forestry and other bio-related industries.

Narrowing down the focus, available estimates for the biotechnology sector suggest that it generates EUR 60 million in annual turnover[103] and a recently published industry analysis[104] focusing on the biotechnology industry suggests that 2012 was a positive year for European Biotechnology as a whole, as it returned to growth (8%) and also saw a return to making profit (net income) after a loss making 2011. The report estimates, that around EUR 3.1 billion in new capital was raised mainly coming from big publicly listed companies (EUR 2.1 billion). Despite this 2012 saw a fall in the total number of companies as the sector consolidated after a difficult previous period. Consideration of this sector is important as consistent, healthy growth within this sector is a positive indicator of future growth within Blue Biotechnology.

The study found that the European sector represents around 17% of the global biotech industry in terms of revenue and around 30% in terms of employment, as shown in the table below. The US remains the global industry leader with revenues four times as large and twice as many employees compared to the European biotech sector. Furthermore the US has twice as many publicly listed companies compared to Europe, while the US biotech sector raised EUR 16.6 billion of new capital in 2012 (or five times more than in Europe).

This suggests that although the European biotechnology sector is doing well and growing, it is still small compared to the US, with plenty of space for development and opportunities.

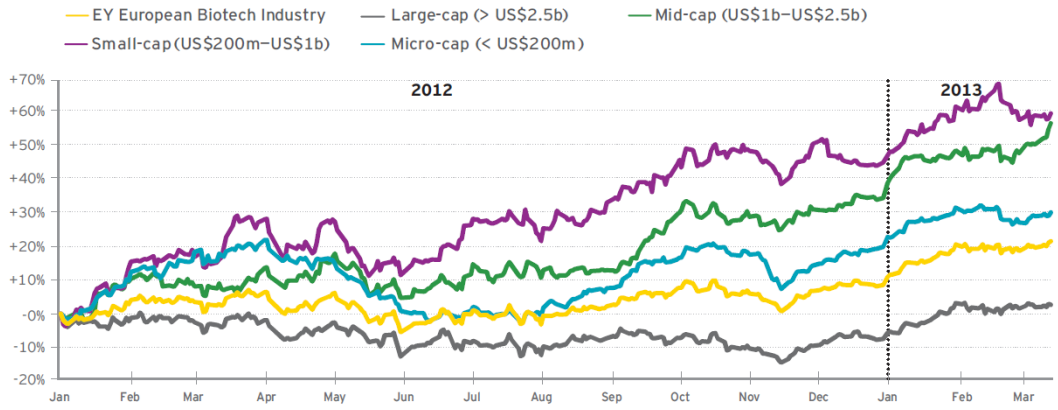
Table 0.2 **European Biotechnology 2011-2012 (EUR million)[105]**

	2011	2012	% change	European size of global Biotech Industry	Europe sector size compared to US
Public company data					
Revenues	14,024	15,085	**8%**	17%	24%
R&D Expenses	3,656	3,627	**-1%**	14%	19%
Net Income (loss)	(14)	175	**-1342%**	3%	4%
Market Capitalisation	52,908	59,073	**12%**	12%	16%
Number of Employees	47700	51,740	**8%**	31%	52%
Financings					
Capital Raised by public companies	1,132	2,133	**88%**		12%

[101] Ecorys, 2012, Blue Growth Scenarios and drivers for Sustainable Growth from the Oceans, Seas and Coasts
[102] European Commission (2012) "Innovating for Sustainable Growth: A Bioeconomy for Europe" http://ec.europa.eu/research/bioeconomy/pdf/201202_innovating_sustainable_growth_en.pdf
[103] European Commission (2012a) "Commission staff working document accompanying the document Communication on Innovating for Sustainable Growth: A Bioeconomy for Europe" http://ec.europa.eu/research/bioeconomy/pdf/201202_commision_staff_working.pdf
[104] Ernst & Young; Biotechnology Industry report 2013
[105] Ernst & Young; Biotechnology Industry report 2013

	2011	2012	% change	European size of global Biotech Industry	Europe sector size compared to US
Number of IPOs	8	3	**-63%**		27%
Capital raised by private companies	986	920	**-7%**		22%
Number of companies					
Public companies	169	165	**-2%**	28%	52%
Private Companies	1847	1,799	**-3%**		97%
Public and private companies	2016	1,964	**-3%**		90%

Figure 0.1 **Performance of European Biotech companies by size[106].**



With regards to drivers in Biotechnology as a whole we can see that it is the Small and Mid Cap[107] companies that are outperforming not only the industry index, but also their larger counterparts. This is mainly due to the structure of the sector, where frontline research is done by the small and mid-cap companies. These companies are usually young and therefore grow faster once a product becomes financially viable. If and when the success of a product is consolidated, larger companies move in to acquire them. Given that the products and the larger companies are of a more mature nature, the risks are much lower, but so are the returns.

Table 0.3 illustrates the concentration of Biotechnology companies in Europe with related revenue and R&D spending. Based on preliminary estimation regarding the activities of the Blue Biotechnology industry we are assuming that it is following similar trends to biotechnology in terms of the concentration of companies. Based on the entries of the stakeholder database the highest concentration of companies was identified in France, Germany, the UK and the Netherlands, as shown in Table 0.3.

Table 0.3 **Financial performance in 2012 of European Biotech companies by country[108]**

Country	Number of public companies	Revenue (EUR m)	Revenue growth (%)	Market Capitalisation 31.12.2012 (EUR m)	R&D spending (EUR m)	Net Income (EUR m)
UK	31	4,048	10%	15,795	950	422
Sweden	25	1,838	-5%	4,623	477	4
Israel	23	98	61%	1,509	84	-111
France	22	2,568	2%	6,052	431	-87
Germany	13	196	-11%	1,473	134	-193

[106] Ernst & Young; Biotechnology Industry report 2013
[107] Small- and mid-cap companies have low market capitalisation (value of stocks issued) and generally tend to raise between $250 million-$2billion capital, these values however vary depending on the country of operation
[108] Ernst & Young; Biotechnology Industry report 2013

Country	Number of public companies	Revenue (EUR m)	Revenue growth (%)	Market Capitalisation 31.12.2012 (EUR m)	R&D spending (EUR m)	Net Income (EUR m)
Norway	9	123	42%	1,157	37	-7
Denmark	8	1,688	4%	7,342	428	88
Switzerland	8	1,420	-10%	4,584	460	133
Belgium	6	252	47%	2,648	158	-58
Netherlands	3	948	8%	3,226	109	62
Other	17	1,907	48%	10,664	359	-78
Total	**165**	**15,085**	**8%**	**59,073**	**3,627**	**175**

Looking with more detail at the different countries in Europe we can see that the biggest cluster of the biotech industry is in the UK (at least in terms of publicly listed companies). This is in most indicators and is showing a very healthy 10% revenue growth and the biggest net income (profit) in nominal terms. However, looking at the revenue growth the biggest growers were in Israel, Norway, Belgium and other smaller countries. At the same time Swiss, German and Swedish companies saw a fall in business with revenue falling.

Blue Biotechnology

The OECD has recently released its first publication on marine biotechnology with a very cautious approach concerning market value estimates, as no global figures has been produced, but only topical examples of the potential global market value of specific products[109].

The only series of reports attempting to regularly define a value for the Blue Biotechnology sector is published by Global Industry Analysts, a market research agency, which forecasts that the Marine Biotechnology sector is to reach USD 4.1 billion (EUR 3 billion) by the year 2015 with a compound annual growth rate (CAGR) of 4%-5%.[110]. This is expected to rise further, reaching USD 4.8 billion (EUR 3.5 billion) by 2018[111]. Given these figures we can calculate that Blue Biotechnology contributes (at the moment) to about 2%-5% of the total Biotechnology industry[112]. Additionally, this means that in 2012 the size of the European Blue Biotech sector can be estimated to be between EUR 302 million - 754 million (in terms of revenues). In terms of end-use, healthcare/biotechnology constitutes the largest and fastest growing end-use segment for marine biotechnology.[113]

[109] OECD, 2013, Marine Biotechnology: Enabling Solutions for Ocean Productivity and Sustainability, OECD Publishing. http://dx.doi.org/10.1787/9789264194243-en
[110] Global Industry Analysts Inc. "Marine Biotechnology: A Global Strategic Business Report" 2011
[111] Global Industry Analysts Inc. "Marine Biotechnology: A Global Strategic Business Report" 2013
[112] Ecorys calculation based on triangulation of ratio of Marine biotech compared to the whole biotech industry in terms of revenue using table Ernst & Young; Biotechnology Industry report 2013
[113] Global Industry Analysts Inc. "Marine Biotechnology: A Global Strategic Business Report" 2011

Annex 3: Stakeholder Database Analysis

Introduction

A Blue Biotechnology database has been compiled to identify some of the major players of the European Blue Biotechnology sectors according to a variety of parameters. The database comprises active contacts (at person level, i.e. including direct contact via email or other means of communication is possible for users of the database) from industry, academia, networks including industry associations, research- and knowledge centres, public and private funding agencies, Member state authorities etc. Whilst not a comprehensive list of stakeholders the database does provide a representative set of stakeholders.

The database includes the following fields:

- Country, organization, proposed stakeholder (name), contact data (incl. Email), webpage;
- Type of organization: academic research, company (personnel<250), company (personnel 250-500), company (personnel >500), funding agencies, policy makers, outreach professionals, infrastructures, clusters, networks;
- Short description;
- Industry sector: Food: Food, Food: supplements, Food: Feed, Energy, Health: Pharma, Health: MedTech, Health: Diagnostics, Cosmetics, Other industries: Environment: Monitoring, Environment: Remediation, Industrial Products and Processes: Process, Industrial Products and Processes: Enzyme, Industrial Products and Processes: Pilot;
- Criterion for selection: Activity in the field, visibility at EU level, relevance for politic, reference to BB sectors, regional diversity & spread;
- Company's activity field: R&D, production, service, marketing.

At this stage, the database has been compiled as an excel list. It has been used to advertise the European Commission's public consultation on marine biotechnology[114]. The database will be updated throughout the study using details gained through research (further desk research, outcome of questionnaire, stakeholder meeting, expert interviews, etc.). For possible external use stakeholders will need to give their consent for their use of data. The database shall be formatted in such way that it can be searched by combined queries (redistributable access file).

The stakeholder database targets were a minimum of 100 individual players spread across at least 80 institutions and a coverage of approximately 15-20 EU countries. Special efforts were made to avoid a biased view on the stakeholders to be involved.

Stakeholders Analysis

The current state of entries is 286 stakeholders covering 25 countries (plus Europe, Baltic Sea Region, Mediterranean Region and Global entries) and 238 institutions.

Table 0.4 and Figure 0.2 present the number of stakeholders per country and region (in the instances that stakeholders were affiliated to a region rather than a country). The top five countries are France, Netherlands, Germany, the UK and Norway.

[114] http://ec.europa.eu/dgs/maritimeaffairs_fisheries/consultations/marine-biotechnology/index_en.htm

Table 0.4 Stakeholders per country

Country	No. of stakeholders
France	43
Netherlands	35
Germany	33
UK	29
Norway	20
Ireland	13
Belgium	12
Italy	12
Denmark	11
Spain	11
Portugal	10
Sweden	8
Finland	7
Poland	5
Switzerland	4
Austria	3
Turkey	3
Iceland	2
Slovenia	2
Estonia	1
Greece	1
Lithuania	1
Luxemburg	1
Mediterranean Region	1
Baltic Sea Region	2
Europe	9
Global	7
Total	286

Figure 0.2 **Distribution of stakeholders by country**

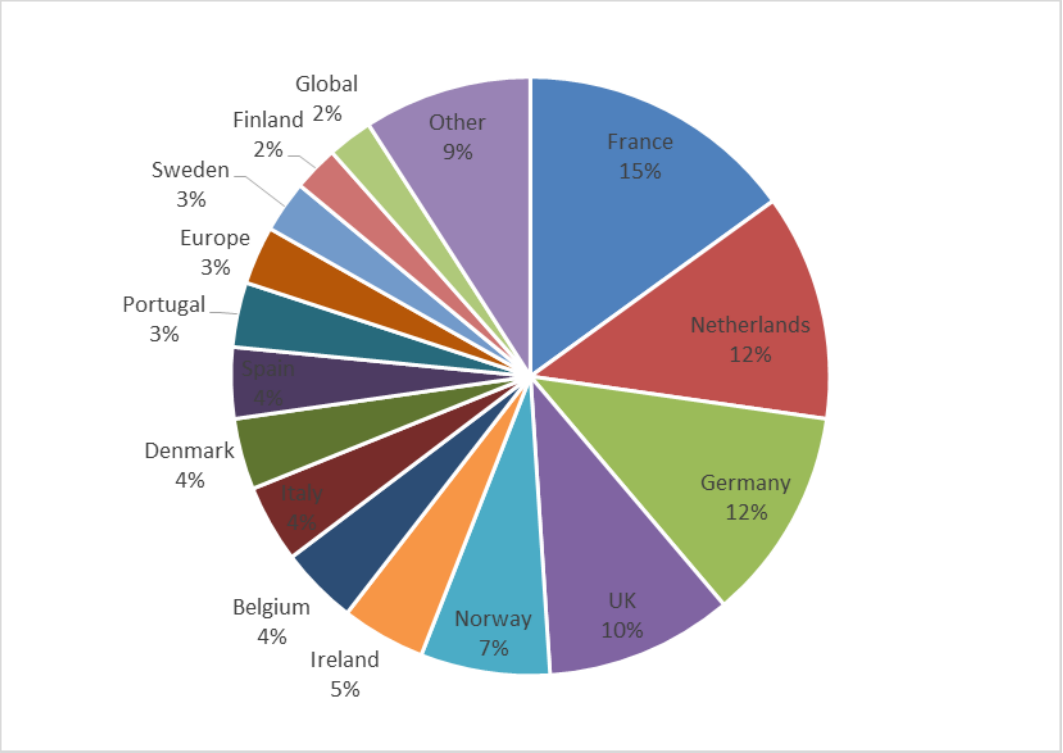


Table 0.5 and Figure 0.3 present the distribution of stakeholders by institutional type. The main proportion of stakeholders affiliate to academia and research, small companies (number of personnel less than 250) and biotechnology networks and clusters.

Table 0.5 **Number of stakeholders per institution type**

Institution type	No. of stakeholders
Academia & research	85
Companies with < 250 personnel	75
Companies with 250-500 personnel	9
Companies with > 500 personnel	23
Funding agencies	11
Policy makers	12
Outreach professionals	9
Infrastructures	17
Network incl. clusters	45

Figure 0.3 **Distribution of stakeholders by institution type**

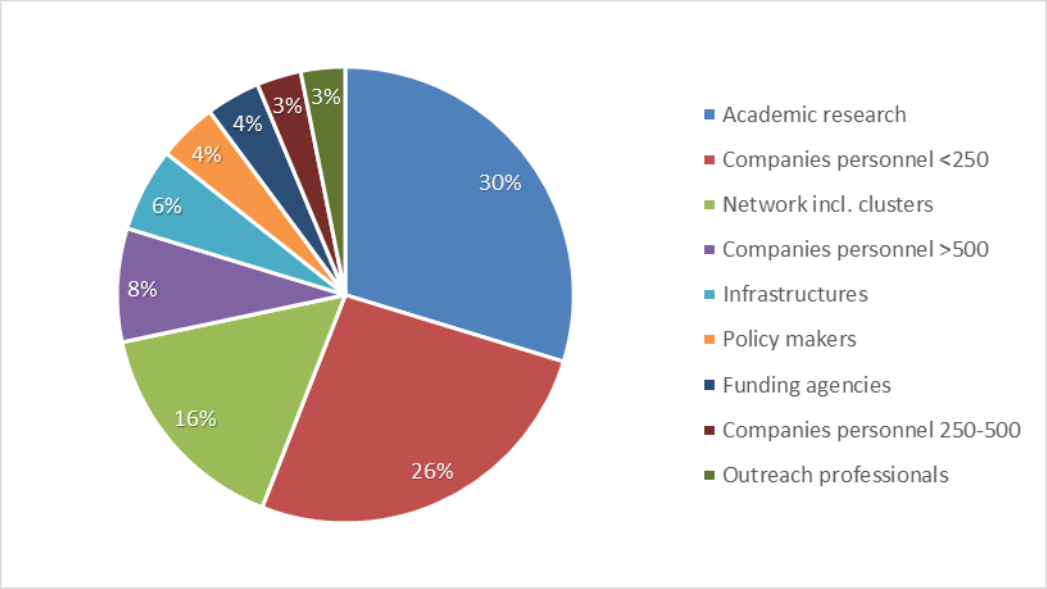
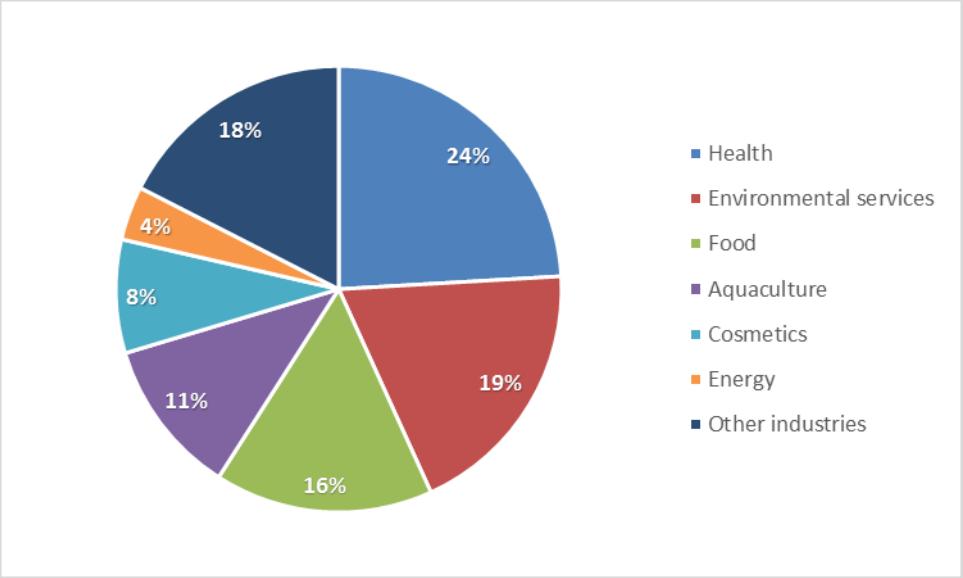


Table 0.6 and Figure 0.4 present the distribution of stakeholders by industry sector. Many stakeholders have activities in more than one industry sector, with a strong emphasis on "other industries" as a second field of activity. This holds true especially for SMEs that work in multiple product fields, e.g. use of one specific marine organism for a cosmetic product and development of the respective process for other purposes. The three key industry sectors with the greatest proportion of stakeholders are the health, environmental services and food sectors.

Table 0.6 **Number of stakeholder per industry sector**

Industry sector	No. of stakeholders
Health	117
Environmental services	93
Food	77
Aquaculture	55
Cosmetics	40
Energy	19
Other industries	85

Figure 0.4 Distribution of stakeholders by industry sector



Annex 4: U.S. National Algal Biofuels Technology Roadmap

In 2010, the US Department of Energy (US DOE) sponsored the development of a complete roadmap towards the production of algal biofuel[115]. The main objectives of this strategy were centred on exploring the various pathways of transforming algae into economically viable energy applications including renewable gasoline, diesel and jet fuel. This roadmap completed the various projects initialised by the US Department of Defence (US DOD) towards the development of a diverse range of biofuels from various sources including plants such as jatropha or babassu as well as microalgae.

Although the roadmap is clearly oriented towards the production of energy, most of the developments supported by the strategy will benefit all blue biotech sectors. Several of the intermediate compounds produced by these processes (e.g. lipids and proteins) will be easily transferable to other sectors and the harvesting and extraction techniques used will be potentially transferrable to any other biotechnology applications based on micro algae and other marine microorganisms. Key aspects of this strategy are;

- The development of general biotechnological techniques that will benefit all blue biotech sectors and may be adapted for other model organisms. The roadmap explicitly mentions the need for applying the whole "Omics"[116] approach to algal applications;
- The identification of algal strains proposed in the strategy will also allow for improvements in existing information, notably about the diversity held by the various algal collection centres. Renewal of existing strains held in culture collection and biodiscovery projects extending the collections are also tasks covered by the roadmap;
- Selecting model algal model extraction/cultivation systems for study that can provide a common platform for all blue biotech sub-sectors;
- Investigating genetic and biochemical pathways for the production of fuel precursors and optimizing the algal productivity for fuel precursors which will serve the entire industry, as these precursors, such as lipids, may have different usages;
- Researching harvesting[117] and extracting[118] approaches for microalgae and additional intermediate compounds. Research into scaling challenges, such as operational temperature, pressure, carrying capacity, side reactions, and separations are not specific to the energy applications and will also be transferable to other sub-sectors.

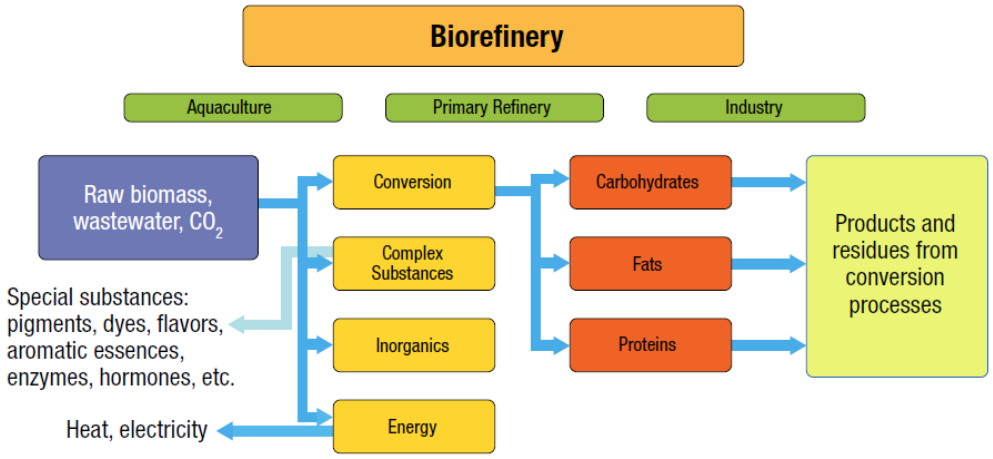
[115] U.S. DOE 2010. National Algal Biofuels Technology Roadmap. U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Biomass Program. http://biomass.energy.gov

[116] Omics is a generic term covering several biotechnological techniques: DNA sequencing, transcriptomics, Proteomics, Metabolomics and Lipidomics

[117] The U.S. DOE strategy mentions: sedimentation, flocculation, dissolved air floatation, filtration, centrifugation, and mechanized seaweed harvesting

[118] The U.S. DOE strategy mentions: sonication, microwave, solvent systems, supercritical fluid, subcritical water, selective extraction, and secretion

Figure 0.5 The biorefinery concept. From the US DOE National Algal Biofuels Technology Roadmap



The roadmap heavily supports development of the biorefinery concept for micro algae and although it mainly targets energy applications, it also incorporates evaluation of the potential applications for co-products, as seen in Figure 0.5. The roadmap includes a specific module aimed at identifying and researching potential co-products with key objectives including:

- Identifying and evaluating the co-production of value-added chemicals, energy, and materials from algal remnants (e.g., biogas, animal/fish feeds, fertilizers, industrial enzymes, bioplastics, and surfactants);
- Optimising co-product extraction and recovery;
- Extensive work on lipids products, particularly into achieving high yield for production-scale installations and not just in laboratory conditions.

Additionally, the roadmap seeks to explore all potential production routes, even those that are currently considered to be less promising. For example, the strategy recommends exploring an array of microalgal cultivation techniques including photoautotrophic, heterotrophic and mixotrophic methods. Photoautotrophic techniques use light energy to grow and create new biomass whereas heterotrophic techniques are conducted in the absence of light. Mixotrophic is a combination of both techniques.

Two US companies may be cited as examples of how the US government is currently pushing for the biofuel sector to emerge and for both companies; the close relationship with the U.S. department of Defence may be seen as the catalyst for their development:

- Launched in 2003, Solazyme has concentrated most of its R&D efforts to produce biofuel using heterotrophic pathways. The company has been awarded several contracts to provide jet fuel and naval fuel to be tested by the U.S. army;
- Sapphire Energy, Inc. launched in 2008, was able to leverage over USD85 million (EUR 62 million) from private investors and to secure USD100 million (EUR 73 million) in grants and loans from various US administrations[119]. The main objective is to develop microalgae race ponds to address the fuel market.

Although both companies are initially targeting fuel applications, they are already exploring markets for co-products. Solazyme is, for example, entering other markets such as food, skin care and chemicals and is developing partnerships with major companies to further strengthen its access to these markets. To date, the company has signed various agreements with Chevron, Unilever and Roquette.

[119] http://www.forbes.com/sites/toddwoody/2012/09/06/the-u-s-militarys-great-green-gamble-spurs-biofuel-startups/

In Europe, competitors in the market of algal biofuel do not benefit from the same support. A French company called Fermentalg is developing microalgal production following a heterotrophic pathway, like Solazyme. Although the first batches of biofuel produced by Fermentalg have been successfully tested on cars, the third round of financing covered only EUR12 million, a much lower level than the funding available to Solazyme or Sapphire Energy Inc. at the same stage.

Annex 5: Patent Profiling – Methodology and detailed results

Methodology

In terms of the methodology used for patent profiling, the online database Espacenet was screened with keywords. Furthermore, the database of the World Intellectual Property Organization (WIPO) was also searched for European inventors in a complementary search strategy. Full access to both databases is obtained via the frontend DEPATIS external client, which enables to search the complete collection including full texts of European published applications. Regional databases of the different countries in Europe were not consulted due to the assumption that all important regional patents are also patented internationally. This approach provides a more accurate measure of the level of inventive activity from a company within the technical space, and a truer picture of the overall level of innovation. Keywords have been defined, a reviewed dataset has been generated[120] and the planned evaluation of the dataset[121] has been conducted. The basic search contained the word "marine" in combination with organisms and the application or basic product, and all European countries of the patent applicant, the inventor and the country where the earliest filing of a patent application is claimed (priority country). For evaluation of the patents, all hits were transferred into PATBASE – a database allowing full-text searching in patents of all countries, which has excellent options for statistical analysis.

The current results include information on the distribution of patents between the Blue Biotechnology sub-sectors and across the main classification of patents, the different types of marine organisms involved in patents, as well as an overview of the main European patent applicants/owners in general and by type of blue-biotechnology sub-sector.

The Search string was constructed using the following parameters:

PN: patent number
AY: application year
AD: application
ICM: main class of international classification
TI_DE: title in German
TI_EN: title in English
TI_FR: title in French
TI_XX: possibly in Spanish
AC: application country
CTZ: amount of citations
PRC: priority country
PA: patent applicant
IN: inventor

Definition and premises

- Because European patents can be written in English, German, or French, the search was done in all 3 languages. Different synonyms and alternative spellings of one term and its translations to German and French (including Latin names of the organisms: Phylum, Phyta, Class, Order or Family, if suitable) are provided in Wikipedia and used in the search string;
- Because the endings of most terms can be flexible (e.g. plural, suffixes, causes), truncations are implemented;

[120] Generation of first dataset comprises the search approach covering all defined marine organisms

[121] Basic evaluation of the dataset "patents assorted by used marine organisms" including checks of the results for false positive results i.e. hits resulting from the used search string but that do not belong to the Blue biotechnology topic. One example are patents describing inventions using sea salts and squid ink for the preparation of food (e.g. noodles) which arise when searching for squids and food. Also, Seashore renaturation methods occur frequently. With some small strings such as "li" in pa, in, prc false positives occur: in a lot of Asiatic names; patents are hits, where neither the country, nor the inventor or applicant is from Europe, but the inventors have a name with "li"

- Patent counting was structured around “patent families”. Each related patent application and granted patent was added to the family record as it is published. This being the case, all counts of records in this project refer to patent families or inventions, and not to individual patent documents. For example, the European application, European granted patent and the US granted patent for a single invention family is counted in aggregate as “1” in all the analyses in this report unless otherwise noted.;
- A search for national patents was performed to reveal their amount and overall role in the Blue Biotechnology sector. From WO-registrations EU-patents might also be generated within 30 months. These patents probably were registered nationally before and it is important to consider them. National patents, where the patent is not written in English, French or German, will not have been found;
- European patents from applicants or inventors of non-European countries were excluded;
- It should be noted that not only Member States of the European Union were considered, but that European countries were considered by their geographical distribution, according to the 38 member states of the European Patent Organization from June 2012 (however without Turkey). This included the two extension states Bosnia and Herzegovina and Montenegro, which have signed extension agreements;
- Concerning aquaculture, we only counted patents applying use of biotechnology for improvement of aquacultures, hence, the International Patent Class IPC A01K61 (Culture of fish, mussels, crayfish, lobsters, sponges, pearls or the like IPC A01K80 (harvesting oysters, mussels, sponges) and A01K63 (receptacles for live fish, e.g. aquaria (keepnets or other containers for keeping captured fish)) were excluded. All other patents in IPC A01K (Animal husbandry; care of birds, fishes, insects; fishing; rearing or breeding animals, not otherwise provided for; new breeds of animals) were also excluded;
- General keywords can be broken down to keywords with smaller domains. The keywords “pharmaceutical” or “drug” have the subgroups “antibiotic”, “anticancer”, “antiinfectiva”,… In the profiling all general and special keywords are taken together;
- The definition of the distance between 2 keywords (especially between “marine” and the residual keywords) is the most crucial step in profiling: the nearer they are defined, the less false positives (patents that do not belong to MBT), but also the less false negative (patents belonging to MBT, but are not detected) hits are shown. This step was defined with each keyword-set separately;
- Priority country is typically the country where the invention was invented and therefore has been used as a proxy to determine levels of patenting output by a particular country. This measurement is used in the absence of an inventor country within the patent data, this particular field is not present across many authorities;
- Where families have more than one assignee, the counts in the assignee tables contain a count for each assignee. However, within the country tables only one count is attributed for co-assigned inventions ensuring no double counting due to multiple assignees;
- Patent Cooperation Treaties (PCT) filings are becoming more popular as they allow entities to delay decisions about large investments of patent maintenance fees. As entities target global markets they need to decide on the correct markets to protect their inventions. PCT filings offer a longer decision period before deciding how many countries they should go to national phase to obtain a granted patent.

Results in numbers and specific screening of the results

The amount of hits for the distinct keywords and their combinations gives a first hint of the European patenting of products and technologies in the field of Blue Biotechnology. The total sum of the database is 27,251 hits, which means that a lot of hits fall in more than one organism-group. After deletion of family members, 10,837 hits remain. After screening the patents concerning false positive results, 1774 patents remain. This 2nd screening was done manually: every patent was

evaluated at least by considering the abstract, but mostly by screening the full text of a patent. There are several reasons for the immense reduction of patents, such as topics, that are dealing with marine organisms, but do not belong to Blue Biotechnology. This included some obviously wrong results, because the keywords fit randomly (e.g. recipes with fish and pasta, cooked in salt water) as well as truncational problems (e.g. the “mariner Transposon”: mariner-like elements as a prominent class of transposons found in multiple species including humans - the Mariner transposon was first discovered by Jacobson and Hartl in Drosophila). Other examples were classical aquaculture topics that do not belong to marine biotechnology, e.g. inventions of new cages for marine fishes.

All these results comprise only patents with European patent owners and inventors, which distribute across topics of marine biotechnology as follows:

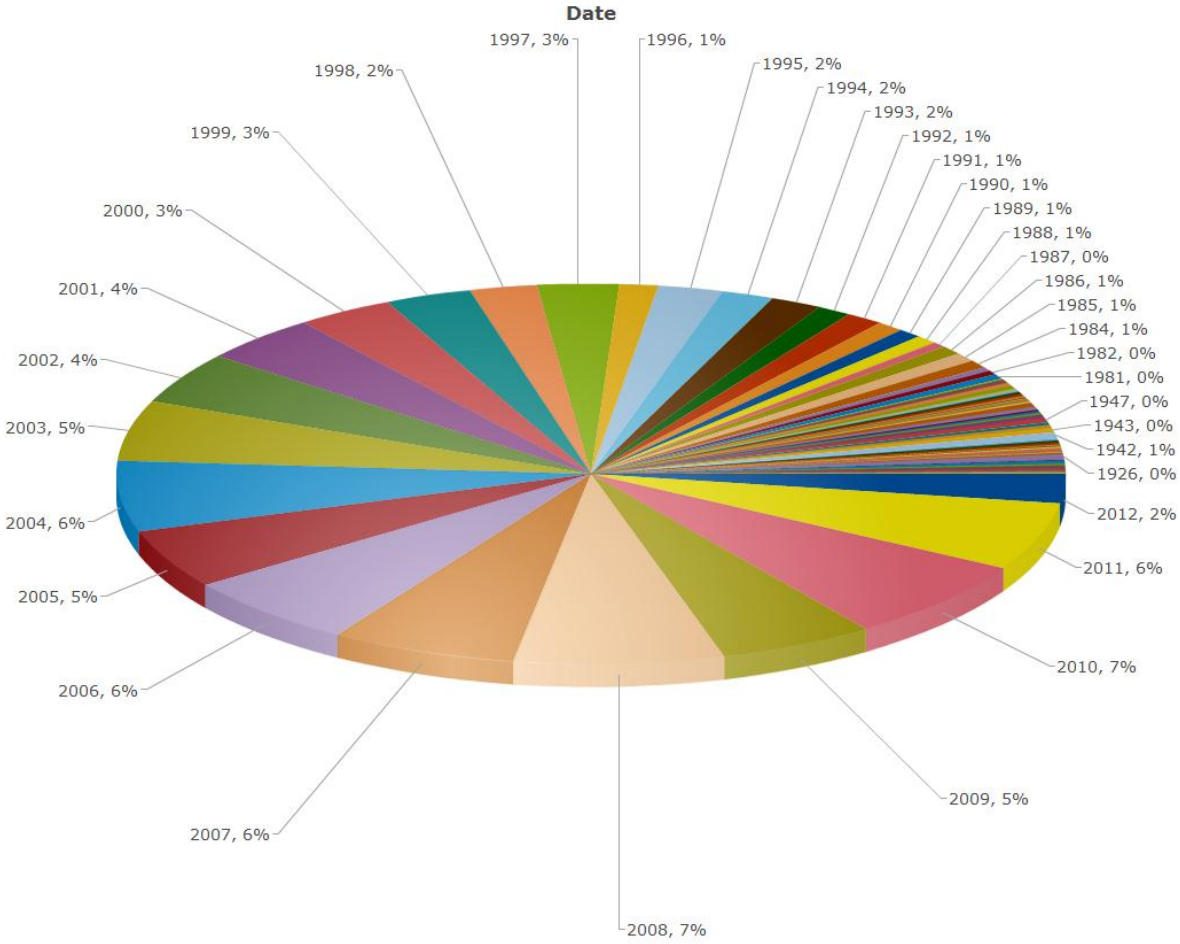
Topics	
Energy	93
Cosmetics	713
Drugs	1204
Enzymes	942
Natural products	1756
Biofilms	10
Biocides	46
Residual	1
	5200

Most of the patents can fall into more than one group, thus the sum of all hits (5200) was far higher than the real amounts of patents (1774).

Time-dependent course of patenting

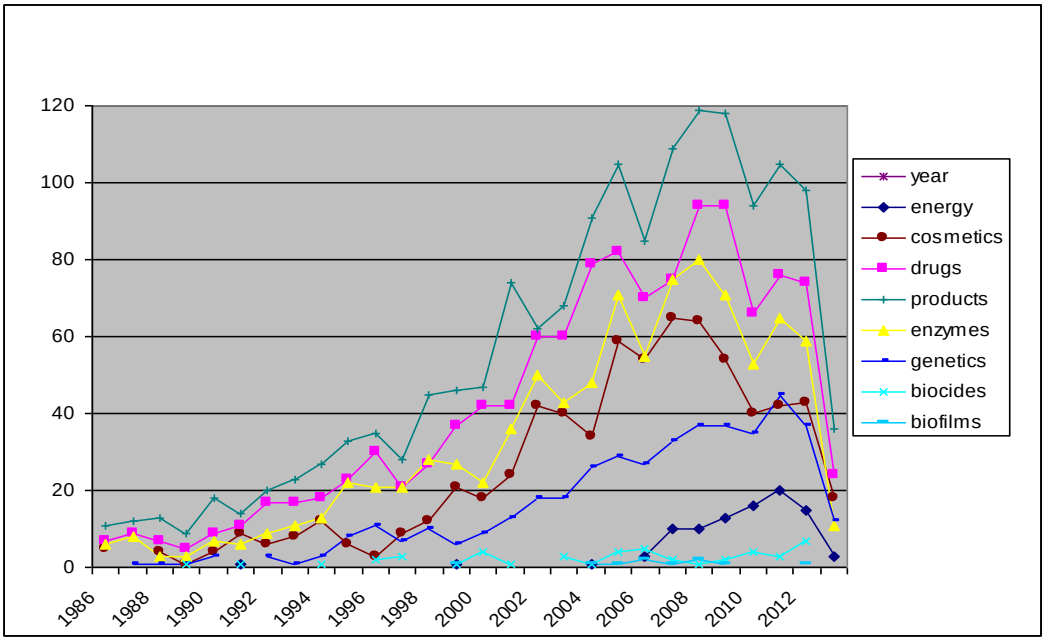
The first visible patenting in MBT occurred in the 1990s. The amount of patents before is negligible. This is in accordance to other publications. Hu et al (Marine Drugs 2011, 9, 514-525), for example, published the worldwide development of marine natural products with a tremendous increase between 1984 and 1986. Therefore the patents until 1985 in the following analyses were only counted in 10-year periods.

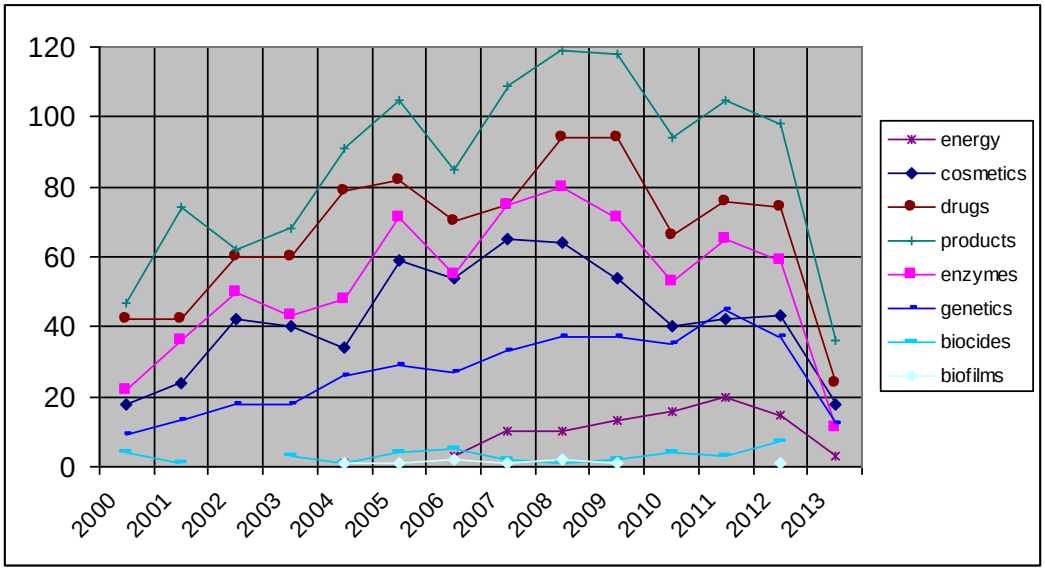
Figure 0.6 Number of patent publications per year



Patents in MBT were exponentially increasing over time. There is a real hot spot of patenting between 2000 and 2010. All later values cannot be interpreted because the period till 2014 has not yet finished. For a closer look onto the development of marine patents the next diagrams are listed in 1-year periods. The years before 1986 were not considered.

Figure 0.7 Comparative patent publications per sub-sector 1986-2012



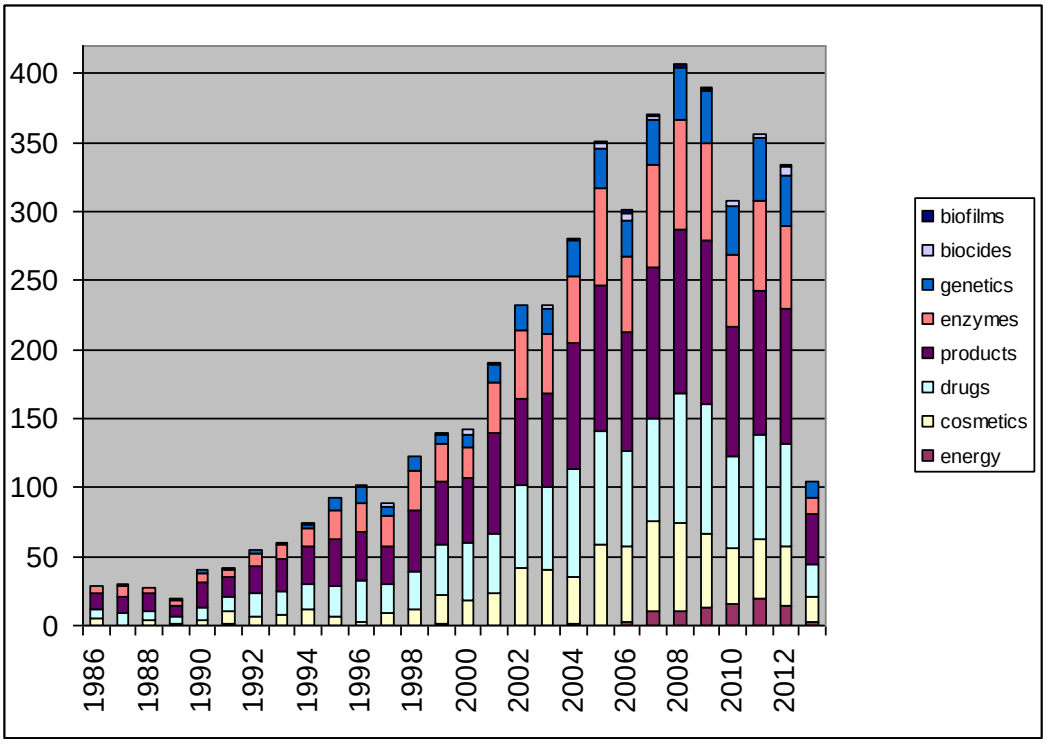


Interestingly in the year 2006 as well as in year 2010 there is a decrease in nearly all fields of MBT. In 2011 and 2012 patenting is again increasing, but the amount does not reach the values of 2008 and 2009.

Trend analysis

Increase rates were comparable across almost all application fields. A trend analysis was performed for all sectors until 2020, indicating a stabilisation in the number of new patents in most of the sectors with probably even a slight decrease in the total number of patents. Only the sectors cosmetic and energy are expected to increase by 10-20%.

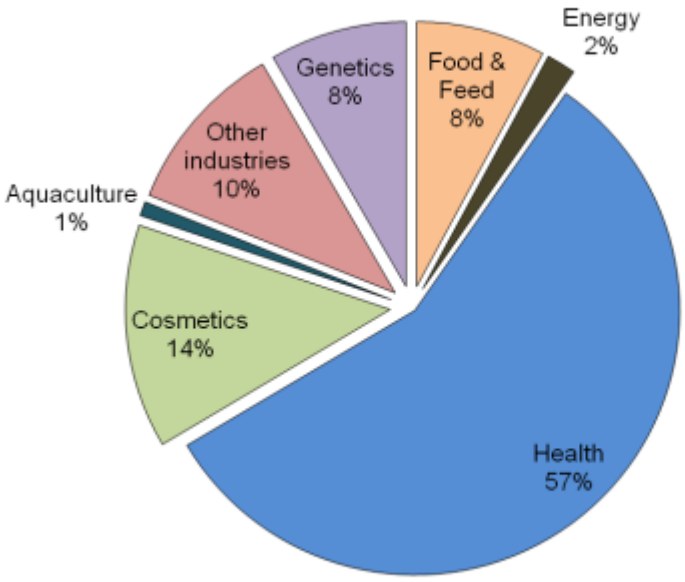
Figure 0.8 Aggregated patent publications per sub-sector 1986-2012



Patents in the blue biotech sub-sectors

Patents were filed in all sub-sectors of Blue Biotechnology, with a strong focus on health topics covering 56% of all patents (Figure 0.9). As most of the patents deal with compounds or genes with more than one application field rather than with specific production processes, many patents belong to more than one sector. For instance, the topic “natural products” contains more or less all other topics; as a result, the patents on natural products belong on average to three of the sub-sectors. The patents on genetic material and tools for molecular research and development were assorted separately, when affiliation to one of the sub-sectors was not possible.

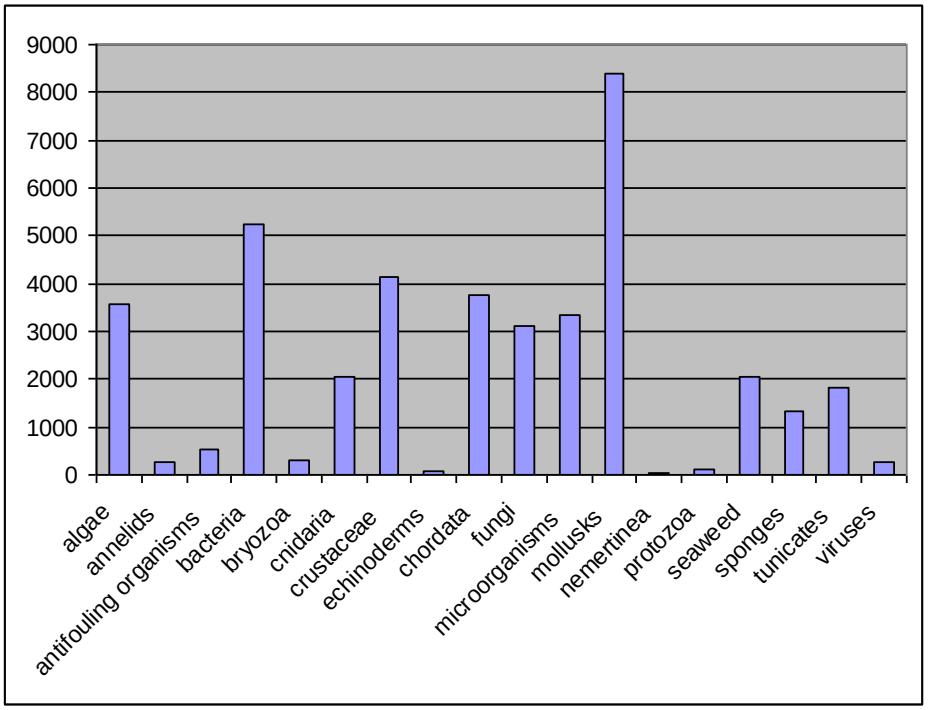
Figure 0.9 Distribution of patents across sub-sectors



Marine resources reflected in patents

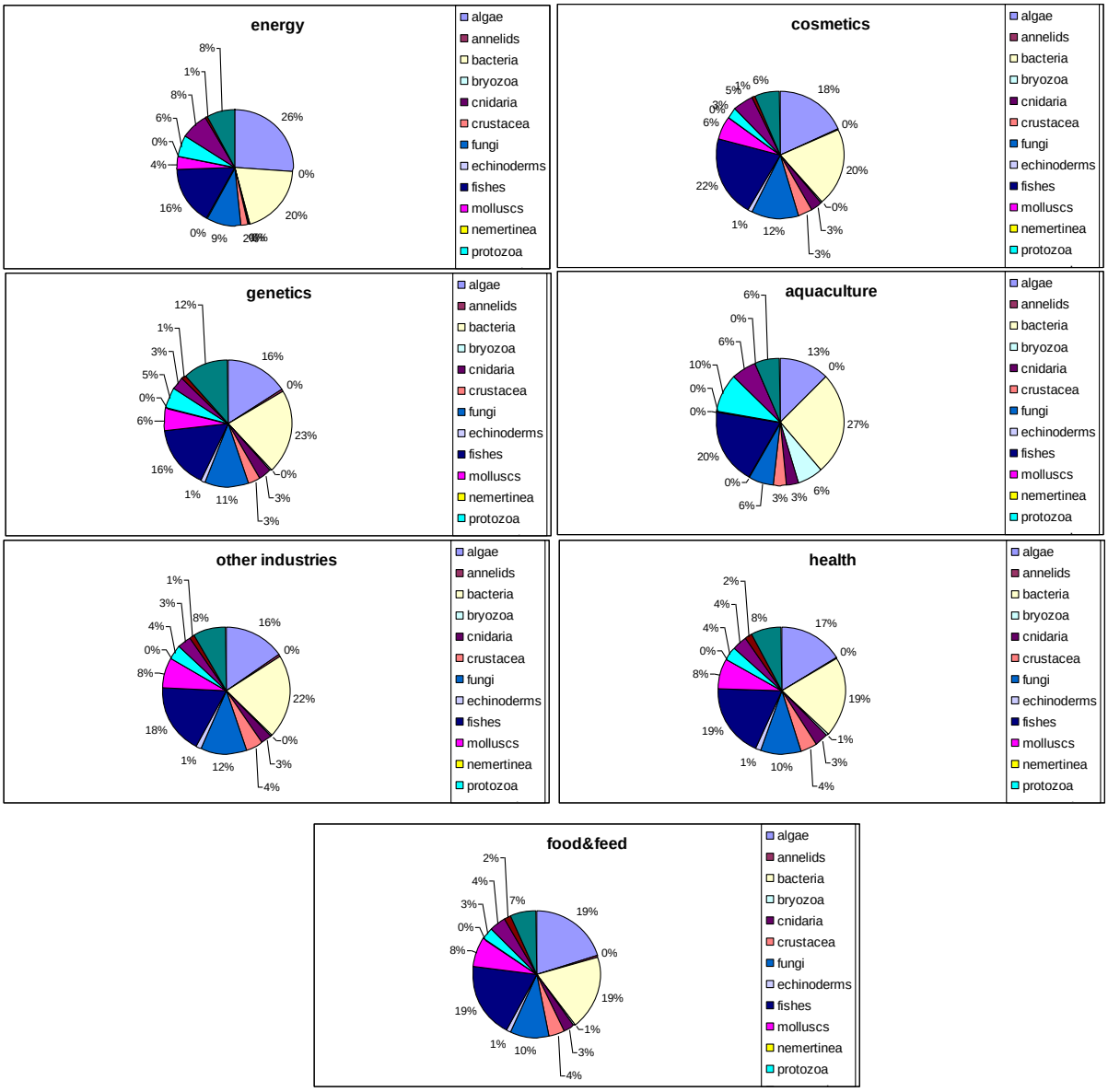
The Blue Biotechnology patents originated from different organisms as shown in Figure 0.10.

Figure 0.10 Patent search results using the word "marine" in combination with keywords referring to organism/groups



Phyla from all domains of live were the source for patents, however, with a strong focus on microbes and molluscs. The further analysis showing the used organisms/phyla by the various sub-sectors actually reveals that the spectrum of used organisms is quite similar across all subsectors.

Figure 0.11 Marine organisms as source for patents sorted per sub-sector



Inventors per institutional type

In general, companies are the main patent filers - research institutions and universities together represent less than 20% of the total number of patents. This may indicate a lack in knowledge transfer or alternative valorisation strategies of academic stakeholders. The recently published knowledge transfer report by the European Commission[122] summarises the strong bottlenecks for patenting of academics: costs, knowledge on patenting strategies and early patenting, as well as lack of interest. In can be assumed that these general bottlenecks also apply to the Blue Biotechnology sector in particular. However with regards to the lack of patenting by SMEs it may be assumed that many SMEs use other IP protection strategies than going through patent filing.

[122] DG RES Inn Knowledge Transfer Study 2010-2012

Figure 0.12 Who is filing? Comparison between academia and industry with respect to patent filing

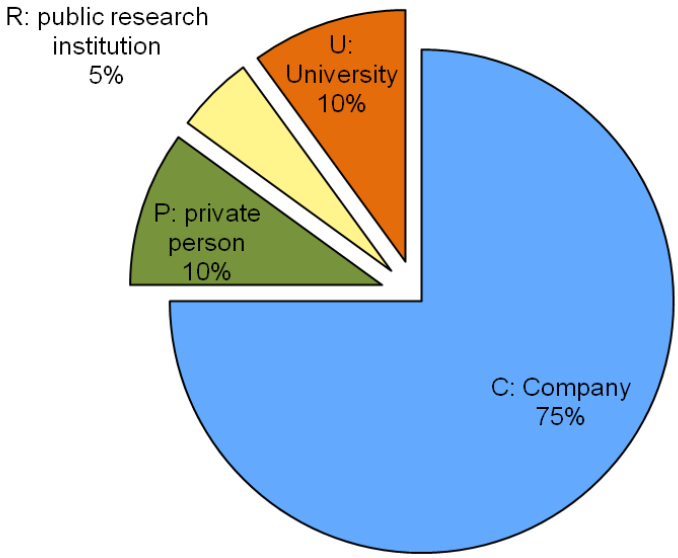
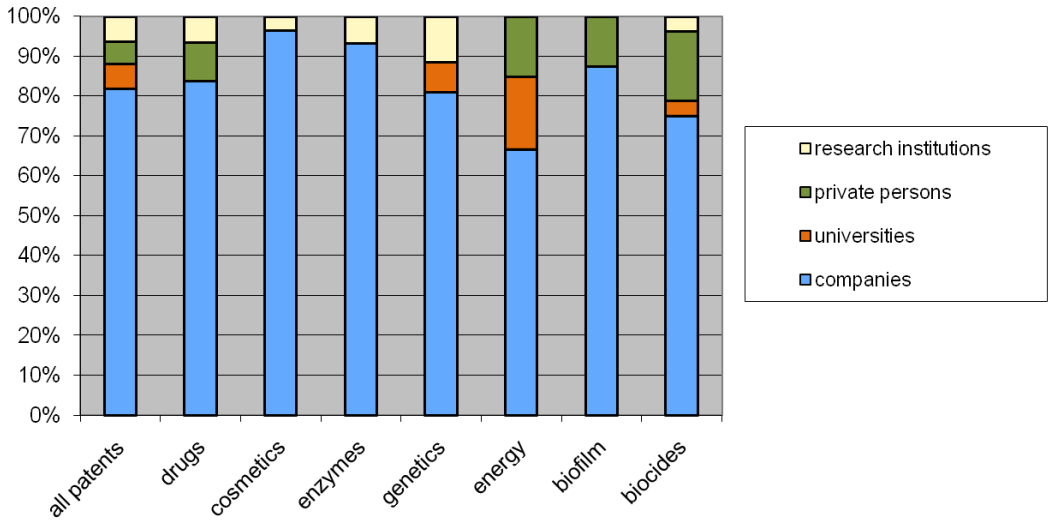


Figure 0.13 Application field specific distribution of inventors by type of institution



Main players in patenting

Table 0.7 TOP Assignee

				Patent frequency						
All Assignees	country	inst. type	all products	drugs	cosmetics	enzymes	genetics	energy	biofilm	biocides
HENKEL KGAA	DE	C	153	73	144	97				
PROCTER AND GAMBLE	global	C	53	40		51	13			5
PHARMA MAR	ES	C	51	49			7			
OREAL	FR	C	45	35	44	25				
DSM IP ASSETS BV	global	C	31	27	14	19	19			
RUFFLES GRAHAM KEITH	GB	P	30	30						
CENTRE NAT RECH SCIENT	FR	R	26	20	9	16	12			1
UNILEVER	global	C	25		12					
BASF AG	DE	C	23		10		11			
PRONOVA BIOPHARMA NORGE AS	NO	C	19	19		16				
IFREMER	FR	R	18							
MARTEK BIOSCIENCES CORP	IS	C	18	17			13			
NOVOZYMES AS	global	C	18			16	8			6
KAO GERMANY GMBH	DE	C	14		14					
NESTEC SA	CH	C	14							
FERMENTALG	FR	C	13							
UNIV CALIFORNIA	(EUR)	U	12				8			
UNIV ARIZONA	(EUR)	U	11					6		
UNIV MAINZ JOHANNES GUTENBERG	DE	U	11							
INST BIOMAR SA	DK	C	10							
GOEMAR LAB SA	GB	C	10							

			Patent frequency							
All Assignees	country	inst. type	all products	drugs	cosmetics	enzymes	genetics	energy	biofilm	biocides
COCKBAIN JULIAN	GB	P	9						1	
SEDERMA SA	FR	C	9							6
NUTRICA NV	DE	C	9							
NUTRINOVA GMBH	DE	C	8							
GELYMA	FR	C	8							
LIPOTEC SA	ES	C	8				7			
UNIV WUERZBURG	DE	U	8							
BEIERSDORF AG	DE	C	7							
ELAN PHARMA INT LTD	IE	C	7				7			
EPAX AS	NO	C	7							
AKER BIOMARINE ASA	NO	C	6							
SHELL INT RESEARCH	Global	C						6		
LS9 INC	US	C						5		
SAPPHIRE ENERGY INC	US	C						4		
SCHAVERIEN COLIN	GB	P						3		
STATOILHYDRO ASA	Global	C						3		
BP BIOFUELSUK LTD	Global	C						2		
CAMPBELL NEIL	US	P						2		
CELLECTIS SA	FR	C						2		1

Institutional type: C = company, P = private person, U = university, R = research cluster

The detailed analysis of all sectors revealed the main players in patenting to be Henkel, Germany (both in cosmetics and health) and Pharmamar, Spain (Top 2 in Health). These are the companies with the highest amount of patents in marine biotechnology in Europe. The chemical industry company Henkel holds many patents in its portfolio concerning hair care with marine collagen; Pharmamar is a leading pharmaceutical company exclusively working with marine organisms.

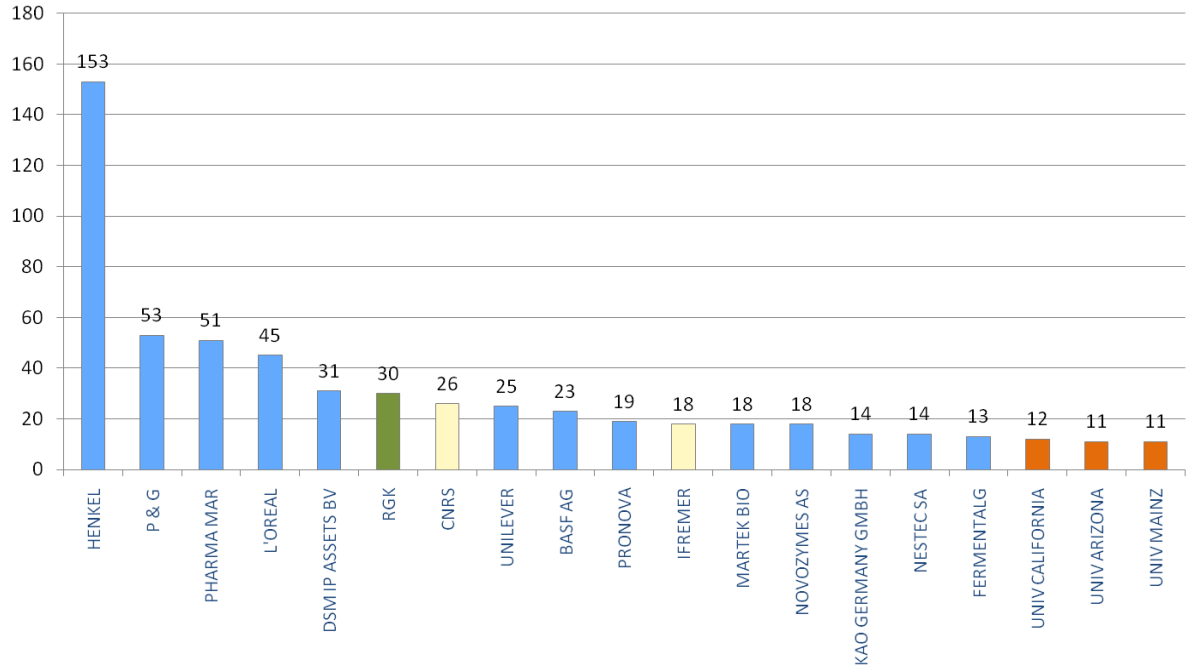
All companies being the main players in the field, i.e L'Oreal, KAO Corp, BASF, Nutrica NV and Procter & Gamble, belong to the previously identified "top 50" worldwide in the Thompson Reuters report[123]. BASF, which was formerly identified as one of the main players, does by now, however, not play a very prominent role anymore.[124]

The energy sector is – as to be expected – different with respect to the main players: Shell is the leading company in patenting. Interestingly, the next important player is a research institution: the University of Arizona with a European co-inventor. American companies are main players in marine biofuels: the field of bioenergy is in non-European hands. There are only some minor inventors from European countries, who patent together with big companies in the US or Asia.

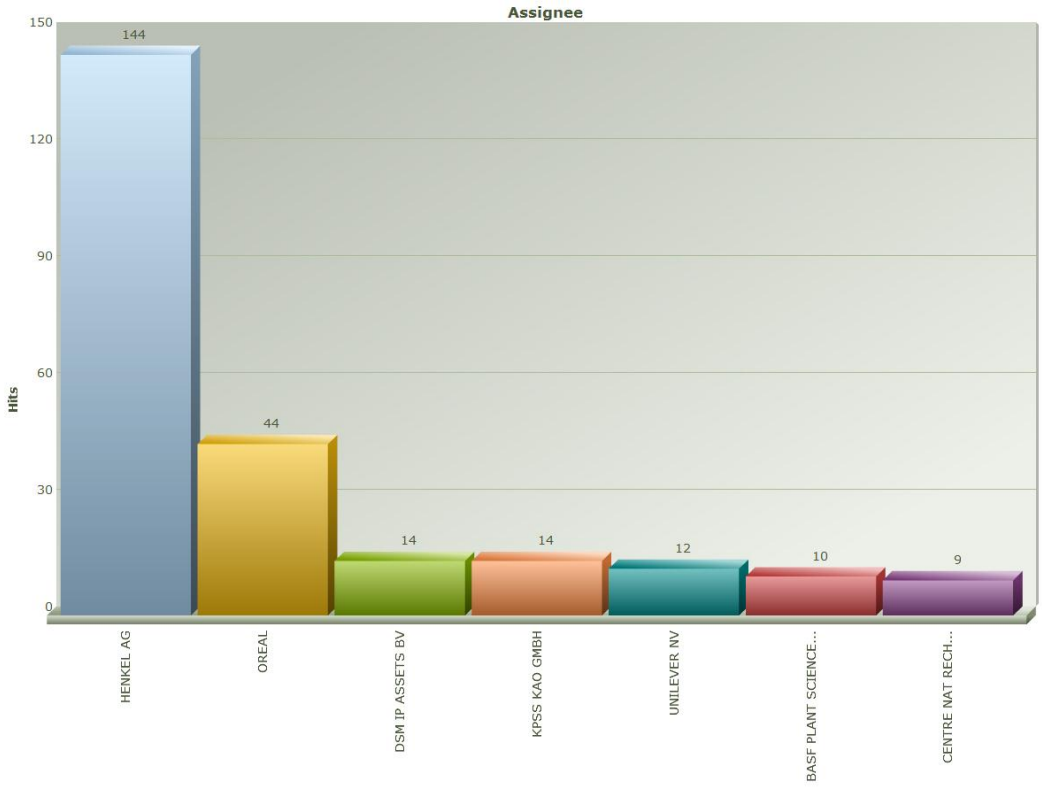
In contrast to the worldwide patenting scene, European universities and other non-industrial institutions have a lot of publications (Reuters report, page 45), but play so far hardly any role in gathering patents in the Blue Biotechnology sector.

Figure 0.14 **Key players in MBT patents (blue: companies, green: private companies, white: research institutions, orange: universities**

Specific results of TOP assignees per sectors: Cosmetics

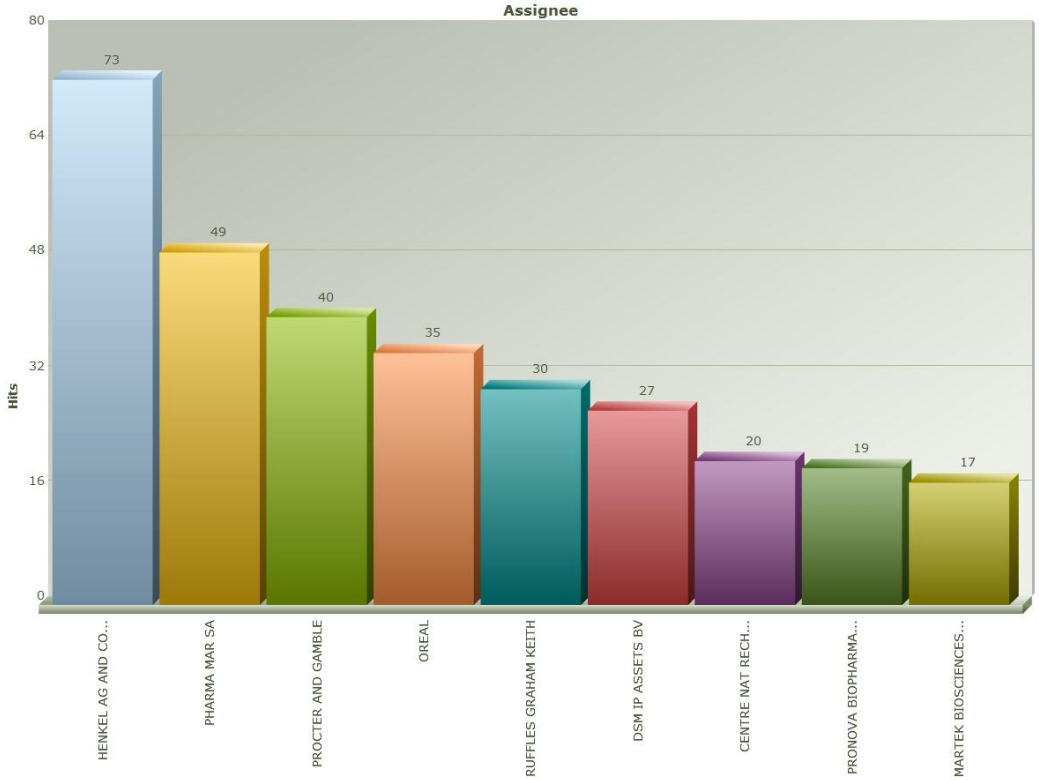


[123] Thompson Reuters Patent Report 2011
[124] See Arnaud-Haond S, Arrieta J (M, Duarte CM (2011) Marine Biodiversity and Gene Patents. Science 331: 1521-1522; see also presentation Concarneau, 20012): 54 out of 149 German patents in the MBT sectors are from BASF.



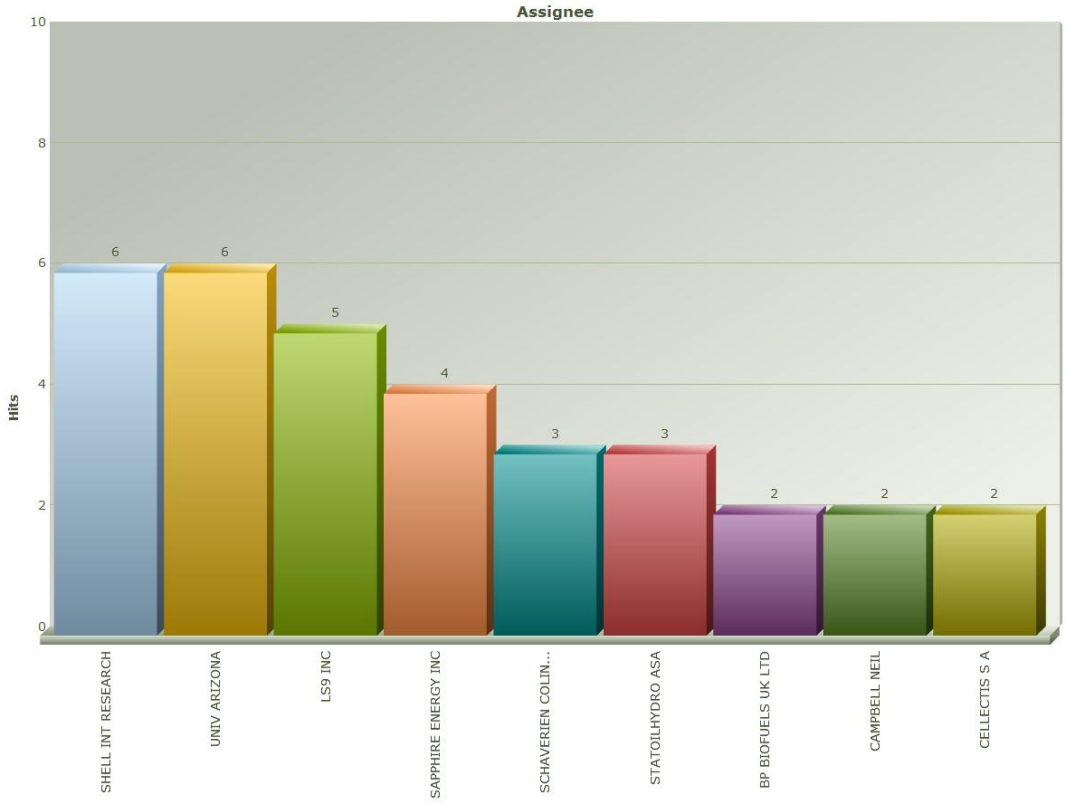
The company Henkel holds the absolute majority in patent applications. Most patents are dealing with fish collagen and marine protein hydrolysates for hair treatment. After Henkel, L'Oreal is the company with the highest amount of patents.

Specific results of TOP assignees per sectors: Health



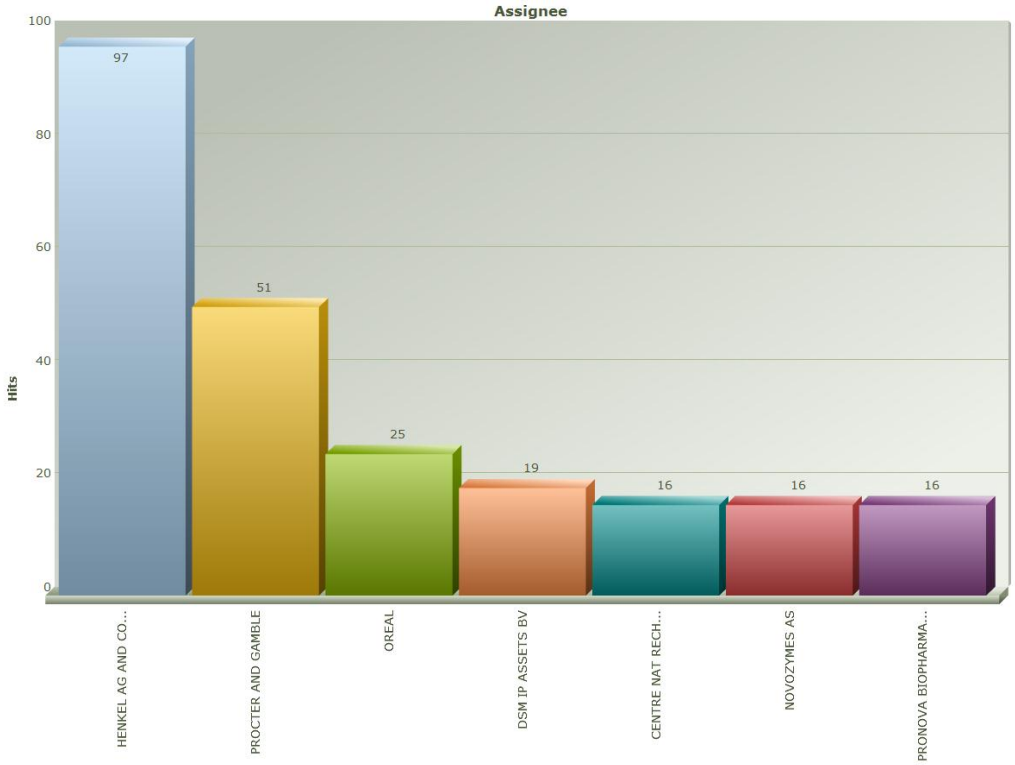
Interestingly, also in this field, Henkel holds most of the patents. The Spanish company Pharmamar, exclusively working with marine organisms, holds the most patents after Henkel.

Specific results of TOP assignees per sectors: Energy



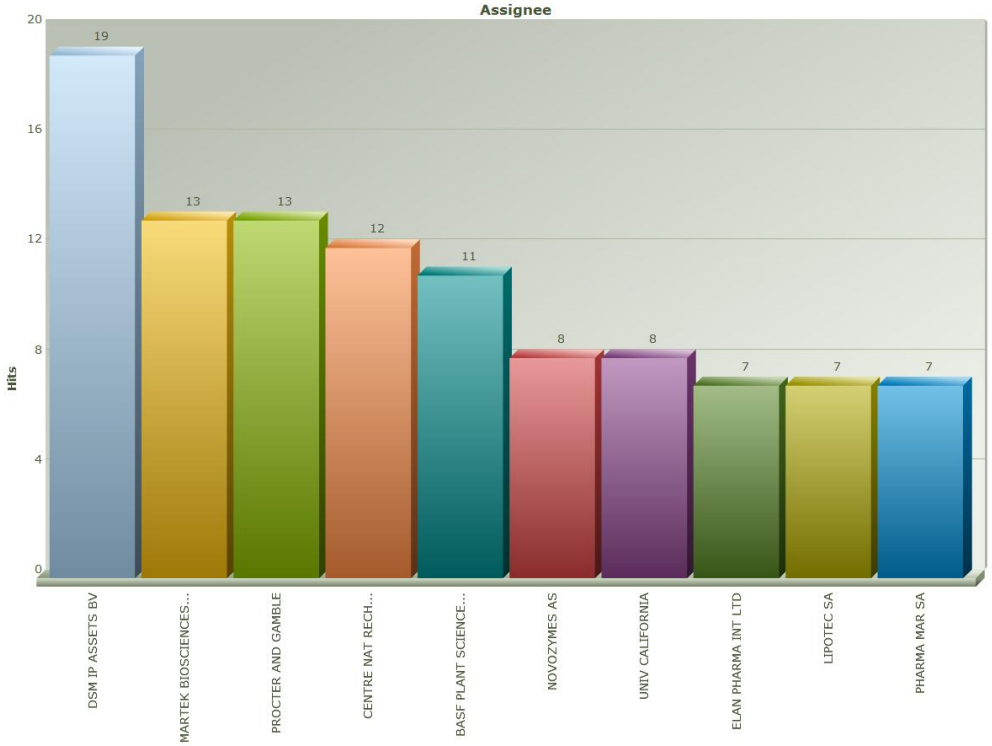
Shell is the leading company in patenting. Interestingly, the next important player is a research institution: the University of Arizona. The US company Sapphire Energy with 4 patent families is specialised in algal biofuels. It has big open ponds located in New Mexico. American companies are main players in marine biofuels: in contrast to most European countries, they have no problems with investments and benefit from widespread acceptance of genetic engineering. Energy from marine micro-organisms (mostly algae and Cyanobacteria) can only be profitable with optimal temperature and light conditions (much better in New Mexico than in the cold and dark European winters). Additionally, genetically modified organisms enhance the yield of oil-production. The only economically viable use of non-genetically modified organisms is to combine their use for different applications. The field of bioenergy is in non-European hands. There are only some minor inventors from European countries, who patent together with big companies in the US or Asia.

Specific results of TOP assignees per sectors: Enzymes



Henkel, Proctor and Gamble and L'Oreal lead the field here with processing enzymes for raw material treatment. DSM and novozymes are companies with a broad enzyme portfolio.

Specific results of TOP assignees per sectors: Genetics

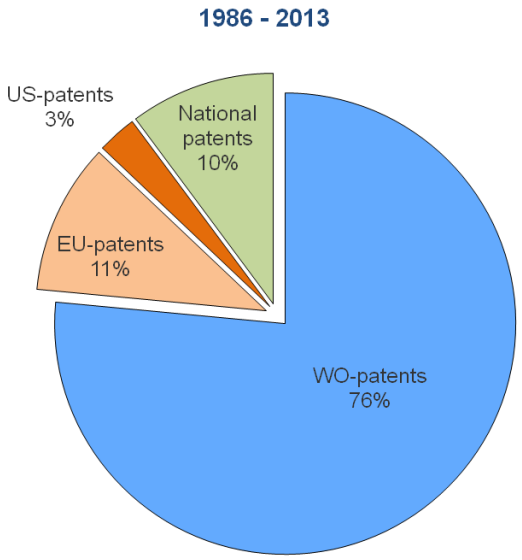


The topic "Genetics" seems to be different compared to the other sectors.

Protection level: WO – EU – National patents

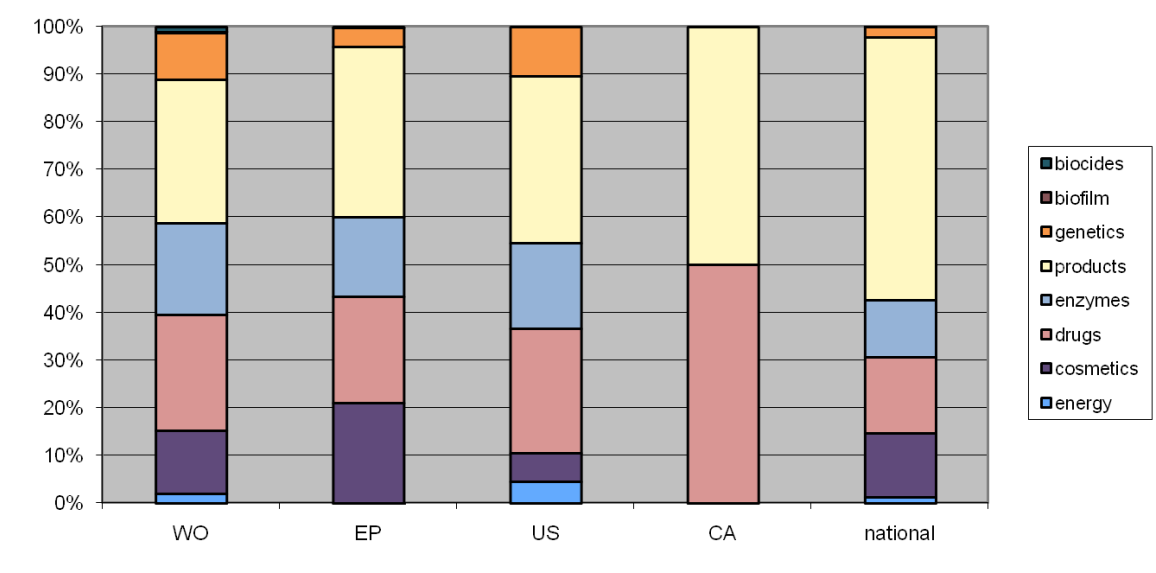
The profiling showed the importance of World patents. European inventors file worldwide rather than using the national level. The importance of worldwide patenting was recognised in the 1980, which is shown in the following comparison: 90% of patents until 1985 were filed as national patents. 135 patents out of these 189 national patents are from France. Most of the French patents were patented until 1950. After 1950, German inventors started patenting with main activities in the 70s and 80s. The total amount of patents in this period is low (212 out of 1774), but nevertheless it has influence on the overall distribution: If considering the patent file between 1986 and 2013, worldwide patents make 76% of all patents (see Figure 0.15).

Figure 0.15 Distribution of patents across protection levels



A few patents are from the US (134) and Canada (2) but were filed by more than one inventor including at least one inventor from a European country. In all cases, the majority of the “drivers” of those patents are from the non-EU-states. The distribution of the various protection areas according to topics is shown in the next figure.

Figure 0.16 Protection level and patent area

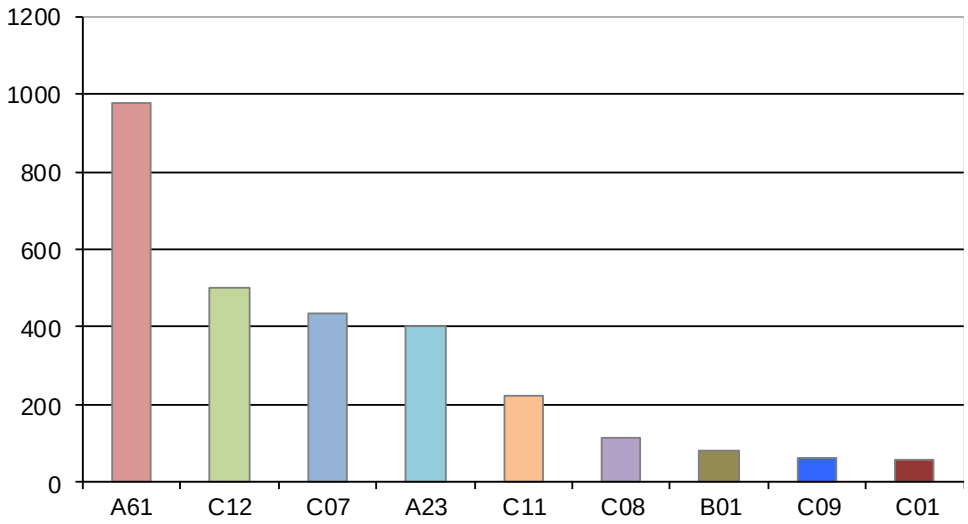


When comparing the number (in total or percentage) of patents in the different topics it is obvious that all patents dealing with genetics and biocides are more internationally patented than the other sub-sectors.

Main international patent classes

All patents were evaluated with respect to the main international patent classes showing the nature of the invention and giving deeper insights in the specific application. Patents belonging to medical or veterinary science and hygiene (IPC A61) were most dominant in marine biotechnology patents. In this class the 7 subgroups A61K31, A61K8, A61Q19, A61Q5, A61K38, A61K35 and A61K9 are under the top 10. Only in the sub-sector “energy” and in the field “genetics”, the application of biochemistry, microbiology and enzymology were the main patented inventions (IPC C12). In total only 10 patent classes could be identified covering mainly chemical methods and products, processing of food and foodstuff as well as physical processes or apparatus in general. For the genetic patents, most patents relate to molecular tools needed to analyse and manipulate genetic material.

Figure 0.17 Patent content: IPC distribution



This general focus on high value products may reflect the relationship between the efforts and cost of patenting and the expected earnings.

Patent situation: Europe vs. World

A recent study[125] compared the European patent situation in the fields of aquatic products (including aquaculture and other industries) and high value products (including health, cosmetic and food) to the world situation. The study indicated a high output of European academia but an overall dominance of Asia in the field of patent filing (main countries: Japan and China), especially in the field of high value products. This is in line with the results of the overall Blue Growth study, which stated that scientific publications on the discovery and the usage of new marine molecules have constantly risen. In a global view, Europe generates almost a third of the scientific publications (in particular the United Kingdom, France and Germany) whereas the USA publish approximately a quarter of the scientific papers related to this field.

When comparing this scientific activity to the trend in patents publications, the difference is striking: Europe only represents 13% of patents filed in relation to new marine molecules, at the same level as the USA. Japan (28%) and China (13%) seem far more active in patent publications than in scientific publications. Top authors in this field are seldom listed as top patent assignees, regardless of whether this relates to institutions or individual researchers[126]. As discussed, European academics still seem to prefer publication rather than patent filing or find others way for valorisation.

[125] Thomson Reuter 2013

[126] Data: Aquatic products top 10 priority countries: Japan, USA, patent cooperation treaty, China, Germany, Korea, European patent office, Canada, UK, Australia, with top 5 inventors: Bayer, Mitsubishi, Chugoku Toryo, Chinese Academy of Science, Nippon; EU research top 5: Fraunhofer, Consejo, CNRS, Univ. Madrid, Univ. Hull; World research top 5: all Chinese; in papers: all European; High value products top 10 priority countries: Japan, patent cooperation treaty, China, USA, Russia, Korea, European patent office, Germany, France, UK, with top 5 inventors: Univ. Kangnung Wonju, L'Oreal, Noevir KK, Nestle SA, Dokurit; EU research top 5: CNRS, Univ. Bashkir med, Consejo, Imperial College, Royal Holloway; World research top 5: all Chinese; in papers: USA, France, UK, Germany, Canada.

Annex 6: Sub-sector reviews

Health

The health sector in marine biotechnology is mainly dominated by the *search for new pharmaceuticals including biopharmaceuticals (i.e. medicinal products)*, however the *development of medical devices*[127] gained more importance over the last years. In terms of value, the market for pharmaceutical drugs is still one of the sectors generating highest revenues. However, risk of failure during development is high and increasing due to very strong regulatory demands. In the case of medical devices, the total value per product is lower but products are much faster developed and less risky in terms of legal and regulatory aspects. In 2006, the global medical device market reached approximately USD 209 billion. The differentiation between health and personal care products is not sharp; hence an overlap between both stakeholders and product lines with the sub sector cosmetics is given.

Value chains specific to the health sector

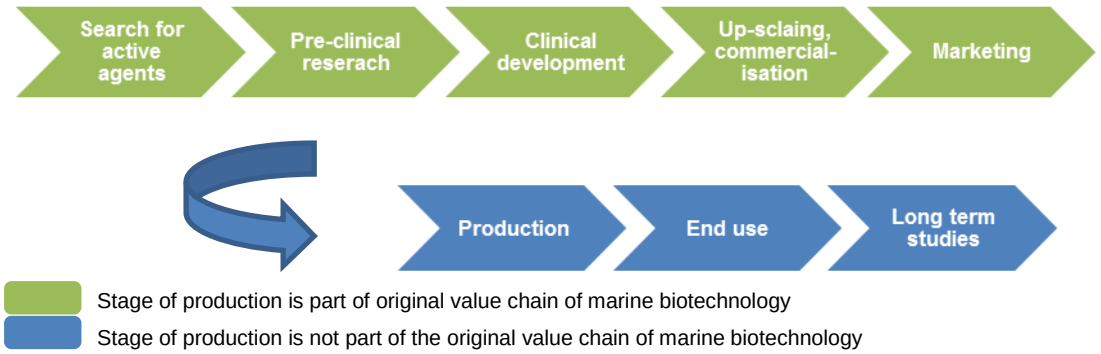
The pharmaceutical sector is looking for new drug developments based on active molecules derived from marine organisms, and is already using marine compounds in its production processes. There is an increasing demand for bioactive compounds by the pharmaceutical industry. However finding a bioactive molecule is just the beginning from a pharmaceutical perspective, as there are several important steps to validate before being able to register a new drug, i.e. proof of the stability, the safety and the quality of the molecule and testing it through various clinical trials. This process is long (between 15 and 20 years) and expensive (various estimates place the cost between USD 500 million and USD 1 billion)[128].

The value chain in the area of pharmaceuticals (Figure 0.18) begins with the search for new active agents. This includes, among other things, the collection of samples from the sea, the cultivation of microorganisms, the genetic identification of the organisms, analysis of the chemical profile, as well as the use of marine extracts or pure substances in initial assays to prove biological activities. Manufacturing procedures are also developed at the same time. Biodiscovery is here understood as the systematic search in the marine environment, for new biological activities and biochemical pathways that can be used for the production of goods, knowledge and services. It is to be understood that when we use this term we do not mean the systematic and continuing harvesting of natural living bioresources from the sea, following the discovery of some new use for marine molecules or biomaterials, but rather the use of new knowledge in controlled and sustainable systems. Themes of active interest differ somewhat among countries, but this theme stands out as the one where all countries have one or more on-going activities and follow up strategies. Both research institutes and pharmaceutical companies themselves can be active in this first stage of the value chain.

[127] A **medicinal product** is defined in the European Union (Dir 2001/83/EC) as (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.' A medicinal product has to be distinguished from medical devices, cosmetics and food products. In contrast, **medical devices** comprise many diverse products: Directive 2007/47/EC defines a medical device as „Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: Diagnosis, prevention, monitoring, treatment, or alleviation of disease; Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap, Investigation, replacement, or modification of the anatomy or of a physiological process; Control of conception. This includes devices that do not achieve their principal intended action in or on the human body by pharmacological, immunological, or metabolic means—but may be assisted in their function by such means.

[128] de la Calle F., 2007, "Marine Genetic Resources: A Source of New Drugs - The Experience of the Biotechnology Sector" Presentation at the conference "Biodiversity and Genetic Resources of the Deep Sea" - ITLOS, Hamburg. Sep, 29th 2007.

Figure 0.18 Value chain of marine biotechnology in the area of pharmaceuticals



Depending on the source and the novelty of the gained product, these first steps ("early drug discovery") can be very complex. Value may be obtained by additional uses of the outcome of these steps, e.g. use of the products in other sectors, energetic use of the wastes and application of the process details to other biotechnological challenges.

The second stage of the value creation process is that of preclinical research. This stage is followed by the clinical development of the active agent, which covers several phases in which people take part in tests to prove the effectiveness as well as the harmlessness of the active agent. Following on from the clinical development, testing and approval, is the commercialisation of the new active agent. For this to be successful, up scaling is required first to ensure that adequate volumes of the new active agent can be produced. Then the active agent can be marketed and sold as an intermediate product to the pharmaceuticals industry, which can use the active agent to launch new drugs onto the market and carry out long-term studies on possible side effects. The stages of value creation after the production and marketing of the active agent derived on the basis of marine biotechnology no longer form part of the original value chain of marine biotechnology as the marine resource is then no longer the focus of the value creation process. Individual pharmaceuticals companies can also be directly involved in the value creation process of marine biotechnology if, for example, they carry out independent research and development activities on marine organisms. All the major pharmaceutical firms (including Merck, Lilly, Pfizer, Hoffman-Laroche and Bristol-Myers Squibb) have marine biology departments[129]. However, only their marine activities (the size of which is seldom identifiable) should be accounted in the blue biotech sector.

Potential products areas currently in research and development stage

Because of the physical and chemical conditions in the marine environment, almost every class of marine organism possesses the capacity to produce a variety of molecules with unique structural features. These molecules offer an unmatched chemical diversity and structural complexity, together with a biological potency and selectivity. In recent years, the chemistry of natural products derived from marine organisms has become the focus of a much greater research effort. This is due, in a large part, to the increased recognition of marine organisms as a source for bioactive compounds with pharmaceutical applications or other economically useful properties. Additionally, nature is still the main source for new pharmaceuticals: 90 % of all drug have their origin in nature. The fact that marine resources are still largely unexplored has inspired many scientists to intensify their efforts by using novel technologies to overcome the inherent problems in discovering compounds which may have potential for further development as pharmaceuticals or as functional products.

[129] European Commission, 2006, "Background paper No. 10 on marine biotechnology". Annex to the Green Paper on Maritime Policy. 13p.

Pharmaceutical clinical pipeline

The current clinical pipeline includes more than 10 marine natural products (or derivatives thereof) in different phases of the clinical pipeline mostly for targeting cancer. However, only one European company (PharmaMar) is active in the clinical development. The clinical pipeline is a very late stage in the development of drugs requesting significant amounts of money and effort. This stage is characterised by medical chemistry researching "druggability", development of processes for supply of the compounds and clinical trials. For Blue Biotechnology, the sustainable supply of the compounds by biotechnological means is a major research and development area.

Pharmaceutical preclinical pipeline

The preclinical pipeline continues to supply several hundred novel marine compounds every year and those continue to feed the clinical pipeline with potentially valuable compounds. From a global perspective, the European marine pharmaceutical pipeline remains very active, and has sufficient momentum to deliver several additional compounds to the market in the coming years. In the last 20 years, the marine pharmaceutical preclinical pipeline involved research with more than 1,000 marine chemicals which demonstrated antibacterial, anticoagulant, anti-inflammatory, antifungal, anthelmintic, antiplatelet, antiprotozoal, and antiviral activities; actions on the cardiovascular, endocrine, immune, and nervous systems; and other miscellaneous mechanisms of action.[130]

MedTech R&D pipeline

The situation is even more complex, when evaluating the medical devices pipeline. Some recent examples of demonstrators gained high interest and public awareness, e.g. sinusitis destabilising agents containing the enzyme nuclease NucB from marine resources or chitosan containing wound healings. Chitosan marine biopolymers are used as pharmaceutical ingredients and as supplements for medical devices. For the latter, BASF and the Norwegian company Seagarden signed a contract to transfer the Chitosan marine biopolymers business in 2012 from BASF's Cognis to the biotechnology specialist.

However, these examples do not describe the full pipeline and the expected potential for products in this area, as the possible products are very divers. In research stage, many activities deal with wound healing (e.g. wound covers), alternative disinfectants (being more environmentally friendly and avoiding resistance development) and with coatings for artificial bones that enhance biocompability.

A better understanding of additional areas being in R&D stage may be gained after specific evaluation of the questionnaire and targeted interviews with stakeholders being active in the medical device area.

Landscape of Marine Biotechnology infrastructures and technologies in the health sector

Marine biotechnology in the health sector takes place in four types of environments:

- especially in the field of health (which has extended funding pathways), an active group of *universities and public research institutes* is spread all over Europe covering mainly the first steps of the value chain of the health sector, which are fundamental research (biodiscovery, biology of marine organisms for targeted isolation) and applied research (lead structure development, process design, semi-synthesis, preclinical development);
- Numerous *start-up and small companies* are concentrating on medical device product development and take part in academia-SME cooperation products for early drug discovery;
- Very few *medium-size companies* (more than 50 employees) dedicated to marine biotechnology development have been identified at the European level.

[130] Mayer, A.M.S., A.D. Rodriguez, Orazio Taglialatela-Scafati and N. Fusetani.. MARINE DRUGS 11:2510-2573, 2013. Published July 16, 2013 and available at http://www.mdpi.com/1660-3397/11/7/2510

Table 0.8 Pharmaceutical preclinical pipeline.

Clinical Status	Compound Name	Trademark	Marine Organism[a]	Chemical Class	Molecular Target	Clinical Trials[b]	Disease Area	Company/ Institution
Phase III	Plitidepsin	Aplidin®	Tunicate	Depsipeptide	Rac1 & JNK activation	7	Cancer	Pharmamar
Phase II	DMXBA (GTS-21)	NA	Worm	Alkaloid	α7 nicotinic acetylcholine receptor	4	Schizophrenia	UCHSC
	PM00104	Zalypsis®	Mollusk	Alkaloid	DNA-binding	3	Cancer	Pharmamar
	PM01183	NA	Tunicate	Alkaloid	Minor groove of DNA	4	Cancer	Pharmamar
	CDX-011	NA	Mollusk/ cyanobacterium	Antibody drug conjugate (MM auristatin E)	Glycoprotein NMB & microtubules	3	Cancer	Celldex Therapeutics
Phase I	Marizomib (Salinosporamide A; NPI-0052)	NA	Bacterium	Beta-lactone-gamma lactam	20S proteasome	4	Cancer	Sponsored by Triphase Research and Development I Corporation (India)
	PM060184	NA	Sponge	Polyketide	Minor groove of DNA	1	Cancer	Pharmamar
	Bryostatin	NA	Bryozoan	Macrolide lactone	Protein kinase C	38	Cancer	National Cancer Institute
	SGN-75	NA	Mollusk/ cyanobacterium	Antibody drug conjugate (MM auristatin F)	CD70 & microtubules	2	Cancer	Seattle Genetics
	ASG-5ME	NA	Mollusk/ cyanobacterium	Antibody drug conjugate (MM auristatin E)	ASG-5 & microtubules	2	Cancer	Seattle Genetics

a) The marine pharmaceutical pipeline consists of natural products, analogs or derivatives of compounds produced by this marine organism or a symbiont (e.g. cyanobacterium).

b) Ongoing clinical/total trials as reported at http://www.clinicaltrials.gov/ in February 2013.[131]

[131] http://marinepharmacology.midwestern.edu/clinPipeline.htm

- Some *large pharmaceutical companies* are active in the field, which have internally developed competencies in marine biotechnology or have acquired promising small blue biotechnological companies to reinforce their activities.

Research priorities and objectives are mainly driven by the aim of developing novel drugs, treatments and health care products. For the R&D activities in the sector, the key research priorities were identified already in the ESF document:

- Increase the focus on the basic research (taxonomy, systematics, physiology, molecular genetics and (chemical) ecology of marine species and organisms from unusual and extreme environments to increase chances of success in finding novel bioactives;
- Improve the technical aspects of the biodiscovery pipeline, including the separation of bioactives, bio-assays that can accommodate diverse material from marine sources, dereplication strategies and structure determination methods and software;
- Overcome the supply problem to provide a sustainable source of novel pharmaceutical and healthcare products through scientific advances in the fields of aquaculture, microbial and tissue culture, chemical synthesis and biosynthetic engineering.

Infrastructures

The long standing tradition in marine and biotech research in many European coastal countries is associated with world class infrastructures, including research vessels, offshore equipment, coastal and offshore stations as well as cutting edge biotechnology facilities. However, a platform oriented connection of these infrastructures is still lacking and only few centres of excellence have been initiated, mainly due to the strong activity of clusters in France and Norway. The initiation of the European Marine Biological Resource Centre (EMBRC)[132] could provide access to marine organisms (microbes, plants, animals) and newest techniques to the scientific community at large, including universities and industry.

Socio-economic performance of the health sector

Undiscovered cancer treatments from marine organisms could be worth between USD 563 billion (EUR 428.5 billion) and USD 5.69 trillion (EUR 4.33 trillion), according to a recent study[133]. Researchers estimate that there may be as many as 594,232 novel compounds waiting to be discovered in unstudied marine species, and that these could lead to between 55 and 214 new anti-cancer drugs.

The study only accounted for anti-cancer drug revenues. In reality, these chemicals from the sea can have numerous other biomedical applications including antibacterial, antifungal, antiviral and anti-inflammatory uses. The researchers used a mathematical model to predict the value of undiscovered anti-cancer drugs from marine sources. Estimates based on economic data for existing anti-cancer drugs suggested that these novel compounds could be worth between US$563 billion and US $5.69 trillion, depending on estimates of total biodiversity and on the discount rates applied to calculate net present values. This economic assessment only included direct market values - in reality, improved cancer treatment is likely to lead to numerous indirect economic and social benefits that are only partially reflected in their market value.

Access to finance is a key issue for this sector: It has been commented that few investors are keen to take risks in these new technological developments. Businesses may access financial through various national funds in Europe at the initial stage. However, according to interviewees, businesses seem to struggle during the second and third rounds of funding, lowering their growth potential.

[132] http://www.embrc.eu/

[133] Erwin, P. M., Lopez-Legentil, S., & Schuhmann, P. W. (2010). The pharmaceutical value of marine biodiversity for anti-cancer drug discovery. Ecological Economics. 70: 445-451

Role of SMEs in the health sector

Numerous start-up and small companies are concentrating their development on niche markets, in the health sector; with many of them being involved in early drug discovery (often funded by public third party money) or aiming for medical device products. A large proportion of these companies seem to be predominantly research laboratories spin-offs. Some data indicate that SMEs struggle to reach a certain critical mass for e.g. pre-clinical proof of concept and first clinical studies, making them less attractive for investment by large established companies of their sector.

However, many SMEs are active in other sectors but feed an internal preclinical pipeline by the income from the other sectors. This income may be described in terms of money, but includes technical development as well. These parallel pipelines will be described in more detail in the final report.

Businesses may access financial sources through various national funds in Europe at the initial stage. Especially SMEs benefit from such funding.

Products and services offered currently and their future prospects

The global marine pharmaceutical pipeline consisted of a limited number of substances. Seven marine drugs (Table 0.9) are on the market, however, only two of them are marketed by European companies: PharmaMar, Spain and Jazz Pharmaceuticals, Ireland. Prialt was the first European marine drug, approved in 2004.

Pharmaceutical demand will be driven by an increasing ageing population, with age-related conditions to be treated: cancer, neurodegenerative disorders, and osteoporosis. Pain relief and antibiotic resistance are also two areas where marine molecules may be relevant[134]. Marine active molecules have already been identified for major conditions but they have to be adapted before entering the validation process to reach the pharmaceutical market.

Medical applications can also been derived from marine polymers: they can be exploited as a new generation of degradable prosthesis allowing bones reconstruction but also as a new type of drug encapsulation.

Driver and Barriers in the health sector

The lack of interest by industry in natural products from all sources can be attributed to a number of common problems, some of which are perceived to present insurmountable obstacles. Some of these problems (taxonomy, variability, supply) are particularly acute for marine-derived compounds. Taking into account that marine biodiversity is still nearly unknown, the “pure” discovery part of the value chains remains large and depends on access to all kinds of marine resources including deep sea. In the same momentum, the sustainable supply of the raw material for further development after the initial discovery arises as an issue. Harvest of large amounts of marine organisms very often results in harm to the marine environment. Avoiding these impacts will be one of the premises for further development.

[134] Schröder, T., 2010, World ocean review: Living with the oceans. Maribus: Hamburg, 232p

Table 0.9 Marine derived drugs on the market

Clinical Status	Compound Name	Trademark	Marine Organism[a]	Chemical Class	Molecular Target	Clinical Trials[b]	Disease Area	Company/ Institution
FDA-Approved	Cytarabine (Ara-C)	Cytosar-U®	Sponge	Nucleoside	DNA polmerase	814	Cancer	Bedford Laboratories
	Vidarabine (Ara-A)	Vira-A®	Sponge	Nucleoside	Viral DNA polymerase	0	Antiviral	NA
	Ziconotide	Prialt®	Cone snail	Peptide	N-Type Ca chanel	5	Pain	Jazz Pharmaceuticals plc
	Eribulin Mesylate (E7389)	Halaven®	Sponge	Macrolide	Microtubules	62	Cancer	Eisai
	Omega-3-acid ethyl esters	Lovaza®	Fish	Omega-3 fatty acids	Trygliceride-synthesizing enzymes	124	Hypertriglyceridemia	GlaxoSmithKline
	Trabectedin (ET-743) (EU Registered only)	Yondelis®	Tunicate	Alkaloid	Minor groove of DNA	42	Cancer	Pharmamar
	Brentuximab vedotin (SGN-35)	Adcetris®	Mollusk/ cyanobacterium	Antibody drug conjugate (MM auristatin E)	CD30 & microtubules	35	Cancer	Seattle Genetics

a) The marine pharmaceutical pipeline consists of natural products, analogs or derivatives of compounds produced by this marine organism or a symbiont (e.g. cyanobacterium).

b) Ongoing clinical/total trials as reported at http://www.clinicaltrials.gov/ in February 2013.

Where to place the screening power in the chain from biodiversity explorer to end-user is also challenging: On one hand industry is often reluctant to take on novel molecules without adequate evidence of likely efficacy and safety, on the other hand it is unlikely that researchers discovering novel molecules have the capacity or resources to carry out such high-content broad-target screening. The main challenges related to pharmaceutical discovery from marine bioresources are linked to: legal aspects (secure access to marine resources and intellectual property rights); quality of marine resources (identification and variability); technology (screening of active compounds and replication, preventing repeated rediscovery and increasing the amount of novel structures); and structural costs of drug discovery from natural products. The access to capital is an important issue as well, as the development of new drugs is an 8-12 year process demanding some billion USD with the very high risk of failure even in late stages of the development.

Drivers of MB in the health sector

Existing Drivers	Current extent	Drivers evolving in absence of measures	Drivers evolving with successful measures
Established value chain with strong End User group	++	++	+++ ↑
Strong demand of innovations, i.e. new active and functional ingredients	+++	+++	+++
Financial incentives: Expanding population and lucrative health business	++	++	++
Market opportunities: Multiresistant bacterial threats incl. reemerging pandemies, growth in resistant strains of bacteria to existing antibiotics.	++	++	++
Knowledge about marine living resources	+	+	**+++** ↑
Research facilities	+	+	++ ↑
Strong academia and SME interconnection	++	++	+++ ↑
Knowledge and technology base	++	++	+++ ↑
Success stories	++	+	**+++** ↑

+++ strong, ++ medium, + small, ↑ supporting drivers

Barriers of MB in the health sector

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Supply issue: Limitation of **sustainable sources** of natural products	+	+++	**+** ↓
Regulations knowledge and effort needed for follow all regulation, lack of harmonisation	++	+++	**++** ↓
Financing, access to venture capital, high costs of innovative techniques and products	+++	+++	**++** ↓
Non-existent synergistic concept of **sustainability and MB** and its clear communication	++	++	+ ↓
Non-existent embedding of MB into technology transfer **policy** and other administrative concepts (e.g. Integrated Coastal Zone Management, fishery policy)	+++	++	+ ↓

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Industry connectivity: A platform oriented connection of these infrastructures is still lacking and only few centres of excellence have been initiated, mainly due to the strong activity of clusters in France and Norway	++	++	+ ↓

+++ strong, ++ medium, + small, ↓suppressing barriers

Cosmetics

Value chains specific to the cosmetic sector

The value chain concerning marine biotechnology in the cosmetics sector is presented in Figure 0.19; it is mainly about extracts. Extracts mean liquid or dry substances made by extracting (part of) a marine raw material by using a solvent such as ethanol or water. Mostly, marine living resources are used, in some cases also sediment (mud) or other non-living resources (amber, chalkstone, pearls etc.). Their target application is as active or functional ingredients in cosmetic formulations used for skin or hair care.

Figure 0.19 The marine biotechnology value chain for the cosmetics industry sector

The value chain begins with R&D activities on marine organisms (physiology, ecology, cultivation etc.), specific compounds therein and their effects on the skin or hair. First instance R&D activities are not necessarily starting “from scratch”, but can build on literature research and networking. It is widely acknowledged that there are undiscovered “biological nuggets” in the ocean, however, exploring the “marine biotechnology treasure” already available, e.g. in European universities, is easier and much more cost-effective than by bioprospecting in the deep sea.

The next step in the value chain is the preparation (cleaning, freezing, drying, grinding etc.), resulting in certain cases in first marketable raw material, e.g. dried seaweed.

Production of marine extracts is often linked with a special (combination of) techniques or machines which are unique for seaweed or other marine organisms and which themselves are marketable, e.g. as seaweed extraction facilities. This is particularly interesting for countries which hold abundant marine living resources (Indonesia, Philippines, Namibia, etc.) and plan to invest in value adding technologies.

Prerequisites of following regulations have to be fulfilled and services for this supplied to evaluate product safety:

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. It entered into force on 11 July 2013;
- REACH is a regulation of the European Union Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). It entered into force on 1 June 2007.

Marketing plays a major role in the cosmetic sector, also for the intermediate good, the marine biotechnology derived extract. The target group are people in the R&D, marketing and/or purchase departments of bigger ingredient suppliers and bigger cosmetic companies. The demands of these special marketing efforts encompass the compilation of reasons for efficacy, sustainability and quality. Each of these features need specialised proof, tests and certifications.

Potential products areas currently in research and development stage

The main potential for marine biotechnology can be found in the following raw material segments, which are already covered by over 2000 SMEs in Europe:

- active ingredients;
- UV-filter, after sun;
- colourants, pigments ;
- fragrances;
- viscosity control agents;
- Liposomes, carrier systems for active ingredients;
- Surfactants;
- Preservatives;
- hair-styling raw materials.

In almost all of these segments, one or more raw materials is already coming from the sea, however, the potential has by far not yet begun to be exploited systematically and sustainably.
In principle, all living marine resources are suitable for cosmetic raw material, if they fulfil the regulatory hurdles, of special interest are:

- bacteria;
- fungi;
- (micro- and macro-) algae;
- Nematodes;
- Annelids;
- Molluscs;
- cnidaria and ctenophora (jellyfish and comb jellies);
- vertebrates.

Compounds of special interest in the cosmetic industry coming belong to the following groups:

- proteins/enzymes and amino acids;
- (poly-) saccharides (mannose, galactose, alginate, fucoidan, laminaran etc.);
- Glycosaminoglycanes;
- minerals and dissolved salts; trace elements: zinc, iodine, selenium, strontium etc.;
- polyphenols;
- terpenes;
- glycosides;
- steroids;
- carotinoids, flavonoids, anthocyanes;
- vitamins;
- other secondary metabolic compounds.

Landscape of Marine Biotechnology infrastructures and technologies in the cosmetics sector

A marine biotechnology ‘infrastructure’ is hardly existent or, at least, cannot be located as a set of interconnected structural elements along the value chain in the cosmetic sector which provides a framework facilitating the production of goods and services. Also the distribution of finished products to markets is lacking in a structured way. Instead, it is a provisional arrangement that

knowledge and technologies flow “randomly” or by sporadic individual actions from other fields, e.g. marine and life sciences, fishery/agriculture or from food into the cosmetic sector.

Infrastructure and technologies of marine biotechnology in the cosmetic sector are very specialised at the beginning and the middle of the value chain - at raw material sourcing, R&D, and up scaling/production.

Most of this rare infrastructure can be found at the coasts, where distances are short between source and first processing of raw material. Just recently, infrastructure for harvesting, cultivating and raw material processing has been established or is actually developing in some European coastal regions, e.g. the Departement Finistere in Britanny, France, the County Galway in Ireland, and the Bundesland Schleswig-Holstein in Germany.

The specialty of these technologies often results from very basic and essential demands: for example, seaweeds have a special texture - a combination of rigidity and flexibility - which is not comparable with “usual” land-born biomass. Harvesting, washing, grinding and other processing steps have to be adapted to this relatively new material for cosmetic use. Another example of special requirements in handling and processing of sea-born organisms and material is the high content of electrolytes resulting in destructive effects on processing machines, but also on end product compositions.

Only very few cosmetic companies in Europe are capable of establishing and operating aquaculture or harvesting equipment; the same with laboratory facilities for analyses and screening. These companies (mostly small companies) are pioneers in establishing infrastructure or in using existing marine biotechnology sourcing, development, production and marketing in the cosmetic sector. At the beginning of their enterprise, they are often operating beneath cost effectiveness, because of the risky and “first mover” nature of their undertaking.

Global players profit from “first mover” developments rather than actively building up marine biotechnology infrastructure. However, the market potential of marine derived substances is well recognised and constantly screened by the large companies of the field, such as P&G, L'Oréal, Unilever & Co. Increasing numbers of products containing active and functional compounds coming from the sea are a good indicator therefor. Only very few global players in the cosmetics sector have been associated with marine biotechnology activities such as networks or events. The bigger cosmetic companies are strong recipients of marine biotechnology products, distributing end-products to the consumers effectively. Therefore, the role of large cosmetic companies can be conceived as the main target group for marine biotechnology derived developments and products.

The role of Universities or other academic institutions is mainly in the question of access and description of new taxa and bioactivities. A fruitful collaboration between the players can be observed in some clusters however, the potential is still not exploited systematically.

Socio-economic performance of the cosmetics sector: the cosmetics market – a growing sector demanding marine innovations

Personal care products industry overall is reaching EUR 487 billion by 2017[135]. Here we will focus mainly on the likes of cosmetics.

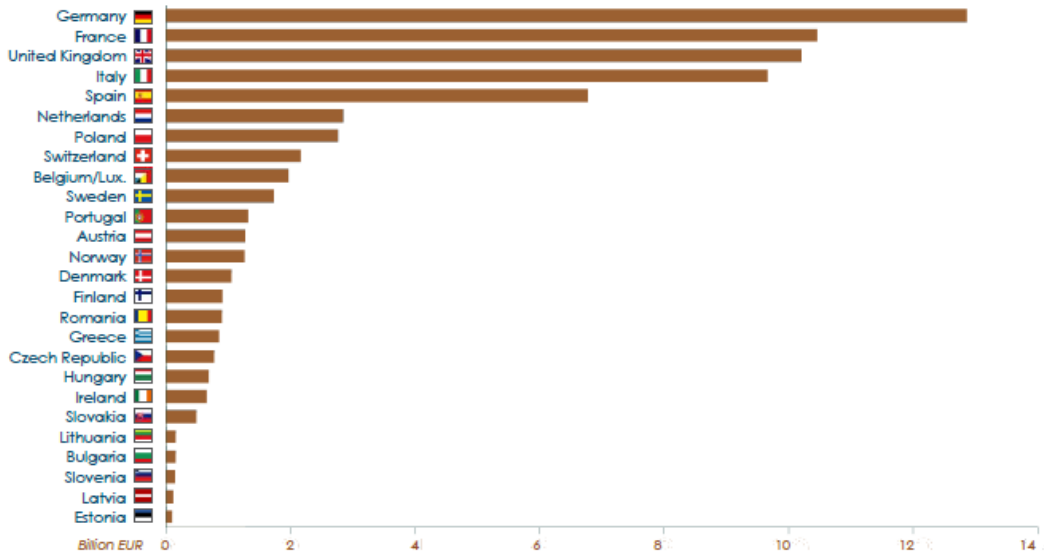
The cosmetics industry is expected to grow at a compounded annual growth rate (CAGR) of 3.4 % over five years, reaching EUR 204 billion in 2017. There is an increasing demand coming from

[135] http://www.lucintel.com/reports/personal_care/global_beauty_care_products_industry_2012-2017_trend_profit_and_forecast_analysis_september_2012.aspx

Europe and the Asia Pacific region[136]. Skincare is the largest segment with huge growth potential by 2017, while the second segment, hair care is reported as following closely behind.

The European (EU27+N+CH) cosmetics industry is a flagship industry, with a value of more than EUR 72 billion[137]. This makes it the world leader by a considerable margin, almost as large as the US and Japanese markets together.

Figure 0.20 European Cosmetic Market Volume by country (in EUR billion retail sales price)[138].



The market for organic skin care grows most rapidly. Worldwide it was estimated at EUR 5.9 billion in 2012, and is expected to rise to EUR 10.2 billion by 2018, giving a CAGR of 9.6 % over the six year period[139]. One of the biggest drivers of this growth across all consumers groups is the fact that they are reaching out for products that are deemed to be more natural, reflecting aspirations for better personal health and hygiene.

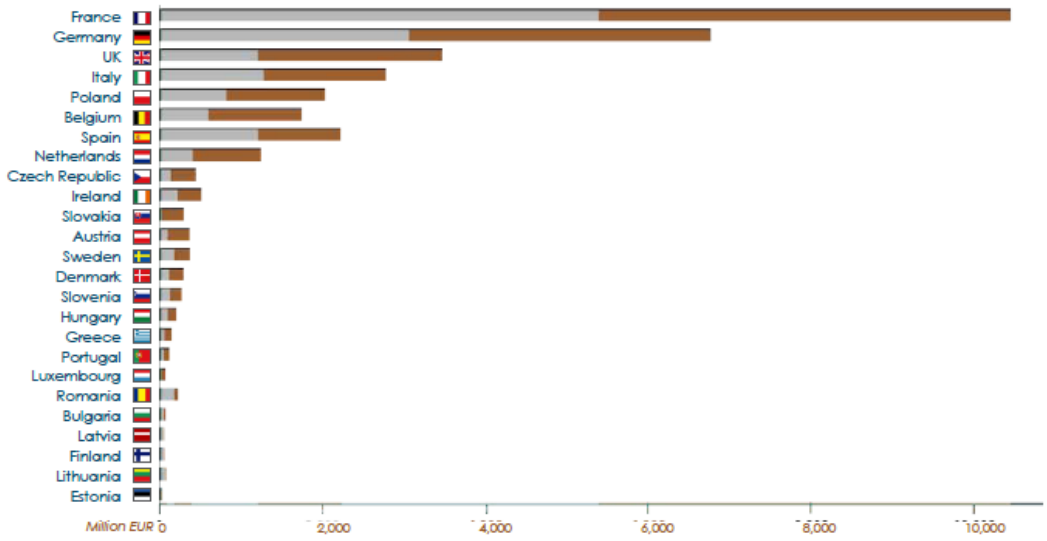
Within the European cosmetic market over 1.5 million people are employed in all areas of the industry from manufacturing to marketing, sales and retail environments.[140] Research & development is particularly important in this fast-moving consumer goods market and the industry employs over 25,000 scientists researching new areas of science, working with new ingredients, developing formulations and carrying out safety assessment; 10% of all patents granted in the EU during 2009 were for cosmetic products. [141]

European cosmetic products are sought after all over the world and export represents a key activity for all sizes of companies, especially SMEs of which there were over 4,000 in 2011. Trade with countries outside of Europe amounted to EUR 18.6 billion at trade prices showing nearly 50% increase over 2010 (EUR 12.5 billion in 2010)[142].

[136] http://www.lucintel.com/reports/personal_care/global_beauty_care_products_industry_2012-2017_trend_profit_and_forecast_analysis_september_2012.aspx
[137] Eurostat
[138] Eurostat/Cosmetics Europe Statistics Working Group
[139] Transparency Market Research
[140] Fabio Fanchina 2012: "Personal Care - an essential component of living", Activity Report 2012 of Cosmetics Europe
[141] Wynberg, R. & Laird, S., 2013, "Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Cosmetics Sector", Published by the Secretariat of the Convention on Biological Diversity 2013, ISBN: 92-9225-491-X
[142] The Cosmetic Toiletry & Perfumery Association - CTPA

The cosmetics industry in Europe is a perfect playing ground for marine biotechnology because there is a demand of innovative compounds while comprising low to medium developmental and regulatory efforts, the latter resulting in a relatively fast development-to-marketing-track.

Figure 0.21 **EU beauty and personal care industry exports within the EU (grey bar) and outside (brown bar) by country (in EUR million)[143].**



Role of SMEs in the cosmetics sector

The cosmetic sector in particular is dependent from innovations. While global players emphasise their innovation-led philosophy of business, their contribution to R&D in relation to sales is relatively low. Beiersdorf AG e.g. has a high reputation as an innovator, but has spent only 2.6% of its sales for R&D investment in 2012 (EUR 159 million). It is an open secret that most of the innovations in the cosmetic sector have its seeds in the SMEs, which often are highly active in R&D. SMEs mostly invest two-digit percentages of their sales into R&D, sometimes even more than 50%. There are over 1,000 SME in Italy, over 500 in France, more than 300 in Germany and 200 in Spain supplying raw materials for the cosmetics industry.

All in all this is a win-win situation, because the global cosmetic players buy intermediate products or in-license know-how and technologies from the SMEs, and put their sales power on the scales.
Lines of specialisation continue along the value chain (see chapter “Value chains...”) and follow characteristic rules of the cosmetic sector. Lines of specialisation can be found in research, especially within the categories “marine science“, “life science“ and “dermatology“, whereas development often is a mixture of the mentioned science fields plus (bio-)technological and regulatory knowledge.

Products and services offered currently and their future prospects[144]

In the “actives” market algae extracts play the most important role. There are only a few companies in Europe (mainly France, UK, Ireland, Spain, Norway, and Germany) developing and selling algae extracts, either directly or via bigger raw material suppliers to manufacturers of cosmetic end products. Interviews with market actors and own numbers result in the estimation of total sales of (micro- and macro-) algae extracts in Europe as active ingredients as high as EUR 15 million. Together with functional ingredients like alginate or agar-agar the total sales of algae extract to the cosmetic sector is about EUR 40 million. Another EUR 15 million is coming from marine-derived

[143] Eurostat/Cosmetics Europe Statistics Working Group
[144] Informations in this subchapter base upon own market research and activity of a stakeholder, oceanBASIS GmbH, Kiel, Germany

collagen and EUR 5 million for other active or functional marine ingredients, summing up to approx. EUR 60 million “marine biotechnology extract” sales in the cosmetic sector.

The cosmetic market space is intensely innovative, with approximately 7,000 new or improved ingredients released, annually, based on natural products. Still marine biotechnology and its products and services in the cosmetics sector are in their infancy and underdeveloped compared to their potential. Reasons for this evaluation are the existing demand of new ingredients, the (still) positive annotation of the ocean, and the high biodiversity (all 33 animal clades are living in the sea, only 15 on land).

Drivers and barriers for the cosmetic sector

Table 0.10 Drivers of MB in the cosmetic sector

Existing Drivers	Current extent	Drivers evolving in absence of measures	Drivers evolving with successful measures
A vivid and growing market	++	++	+++ ↑
Strong demand of innovations, i.e. new active and functional ingredients	+++	+++	+++
Organic and nature orientated consumer needs	++	++	++
Helpful marketing propositions: grand and mystical connotation of “the ocean”	+	+	++ ↑
Knowledge about marine living resources	+	+	**+++** ↑
Research facilities	+	+	++ ↑
Highly developed SME landscape	++	++	+++ ↑
Knowledge and technology base	++	++	+++ ↑
Development time and efforts	++	+	**+++** ↑

+++ strong, ++ medium, + small, ↑ supporting drivers

Table 0.11 Barriers of MB in the cosmetic sector

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Limitation of **sustainable sources** of natural products	+	+++	**+** ↓
Regulations	++	+++	**+** ↓
Financing, venture capital, high costs of innovative techniques and products	+++	+++	**+** ↓
Non-existent synergistic concept of **sustainability and MB** and its clear communication	++	++	+ ↓
Non-existent embedding of MB into technology transfer **policy** and other administrative concepts (e.g. Integrated Coastal Zone Management, fishery policy)	++	++	+ ↓
Subjective **un-alluring sector** in researcher's minds compared to pharma or medical product sector	++	++	+ ↓

+++ strong, ++ medium, + small, ↓suppressing barriers

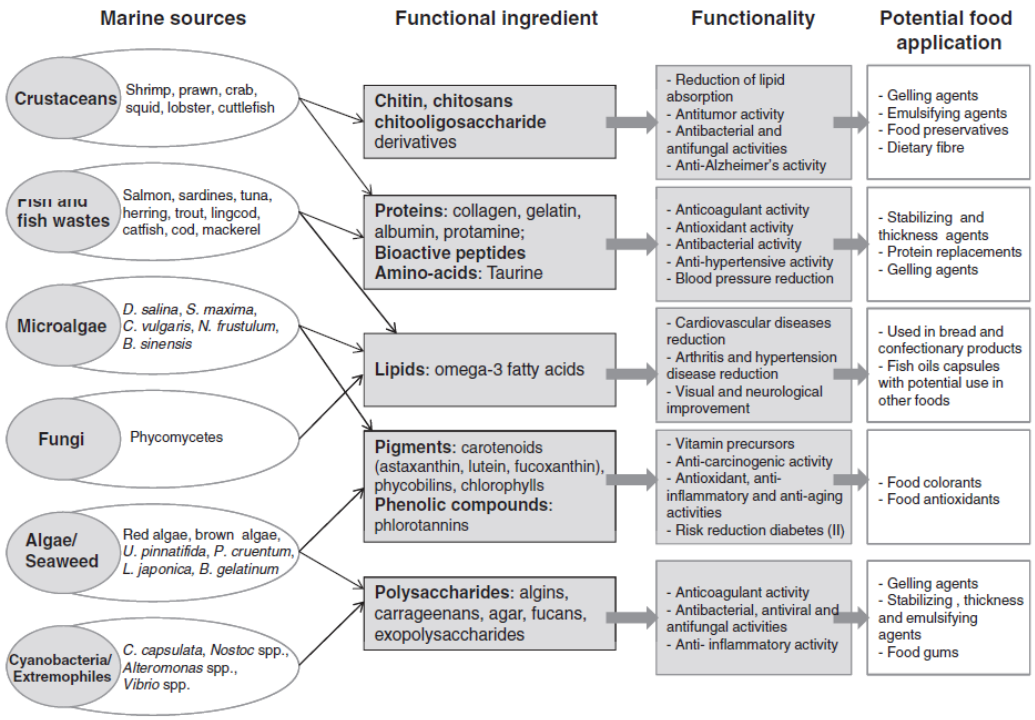
Food

Addressing the increasing demand for seafood is one area of food supply that marine biotechnology can address and this is dealt with in more depth in Section 0 on aquaculture. In addition, there are a number of areas where products of marine biotechnology can contribute to various aspects of food production. This is explored further in this section with particular reference to the use of seaweed[145] for functional food and food ingredients. .

Seaweeds are remarkable marine organisms with many new and emergent applications. Several new substances are derived from seaweeds and find their way to the markets. These include functional foods and food ingredients. The term “functional food” is commonly used for enriched or fortified food or food additives like vitamins, probiotic elements and antioxidants. Food ingredients are extracted components of the seaweed types described the previous section. In line with the requirements of EU regulation 1925/2006, all health claims that are made surrounding both feed and food ingredients must be substantiated by scientific evidence.

Although seaweed and microalgae are the main sources for new biotechnological applications, the full scope is wider. In Figure 0.22 the main marine sources, ingredients, functionality and potential food applications are displayed.

Figure 0.22 Main marine functional ingredients with potential food applications, sources and inherent functionality[146]



Crustaceans are used to produce chitin and chitosan. Apart from the pharmaceutical application of these substances chitosan is also investigated to be used as antibacterial packaging material for the food sector. Chitin is used as functional food because it helps to block absorption of dietary fat and cholesterol.

[145] Seaweeds are defined as brown, red and green seaweeds.
[146] Freitas AC, et al, Marine biotechnology advances towards applications in new functional foods

Fish waste is used to produce bioactive peptides and omega-3 fatty acids that are sold as food supplements.

Extremophiles are bacteria (and other organisms) that strive under extreme conditions like high temperatures or high salinities. In the (food) industry where biological processes are common, these microorganism have potential and unique properties. Researcher expect that the enzymes inside extremophiles could replace common enzymes used in the industries.

Value chains specific to the food sector

Figure 0.23: Value chain for the production of functional food from macroalgae

Figure 0.24: Value chain for the production of food ingredients

Potential products areas currently in research and development stage

The research in Europe is aiming at more sophisticated extraction and conversion processes to produce food ingredients. The combination with protein extraction and/or the production of functional food is proposed (examples from the Energy Research Centre of the Netherlands and Wageningen University). Food ingredients like alginate have also large applications in the industry. This industrial grade alginate could also be coproduced by a biorefinery.

There are a number of potential products in the food sector that can be derived from macro- and microalgae as shown in Table 0.12 .

Table 0.12 Products derived from macro- and microalgae with potential use in the food sector.

Product	Source	Potential food application and other benefits
Fucoidan	Brown seaweed	Fucoidan is also a natural antioxidant and can help improve gut health. Fucoidan also has anti-coagulant, anti-viral, anti-inflammatory and anti-tumour properties
Fucoxanthin	Brown seaweeds and microalgae	Fucoxanthin is an antioxidant. Through its metabolites, Fucoxanthin appears to be stored in fat cells for a prolonged period of time. It can induce fat loss while inhibiting fat cell differentiation and proliferation and takes up to 16 weeks to work. Other health benefits include the ability to correct abnormalities in glucose metabolism in muscle tissue, helping diabetics and potentially reducing cholesterol levels.
Lectins	Codium fragile, Eucheuma and Soleria robusta	This protein has several bioactive properties useful in the medical sector, including anti-inflammatory properties, anti-HIV properties, antibiotic and mitogenic properties. It is also involved in the induction of apoptosis, in host-pathogen interactions as well as cell-to-cell communication. Nevertheless, if consumed in excessive quantities this substance may damage the digestive tract.

Product	Source	Potential food application and other benefits
Laminarin	Glucan polysaccharide found in brown seaweed.	It is an anti-coagulant and has prebiotic effects and anti-tumour properties, as well as the ability to decrease cholesterol absorption and modulate the immune system. It has been heralded as a potential cancer therapeutic as well as for its ability to repair wounds.
Iodine	Brown algae	Food supplements including brown seaweed extracts can be used in humans to treat iodine deficiency, goitre and myxoedema. Iodine from *Undaria pinnatifida* may also have an antitumorogenic role, inhibiting tumorogenesis. It has been suggested that the high seaweed content of the Japanese diet partially accounts for the low incidence of breast cancer among Japanese women.
Bioactive amino acids	Macroalgae	Depress the contraction of excited smooth muscles, thus exerting a transitory hypotensive effect. Kainoid amino acids have high insecticidal properties. Due to their neuroexcitatory properties, such bioactive amino acids are currently been used in medical research concerning Alzheimer's and Parkinson's disease, as well as epilepsy
Ulvan	Green seaweed	For the treatment of gastric ulcers. Ulvan is also known to modify the adhesion and proliferation of normal and tumoral human colonic cells, as well as strain-specific anti-influenza activities.
Mannitol	Brown seaweeed	It can be used to replace sucrose in the production of sugar-free compound coatings. This presents part of the solution to diabetes, which is a growing problem in modern day society. Mannitol is also used as platform chemical by the industry.
Chitosan	Crustaceans	Chitosan could be used for a wide range of applications due to its biodegradability, biocompatibility and antimicrobial activity. It can be formed into fibers, films, gels, sponges, beads or nanoparticles. Chitosan films have been used as a packaging material for the quality preservation of a variety of foods. Chitosan has high antimicrobial properties against a variety of pathogenic and spoilage microorganisms

Substances derived from seaweed are currently used in many food products. E-numbers 400 up to 407 are all seaweed products.

E	substance	main function
400	alginic acid	thickener, vegetable gum, stabilizer, gelling agent, emulsifier
401	sodium alginate	thickener, vegetable gum, stabilizer, gelling agent, emulsifier
402	potassium alginate	thickener, vegetable gum, stabilizer, gelling agent, emulsifier
403	ammonium alginate	thickener, vegetable gum, stabilizer, gelling agent, emulsifier
404	calcium alginate	thickener, vegetable gum, stabilizer, gelling agent, emulsifier
405	propylene glycol alginate, propane-1,2-diol alginate	thickener, vegetable gum, stabilizer, emulsifier

E	substance	main function
406	agar	thickener, vegetable gum, stabilizer, gelling agent
407	carrageenan	thickener, vegetable gum, stabilizer, gelling agent, emulsifier
407a	processed eucheuma seaweed	thickener, vegetable gum, stabilizer, gelling agent, emulsifier

Landscape of marine biotechnology infrastructures and technologies in the food sector

Various methods utilised to extract the relevant compound to be used in functional foods, food ingredients, and feeds. Some specific examples are given below:

- Fucoidan must be extracted from its source of brown seaweed using an acid such as hydrochloric acid, acetic acid or (as with the organic method) citric acid. Filtration and salt removal also need to be carried out[147];
- For Fucoxanthin the seaweed is cultured in a controlled environment so that the quantities of extra nitrogen and light can be monitored. Nitrogen and light determine the levels of Fucoxanthin that emerges as the seaweed grows. Fucoxanthin is then extracted and then purified through silica gel column chromatography and preparation high performance liquid chromatography (prep-HPLC)[148]. Extraction efficiency is something that still needs to be improved in order to increase the viability of mass production of Fucoxanthin;
- For alginates seaweed is collected, washed dried and crushed. It is then swelled in acidic water. Extraction of sodium alginate then takes place through the addition of caustic soda. The alginate in seaweed is extracted first by conversion to water-soluble Sodium alginate. The aqueous alginate solution is then isolated first through a clarification procedure. This solution is diluted since it is highly viscous, by adding a large amount of water. To separate the Sodium alginate from the fibrous seaweed residue such as cellulose, the seaweed extract is filtrated. The 'acid precipitation method' of the 'calcium method' are used to extract alginic acid, which is then dehydrated and pulverised. Several different chemical processes, such as ion-exchange and esterification, may also be used to arrive at the final alginate product. The extraction technologies used in the current producing countries are basic. More effective production process based on the use of a twin screw extruder is proposed by INFRIMER and others[149];
- For agar there are several methods of production. However, the main method involves dissolving the agar from the seaweed using hot water. After this, the agar itself is separated from the cell wall by filtration and isolating the agar from the dilute solution. This isolation may be done by cutting the gel into strips and allowing it to freeze overnight and thaw out the next day in the sun. Freezing and cooling continues until a dry strip is formed. 'Gel pressing' and 'roller drying' are more large-scale techniques that are used at the industrial scale to achieve similar effects. Additionally, alkali treatment can make pressing easier. Agar is then sold in strip or block format[150];
- The four basic processes involved in Carrageenan extraction are: alcohol precipitation, KCl (Potassium chloride) precipitation (or gel press), danisco process, and semi refined process. The traditional method of Carrageenan extraction is alcohol precipitation[151].

Chitosan is produced form waste of several types of crustaceans by crushing, decalcification, deproteination and deacetylation.

[147] http://www.zenmony.com/fucoidan-manufacturing-process-a22/
[148] http://www.mdpi.com/1660-3397/11/7/2667
[149] Vauchel et al. (IFREMER): A New Process for Extracting Alginates from Laminaria digitata : Reactive Extrusion (2008)
[150] http://www.cybercolloids.net/information/technical-articles/introduction-agar-production
[151] http://www.cybercolloids.net/information/technical-articles/introduction-carrageenan-production

Socio-economic performance of the food sector

The market for enriched or fortified food or food additives like vitamins, probiotic elements and antioxidants has experienced tremendous growth over the past years[152]. Europe has experienced industries that develop these products from seaweed. Value added production processes find place in Europe. However, with almost no production of seaweed Europe is heavily dependent on import of raw materials from Asia.

The world market for functional foods and drinks is expected to reach USD 130 billion by 2015, according to Global Industry Analysts[153]. The retail price of alginate is USD 5-15/kg, with an approximate gross global market value of USD 230m per year[154]. The potential use of alginates is much larger than the current market size. If the price of alginate could drop under the EUR 1000 per ton it could be en replacement of the common used substance CMC[155]. Alginates are completely biodegradable and could be used to improve soil, to produce slow release fertilizers and as additive in drilling fluids. If the price could be lower than 1000 EUR/ton alginate could be an alternative for CMC (Carboximethylcelluloses). Additionally, it is used by celebrity chefs for molecular cooking. Alginate is also used as food ingredient, additive to textile printing ink and in welding rods.

Currently, the largest seaweed producing countries in the world are the Philippines and China. Indonesia also has a fast growing seaweed sector which will produce 10m tonnes of seaweed per year by 2015. In the western hemisphere the seaweed industry is developing in Chile and Canada. Generally, the cultivation of this resource requires intensive manual labour. Offshore seaweed harvesting is also possible but requires a much higher degree of mechanisation.

Europe's production on the other hand is small scale, in particular in comparison with production in Asia. In Europe the seaweed industry is working on the modernisation of the cultivation techniques. Traditional European seaweed industry relies on wild harvested seaweeds. This is or was done in Ireland, France and Norway on a small scale basis. Competition with East Asian seaweed cultivation seems to be highly challenging without mechanised production systems.

Role of SMEs in the food sector

The European Union is responsible for 21 percent of the world of hydrocolloids, and for 38 percent of the world production of alginates. For the production of these hydrocolloids an estimated 39,000 tonnes of dry seaweed is needed, based on 45 percent of dry weight percentage which can be used for the production of hyrdocolloids.[156] Converted to wet weight (with a conversion percentage of 15 percent of dry weight in wet weight), the required production of wet weight is over 263,000 tonnes.

Cargill Incorporated, the large privately-owned agricultural commodities trader, has recently planned to invest around EUR 11.3m to expand and improve its alginates production plant in Lannilis, France[157]. The plant itself is said to have a substantial focus on the sustainable supply of brown seaweed. Another widely known producers involved in European alginate production is FMC Biopolymer, which produces alginates in its plant at Sandvika, Norway.

[152] http://www.adlittle.com/downloads/tx_adlprism/1999_q2_26-30.pdf
[153] http://www.reportlinker.com/ci02036/Functional-Food.html
[154] Susan Løvstad Holdt & Stefan Kraan, 2011, Bioactive compounds in seaweed: functional food, applications and legislation, Journal of Appl Phycol
[155] Personal communication Frans Hofhuis.
[156] Average based on: http://www.nmfs.noaa.gov/aquaculture/docs/research/2013%20AAAS/2013_aaas_forster_presentation.pdf
[157] http://www.foodnavigator.com/Financial-Industry/Cargill-invests-15m-in-French-alginates-plant

In Europe the interest for this new market is growing. The SME Feyecon (the Netherlands) and Evonik (Germany) are working with new extraction techniques that could be used to produce the high value ingredients form micro and macroalgae.

Products and services offered currently and their future prospects

There are experienced industries in Europe that develop alginate, carrageenan and agar from seaweed. Value added production processes have a place in Europe. However, with almost no production of seaweed Europe is heavily dependent on import of raw materials from Asia. Alginates, carrageenan and agar are commonly used to enhance viscosity in food products. The food applications of alginates are presented in Table 0.13 .

Table 0.13 Food applications of alginates

Use	Function	Approx. use level (%)
Dairy products		
Ice cream	As a stabilizer in ice cream. Algin maintains a smooth texture and creamy consistency and prevents formation of large ice crystals.	0.1–0.5
Ice milk	A frozen dessert, as a stabilizer, Algin gives good dryness and stiffness and slow meltdown to soft-serve ice milk.	0.2–0.5
Milk-shake mixes	Hard-frozen ice milk, as a stabilizer, Algin provides good secondary overrun and creamy, thick milk shakes.	0.25–0.5
Sherbets and water ices	Sherbets are frozen desserts, stabilized with PGA, and have clean flavour, smooth texture, and good body without crumbliness or sugar syrup separation.	0.3–0.5
Chocolate milk	Algin-carrageenan compositions are used as a suspending agent to suspend cocoa fibre and to give a smooth, uniform-viscosity chocolate milk product.	≤ 0.25
Yogurt, sour cream and imitation dairy products	Algin used as a bodying agent for viscosity control	
Bakery products		
Icings	Bakery icings, it gives a soft gel consistency and light body and smooth texture, as a bodying agent.	0.1–0.5
Cake fillings and toppings	Algin gives the products with a tender body and smooth texture, as a stabilizer. Upon aging, the fillings and toppings retain their texture and do not become tough or rubbery.	0.3–0.5
Bakery jellies: Meringues	A freeze-thaw stable, bakery jelly. Liquid egg white meringues and dry meringue powders, containing PGA, gives good texture, and bleeding is reduced.	0.25–0.75 0.2
Glazes	Algin-sugar combinations resist sweeting and do not become brittle.	0.3–0.5
Pie fillings	Algin prevents separation and cracking, the filling has a soft, smooth gel body. For neutral or acid-type chiffon pie fillings, and for lipid-based, aerated, gelling filling.	0.3–0.5 0.7–1.5 1.25–6.0
Other products		
Dietetic foods	Algin has a caloric value of about 1.4 cal/g. As most applications require less than 1% of algin, so the number of calories contributed by algin to dietetic foods is very	-

Use	Function	Approx. use level (%)
	low.	
French dressings	PGA in French dressings gives uniform emulsion ability, body, and flow properties.	≤ 0.5
Salad dressings	PGA gives soft, smooth-textured salad dressings, produces a desired gel body that resists cracking and oil separation.	0.1–0.2
Dessert gels	Algin gels are clear and firm, and can be easily moulded, since it does not melt at room temp.	0.4–1.0
Candy gels	Ca^{2+} and algin makes candy gels ranging from soft tender types to chewy bodied gels.	0.1–0.7
Beer foam stabilization	PGA produces stable, longer life and creamier foam.	40–80ppm
Creaming	In canning foods containing sauce or gravy.	0.3–0.8
Noncarbonated fruit-flavored drinks	PGA gives a smooth-tasting product with better flavour release, as a suspending agent.	0.1–0.25

From other sources than seaweed chitosan will be used in a wide range of new products. Chitosan from crustaceans is a biodegradable and even edible polymer that is used to conserve food. Research is done by Novima in Norway, Inventia in Stockholm and Wageningen University in The Netherlands. Chitosan as packaging material has also antimicrobial properties that are very important for the food industry. It is considered to use chitosan also as film or coating on food to enhance shelf time.

Seaweed contains interesting amounts of marine proteins. If harvested in the right season seaweed could contain more than 25% (dm) proteins (ECN/WUR). The amino acid composition of these proteins is interesting for the animal feed industry. However, the costs of seaweed proteins at this stage are too high to compete with the large scale production of soy and other raw material used in the animal feed industry. Marine proteins are successfully used in the fish feed industry. Marine proteins seem to be better converted by the fish than land based proteins. Also the use of medicine to keep the fish healthy could be considerably lower. Taste and colour could also be improved by using seaweed as raw material for the production of fish feed.

The use of marine proteins and other feed rather than traditional fish feed in fish farms could help to combat overfishing. Trial results from feed products patented by the Irish company Ocean Harvest Technology Limited have been successful feed (OceanFeed™) for salmon, swine, shrimp and pets.[158] The key selling points include decreased mortality, improved yields and generally improved health. When farmed salmon was fed with OceanFeed™ they experienced a 40% decrease in sea lice infestation, 2.7% higher weight gain and the resulting fish was said to be more flavoursome and with an improved texture. One of the highlights of feed composed of seaweed would be to replace artificial ingredients, antibiotics, colorants and preservatives currently being used. OceanFeed™ is currently also being developed for the bovine, mink, equine and sheep feed markets.

Driver and barriers in the food sector

Drivers for growth in the food sector industry are:

- The health concerns of aging baby boomers in industrialized countries;
- A growing desire for alternatives to traditional pharmaceutical products,
- An increased awareness among consumers of the links between nutrition and health.

[158] See http://www.oceanharvest.ie/

The main challenges for the food sector industry are:

- High dependence on import; combined with;
- High cost of cultivation of seaweed in Europe.

Table 0.14 Drivers in the food sector

Existing Drivers	Current extent	Drivers evolving in absence of measures	Drivers evolving with successful measures
A growing market for health and functional food	+++	+++	+++
Strong demand for technical innovations	++	+	+++
Organic and nature orientated consumer needs	+++	+++	+++
Drive to reduce production costs and increase efficiencies	++	++	+++ ↑
Knowledge about marine living resources	++	+	+++ ↑
Research facilities	++	++	+++ ↑
Highly developed SME landscape	+	+	+++ ↑
Knowledge and technology base	++	++	+++ ↑

+++ strong, ++ medium, + small, ↑supporting drivers

Table 0.15 Barriers of in the food sector

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Sources of raw materials	++	++	+ ↓
Regulations	++	+++	+ ↓
Recognition of the value of innovation within the sector	++	++	+ ↓
Public perceptions of the risks associated with biotechnology in the sector	++	++	++
Financing, venture capital, high costs of innovative techniques and products	++	++	+ ↓
Recognition within policy of the contribution that MB can make within the sector to improved sustainability	++	++	+ ↓
Recognition of the contribution that MB can make to the competitiveness and productivity of the sector	++	++	+ ↓
Attractiveness of the sector compared to the agro food sector	++	++	++ ↓

+++strong, ++medium, +small, ↓suppressing barriers

Energy

Biomass is a growing resource for the energy sector. It is used directly as fuel in power plants and heating devices. Biomass is also used to produce biofuels used in the transportation sector. The increase of the biofuel consumption in the world has led to a societal discussion on the use of limited land resources for the production of food or fuel. In the EU the acceptance of land use for fuel production has decreased. In the EU biofuel policy, biofuels produced from waste and not land

based resources (waste, algae and seaweed) are given extra incentives while the usage of conventional biofuels is limited.

As 70% of the surface of the earth is covered with oceans and seas it is logic to look into ways to produce biomass in the marine area. Marine biotechnology is used to convert the harvested biomass to energy and industrial chemicals (platform chemicals) in biorefinery processes. These processes are comparable to the processes used to convert land based biomass. But the land based microbes and enzymes are not working well on the marine biomass.

Energy production form marine biomass is focussing on 2 separate value chains:

- On land cultivation of marine microalgae used to produce biodiesel or sometimes ethanol;
- Off shore cultivation of macroalgae (seaweed) to produce ethanol, butanol or methane in a biorefinery.

Value chains specific to the energy sector

Figure 0.25 Value chain for energy and platform chemicals form macroalgae

Figure 0.26 Value chain for biodiesel production form microalgae

Potential products areas currently in research and development stage

Biofuel production from micro- and macroalgae

There are two distinct organisms from which to harness energy from marine biological resources: microalgae and macroalgae (seaweed). Marine algal biomass can produce a range of biofuels including biodiesel, bioethanol, biogas, biomethanol, biobutanol and other biofuels, through the application of marine biotechnology. There are a number of advantages associated with marine algal biofuel production compared to biofuels produced from grain, seeds and other terrestrial commodities such as maize and corn.

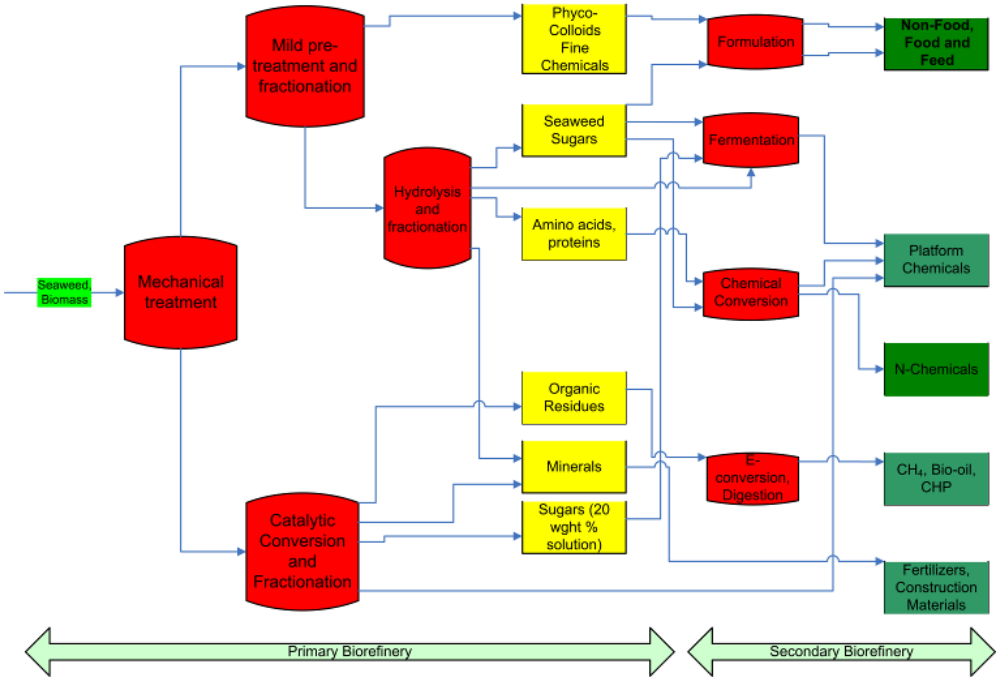
Microalgae can produce polysaccharides (sugars) and triacylglycerides (fats) that can be used for producing bioethanol and biodiesel. Biofuel production from microalgal tri-acylglycerides is a specific area of interest. Seaweed contains large amounts of polysaccharides and almost no lipids. Therefore, seaweed to energy conversion is similar to the conversion of sugar or corn. Bioethanol and butanol through fermentation are likely products as well as biogas through digestion.

The development of both resources is quite different. Microalgae are small organisms that cannot be harvested from the sea but need to be cultivated in a protected environment like a raceway pond or a photo bioreactor. Macroalgae on the contrary can be cultivated and harvested directly form sea.

Research for conversion of seaweed to energy and platform chemicals is mostly oriented at the biorefinery concept. In this concept the aim is to produce as many valuable substances from a raw material as possible to maximize the economic efficiency of the process. For seaweed this means

the production of 5 product types in a two-staged process as proposed by ECN and WUR. See figure.

Figure 0.27 Seaweed production[159]



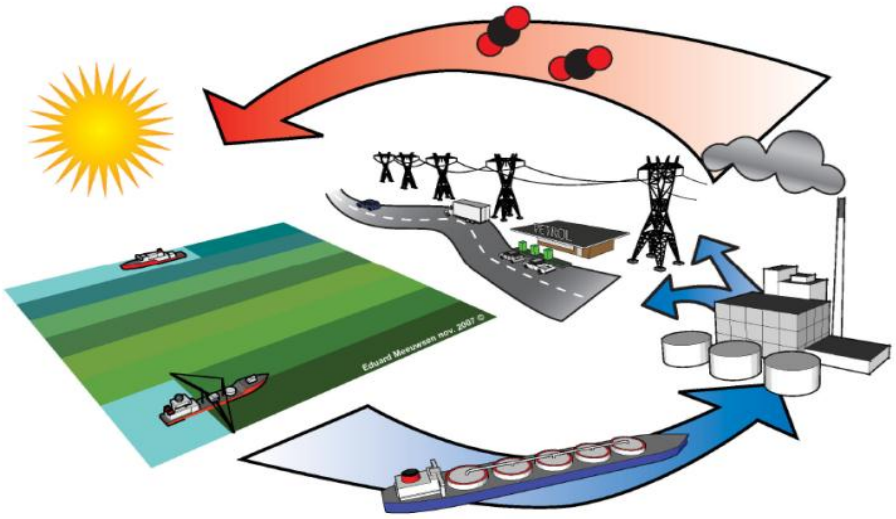
Global efforts to harness energy form macroalgae are still in a research and pilot phase. Some commercial experience exists on digestion of seaweed removed from beaches to form bio methane. Research is actively done in Europe, Japan and the United States. In Europe research is generally in the hands of the large energy and sea oriented institutes including the Energy Research Centre (ECN) of Netherlands, Wageningen University, SAMS in Scotland and IFREMER in France. Also SME start-ups like Hortimare in the Netherlands and Norway and OceanHarvest in Ireland are investing in research.

Almost all research is aimed at the large scale cultivation of macroalgae (seaweed) for the production of biofuel, in combination with the production of proteins and chemical building blocks. Large scale production of seaweed is possible in eutrophicated seas like the North Sea. The seaweed grows on lines, nets or sheets, a few meters below the surface.

Another approach is proposed by ECN and others[160]. ECN propose to use a floating seaweed species *Sargassum natans* or *Sargassum fluitans*. These seaweed species grow in the tropical gyres around the world. The ECN[161] research suggests that it should be possible to cultivate these seaweed in very large fields without using any structure or boundary. Harvesting is done by large ships with harvester arms.

[159] Energy Research Centre (ECN) and Wageningen University Research (WUR)
[160] For example David P. Chynoweth, 2005, Renewable biomethane from land and ocean energy crops and organic wastes, Hort Science.
[161] W.J. Lenstra, J.W. van Hal & J.H. Reith, 2011, Ocean Seaweed Biomass For large scale biofuel production, Presented at the Ocean Seaweed Biomass, Bremerhaven, Germany (Conference 5-7 September 2011)

Figure 0.28 Concept for offshore open ocean farming[162]



The available surface for this type of cultivation is enormous (more than 25 million km^2). The seaweed produces polysaccharides that could be converted to ethanol, Butanol or methane. *Sargassum natans* also contains interesting amounts of proteins that could be used as feed for animals. ECN suggests that the potential of this resource may be large enough to replace all oil and soy production in the world.

On a global scale there is significant microalgae research. Most research on microalgae for energy production is aiming at the production of lipids. A microalgae produces lipids as a reaction to a shortage of food. As shown in Table 0.16 Algal strains suitable for Marine cultivation, *Isochrysis galbana*, *Tetraselmis sp*. and *Phaeodactylum tricornutum* have high proportions of lipids.

Table 0.16 Algal strains suitable for Marine cultivation

Marine strain	Lipid%[163]		Stage
Isochrysis galbana	25-33 %	Biofuel	Research
Tetraselmis sp.	15-23%	Biofuel	Research
Synechococcus sp.			
Chlorococcum littorale		Ethanol	Research
Chlamydomonas sp.		Hydrogen	Research
Nannochloropsis salina		Biofuel	Research
Phaeodactylum tricornutum	20-30%		
Dunaliela tertiolecta	23%		
Chaetoceros muelleri			
Botryococcus braunii			
Emiliania huxleyi			

Some researchers in Europe and the US are working on a different approach for the biofuel production with microalgae. They use microalgae to directly produce ethanol. So not the hard to harvest microalgae need to be collected but only the ethanol need to be recovered from the process water. The microalgae stay alive and are used as living ethanol producers. The European research project DEMA is working on this[164].

[162] Ursem, Herfst, TU-Delft, 2008
[163] See: http://www.whoi.edu/cms/files/Goepfert_Defense_60363.pdf
[164] See: http://cordis.europa.eu/fetch?CALLER=EN_NEWS&ACTION=D&SESSION=&RCN=36026

Landscape of Marine Biotechnology infrastructures and technologies in the energy sector

The conversion technology of macroalgae and microalgae to energy is in general the same as for land based biomass. Although the fermentation and digestion processes do not work well with the common used microbes and enzymes. New types of, sometimes modified, organism are needed to improve the conversion efficiency. For example, the digestion of seaweed to bio methane with the normal land based organisms remains much lower than could be expected. For the production of ethanol form the polysaccharide in seaweed the same challenge is met. BAL had to use modified enzymes to produce ethanol from seaweed.

Much attention is paid to processes that do not form ethanol but isobutanol. Companies like Gevo (US) and DuPont (Europe) are working on these processes. The advantage of isobutalnol is that it could be blended in higher percentages in the fossil fuels. And isobutanol could be further processed by hydrolysation (HDO) to produce bio kerosene or biodiesel. These process steps are the same for land based biomass as for marine biomass.

Microalgae are harvested by centrifuges that are concentrating the microalgae mass. The algae mass need to be further processed to break down the cells and extract the lipids. The lipids need to be refined to be used as a biodiesel or kerosene. The processing of marine microalgae is not different form the processing of land based microalgae.

Socio-economic performance of the energy sector in relation to biofuels

The development of biofuels from marine biomass in Europe is not very strong. In the microalgae sector the position of the US is leading. Europe is strong in research and has some start-ups. It is not possible to distinguish the development of marine based microalgae form other microalgae. The current production costs of biofuels from microalgae are in the range of USD 5 to USD 10 per litre of fuel.

In the seaweed sector Europe has just started with research pilots and demonstrations. Around the North Sea and in Ireland are many groups and SMEs active with some encouraging results.

Nations with large coastlines, such as Japan and Indonesia (the longest coastline in the world), have great potential for developing a seaweed biofuel industry. Canada's province of British Colombia also has a vast coastline. This year, the University of Victoria showed that this coastline could produce 1.3 billion litres of seaweed-based ethanol, more than enough to replace what is currently being imported to the province. By-products have also been identified, such as animal feed.

The expected costs for biofuels from seaweed are between € 0.5-1per litre. The lower figure is for large scale ocean biomass cultivation and the higher figure is expected with seaweed cultivation in wind parks or near fish farms.

Biofuels from micro and macro algae are seen as 3rd generation biofuels and expected to be strongly stimulated by the EU biofuel policy. In the mandatory blending regulation they are expected to be counted 4 times in the blending target. This policy makes the market value of 3rd generation biofuel much higher than the current bio ethanol. Some researchers estimate that the 3G biofuel value could be around €1.5 /litre ethanol.

Role of SMEs in the energy sector in relation to biofuels

At the global scale there is much research on the use of algae for energy. In the US large start ups like Sapphire, Solazyme and Algenol are attracting serious amounts of venture capital. In Europe companies like AlgaEnergy (Spain), Alvigor (Germany), LGem (The Netherlands) are working on production of algae fuels. Wageningen Univerity (The Netherlands) has a large research facility called AlgaePARC.

For macroalgae (seaweed) almost all research is aimed at the large scale cultivation for the production of biofuel in combination with the production of proteins and chemical building blocks. The research for microalgae is mainly based on venture capital. Only a few algae strains are coming from the marine environment.

- In the energy field Statoil has invested in research in the cultivation of seaweed in Chile and the conversion of seaweed in the US Bio Architecture Lab (BAL). BAL has found that seaweed could be used as a resource for ethanol production, using genetically altered enzymes[165];
- In Europe Novozyme is working in this area[166];
- In Norway the company SES is working on commercial viable cultivation methods[167];
- Hortimare (the Netherlands) is working on the improvement of the propagation methods of macroalgae.

Apart from several seaweed research projects there is only limited commercial interest for the energy options, simply because the production is currently too expensive. Most economic activities focus on value chains with higher value products than energy.

Products and services offered currently and their future prospects

In Europe the marine biomass sector is still in a research phase. No commercial production of energy is taken place. In the microalgae sector there is some commercial production for demonstration projects in the transport sector (i.e. aviation). It is not clear if this is based on marine microalgae.

Seaweed bioethanol is produced in Japan, as part of the Ocean Sunrise Project and farming and harvesting *Sargassum horneri*. This project proposes to use around 4.5 million km^2 of unused areas of the exclusive economic zone (EEZ) and maritime belts of Japan. Different types of seaweed produce different yields of bioethanol and different locations, influenced by seawater nutrition, and seasons result in different growth.

Drivers and barriers in the energy sector

The main driver for the production of 3rd generation biofuels is the expected high value in the European market. The market for bioplastics is driven by companies like Coca Cola investing in projects like Plant Bottle. The market for biodegradable plastics is driven by environmental concerns and public procurement programs.

The potential for both industrial platform chemicals and biofuels is large. The main challenge is to develop low cost and large scale production of raw material (seaweed). Research on mechanical cultivation is currently done in Ireland, the UK, Norway, France, Denmark, Belgium and the Netherlands. This research is out of the scope of this Blue Biotechnology study. Outside Europe Japan, the US, Canada and Chile are also active in the research for low cost mechanised seaweed cultivation.

[165] See http://www.biofuelsdigest.com/bdigest/2010/09/16/statoil-invests-partners-with-bal-in-macroalgae-how-big-will-big-algae-be/
[166] See http://www.novozymes.com/en/news/news-archive/Pages/From-seaweed-to-biofuels.aspx
[167] See http://www.seaweedenergysolutions.com/

The cultivation of macroalgea needs to focus on local species for ecological reasons. Conversion of these local species to products needs to be coupled to the cultivation experiments. So research should be focused on the whole chain from sea to end product. Most research programs from governments are focused on specific products or on parts of the chain. This fragmented research funding forms a important barrier to the further development of the marine biomass industry in Europe.

The main challenges for the production of energy from microalgae are:

- High cost of cultivation;
- The need for CO2 injection in the process water to stimulate the growth rate;
- The need for oxygen removal in closed (photo bioreactor) systems;
- Harvest of the very small organisms;
- Breakdown of the algae cell to free the produced oil/lipids; and
- Conversion of the lipids to diesel or bio kerosene that could safely be used in the market.

Table 0.17 Drivers in the energy sector

Existing Drivers	Current extent	Drivers evolving in absence of measures	Drivers evolving with successful measures
A growing market of biofuels	+++	++	+++
Strong demand for technical innovations	+++	+++	+++
Need for sustainable low GHG emitting biomass sources	+++	++	+++ ↑
Drive to reduce production costs and increase efficiencies	++	+	+++ ↑
Knowledge about marine living resources	++	++	+++ ↑
Research facilities	++	++	+++ ↑
Highly developed SME landscape	++	++	+++ ↑
Knowledge and technology base	++	++	+++ ↑

+++ strong, ++ medium, + small, ↑supporting drivers

Table 0.18 Barriers of in the energy sector

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Large scale cultivation of raw materials	+++	+++	++ ↓
Necessity of combined cultivation and biorefinery pilots for a broad rang of products	++	++	+ ↓
Regulations	++	+++	+ ↓
Recognition of the value of innovation within the sector	++	++	+ ↓
Public perceptions of the risks associated with biotechnology in the sector	++	++	++
Financing, venture capital, high costs of innovative techniques and products	++	++	+ ↓
Recognition within policy of the contribution that MB can make within the sector to improved sustainability	++	++	+ ↓

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Recognition of the contribution that MB can make to the competitiveness and productivity of the sector	++	++	+ ↓
Attractiveness of the sector compared to the land biomass sector	++	++	+ ↓

+++strong, ++medium, +small, ↓suppressing barriers

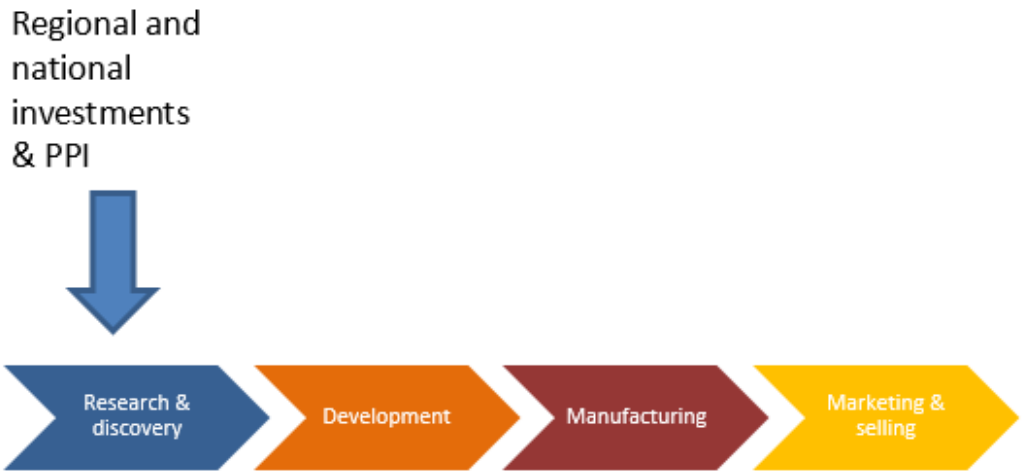
Aquaculture

Aquaculture is an important and growing global food production sector. Indeed it has been identified as the fastest growing form of food production in the world. With stabilisation of catches from wild capture fisheries, aquaculture has increased in importance with supply expanding by over ten times in the last 30 years. Within Europe, marine aquaculture has also increased in volume and value over the past 30 years with increases in production of 'traditional' cultured species such as mussels and oysters and the development of aquaculture for new species including Atlantic salmon, sea bream and sea bass.

The European sector is now dominated by Atlantic salmon production but mussels, oysters and seabass and seabream also make significant contributions. Advances in the sector have increased significantly in importance in terms of volume and value of production over this period such that European aquaculture production currently provides direct employment to around 65,000 people with an annual turnover of EUR 3 billion. The development of aquaculture, particularly that which is based on carnivorous finfish species, has led to the emergence of a number of issues associated with aquaculture including limited additional sites left for aquaculture activities, environmental impacts, disease and the effect of escaped animals and the reliance on wild fisheries for feed inputs. The critical challenge, and one that marine biotechnology has a role to play in, is to increase the efficiency of production while, at the same time, also reducing the impact of culture activities on the wider environment.

Value chains specific to the aquaculture sector

Figure 0.29 Marine biotechnology value chain for the aquaculture sector



The value chain concerning marine biotechnology in the aquaculture sector is mainly concerned with the research & discovery and development stages. After this the products (mainly seed, feed and disease treatments) can be up-scaled and marketed in similar ways to non-MB products.

The value chain begins with Research and discovery activities. These are mainly utilising marine organisms that are already known to science and there is far less emphasis on bioprospecting. Within the value chain there are only a few companies that have dedicated R&D departments, mainly feed companies. Given the scale of the sector, aquaculture companies tend to collaborate on an ad hoc basis with research institutions and universities. As a result, public private initiatives and research investments (e.g. FP6 & FP7) can provide important sources of support to the R&D stage of the value chain. The successful growth of Aquagen is based on a history of effective public private sector partnership that included government financial support, research institutions and major industry players[168]. The European Aquaculture Technology and Innovation Platform was created in 2007 and this also helps to identify and support research, including biotechnology, in key areas of importance within the aquaculture value chain.

The nature of the aquaculture value chain itself has an impact on the marine biotechnology value chain and the emphasis of activities within in. With increasing consolidation there has also been a trend toward concentrating distribution though large-scale retail chains, especially in UK, France and Germany[169]. The demands of these retail chains in terms both of volume and predictability of supply is considered to have acted as a constraint on the development of new species[170]. The emphasis within the aquaculture value chain is therefore towards diversification and development of new processed product forms using the available species. As a result there is reduced demand for R&D activities in the marine biotechnology value chain aimed at identifying new culture species.

There has been support to European R&D efforts through the current FP7 programme. Specific projects that have sought to deepen knowledge at the nexus of biotechnology and marine aquaculture. Specialised courses have also emerged in areas where there aquaculture is an important industry. One example is the Institute of Aquaculture which offers a postgraduate degree in Aquaculture Biotechnology. Further along the value chain there has, to date, been limited private equity investment in aquaculture. Cyclicality and biological risk limit the potential for investment and most investment is from within the fisheries sector overall.

Potential products areas currently in research and development stage

The main potential for marine biotechnology in relation to the aquaculture sector can be found in the following areas:

- Developing culture species;
- Developing methods to diagnose and treat disease;
- Transgenic approaches;
- Surrogate broodstock technologies.

Within the aquaculture sector, the application of marine biotechnology, including genomic knowledge and technologies to the practice of aquaculture have been termed ‘molecular aquaculture’, distinguishing them from the more traditional fish husbandry and selective breeding types of approaches. In this section we will be focusing on these novel approaches and their application.

[168] e.g. Bostock et al. (2010)
[169] FAO Fisheries Circular No. 972/4, Part 1
[170] e.g. Bostock et al. (2010).

Developing culture species

Identification of new species for culture, e.g. cod and seaweeds as well as selective breeding of existing cultured species for novel and disease resistant hybrids. Within this the application of genomics and recombinant DNA technologies has facilitated selective breeding for economically important traits[171]. In addition to improvements to the culture of existing domesticated species, genomic knowledge is also being used to identify possible new species for culture. Through the application of genomics an improved understanding of the life cycle, nutritional requirements and, critically, pathogen susceptibilities of these species can be gained. Key products are seed and eggs of existing and new species that are viable for culture and disease resistant strains.

Enhanced selective breeding

Polyploidy, in which treatments result in individual animals with extra sets of chromosomes, is a technology that creates animals with faster growth, improvement of hybrid viability through gynogenesis to fix desirable genetic traits, sex control, and sterile organisms. These techniques allow for the production of sterile animals that can have benefits both in allowing higher stocking densities and in those sterile animals avoid issues associated with the maturation of diploid animals wherein maturing animals can become aggressive, stop growing, lose condition and become more susceptible to disease[172], affecting both production efficiencies and marketability. While there are many advantages to polyploidy, some drawbacks have been identified as polyploidy can decrease performance for some traits. In oysters for example it has been suggested that while triploidy can enhance growth it may also reduce resistance to some key diseases. Key products from this subsector are shellfish seed and fish eggs.

Developing methods to diagnose and treat disease

The growth in aquaculture and intensification of production has been accompanied with an increase in diseases caused by bacterial, viral, fungal and parasitic infections. Disease in aquaculture can result in significant economic impacts (e.g. oysters in France) and also affects animal welfare. New vaccines and molecular-based diagnostics have been developed through the application of marine biotechnology. These have helped to improve animal welfare, increase fish production and reduce the use of antibiotics[173]. In addition, genome techniques have been used in selective breeding programmes, either for selection of specific pathogen-free (SPF) or specific pathogen resistant (SPR) strains. For example DNA markers have been applied in aquaculture breeding for direct and highly accurate selection of infectious pancreatic necrosis (IPN) resistant fish[174]. Reducing the use of antibiotics is significant both because of the potential human health issues associated with antibiotics and the emergence of resistances to antibiotics in farmed animals. In Norway for example, over 90% of farmed salmon are produced without the use of antibiotics. For viral diseases, avoidance of the pathogen is critical. Techniques developed through marine biotechnology, such as gene probes and polymerase chain reaction (PCR) tests are showing promise as methods for the rapid detection of pathogens in the culture environment.

Transgenic approaches

Transgenic technology focuses on genetic modification and has been applied to a number of fish species in recent years, although mostly for research. The aim of the technology is to introduce new traits or enhance existing traits. Investigations to date have been limited but potential areas of interest include disease resistance, temperature tolerance, modification of metabolic pathways

[171] OECD (2013) Marine biotechnology: enabling solutions for ocean productivity and sustainability. Organisation for Economic Cooperation and Development 116p

[172] Bostock, J., McAndrew, B., Richards, R., Jauncey, K., Telfer, T., Lorenzen, K., Little, D., Ross, L., Handisyde, N., Gatward, I. and Corner, R. (2010) Aquaculture: global status and trends. Phiospohical Transactions of the Royal Society B. 365: 2897-2912

[173] e.g. Bostock, J., Murray, F., Muir, J., Telfer, T., Lane, A., Papanikos, N., Papegeorgiou, P. and Alday-Sanz, V. (2009) European aquaculture competitiveness: limitations and possible strategies. Report prepared for the European Parliament's Committee on Fisheries

[174] Aquagen (2010). QTL-rogn - dokumentert IPN-beskyttelse fra første dag. In: AquaGen Kunnskapsbrev. No.1.

(allowing replacement of fish oil in feeds with vegetable oils), sterile animals and the use of fish eggs as bioreactors in the production of pharmaceuticals. In the United States, genetically modified (GM) Atlantic salmon, containing a growth hormone gene from a Pacific salmon species that allows the salmon to grow to market size in half the normal time is currently under consideration for approval by the Federal Drug Administration (FDA)[175]. Challenges for the use of transgenic approaches in marine aquaculture include the rapid development of embryos that mean that it is difficult to treat many and the low survival rates of fish larvae. In the EU, the high level of public concern about GM technology might be expected to lead to consumer resistance for transgenic fish[176]. The current policy of the Federation of European Aquaculture Producers (which represents more than 80% of European finfish production) is currently one of not using GM organisms. As a result, it is unlikely that GM fish will be used in the EU in the near future[177].

Surrogate broodstock technologies

The aim of these approaches has been to produce species or strains from surrogate parents, particularly where those parents may be easier to manage. For example, there is interest in the potential to produce bluefin tuna using mackerel tuna broodstock that are smaller and can be held in cages more easily[178]. Further applications of the technology include producing endangered species and strains from material held in gene banks. To date the technology has been applied almost exclusively to freshwater species that have larger embryos and simpler life histories. The main products will be seed and eggs.

With the exception of the animal health aspects, the main focus within the aquaculture sector is on fish and molluscs as sources of raw material for biotechnology although there is some 'green to blue' sourcing, e.g. in transgenic approaches.

Landscape of Marine Biotechnology infrastructures and technologies in the aquaculture sector

One of the important features of the marine biotechnology infrastructure for the aquaculture sector is that it differs for the different species being cultured and the industry configuration for these. There are important differences between salmon aquaculture and that for other finfish or shellfish species. Salmon aquaculture is characterised by increasingly integrated and consolidated companies that are global in the scope of their operations, developing differentiated products across their production facilities, e.g. niche organic salmon from Ireland and high volume products from operations in Chile. By contrast, many of the EU shellfish culture activities are smaller operations, many family run businesses. The scope for, and scale of, returns from investments in biotechnology therefore differs across culture operations.

Selective breeding programmes and feed development are some of the most costly research and development activities in aquaculture. As a result, there tends to be specialisation and concentration. This can be seen from the fact that the feed industry for fin-fish is dominated by three firms (Skretting, Ewos and Biomar.) while production of salmon and trout eggs has also been concentrated in the hands of a small number of specialist producers with global outreach, e.g. Salmobreed, Landcatch Natural Selection and Aquagen. There is also interest in the wider biotechnology industry in the potential of Blue Biotechnology applications. In 2008 world's leading poultry genetic holding company, Erich Wesjohann Group GmbH (EW Group) purchased a majority holding in AquaGen, a leading selective breeding company. EW Group went on in 2013 to also buy stakes in Skretting (a feed manufacturer) and Marine Harvest (salmon producers), illustrating the

[175] OECD 2013
[176] e.g. Bostock et al. (2010)
[177] Consensus (2008) Towards sustainable aquaculture in Europe. Consensus Partnership.
[178] e.g. Lioka C., Kani, K., and Nhhala, H. (2000) Present status and prospects of technical development of tuna sea farming. Recent advances in Mediterranean aquaculture finfish species diversification. CIHEAM, p. 275-285

integrated nature of salmon production. Similarly, Landcatch Natural Selection, a UK based selective breeding company was bought in 2011 by Hendrix Genetics, a global, multi-species breeding company that has focused on pigs and poultry.

The difference in the structure between different culture operations mean that is not possible to describe the marine biotechnology infrastructure associated with the sector as a single set of of interconnected structural elements. It is the case that biotechnology has developed in association with culture activities so that there is evidence of clustering of companies and operations around areas where aquaculture is an important sector, e.g. West coast of Scotland, Norway, and Galway in Ireland etc. The marine biotechnology infrastructure and technologies in the aquaculture sector are mainly focused on at raw material sourcing, R&D, and up-scaling/production. These operations have generally emerged from the aquaculture sector and it is only more recently that wider biotechnology companies are seeing the potential of aquaculture as a blue application of existing technologies.

Universities and other academic institutions play an important role in the development of techniques and products and many of the advances are the result of fruitful collaboration between industry and academia that is often further enhanced by public as well as private investment.

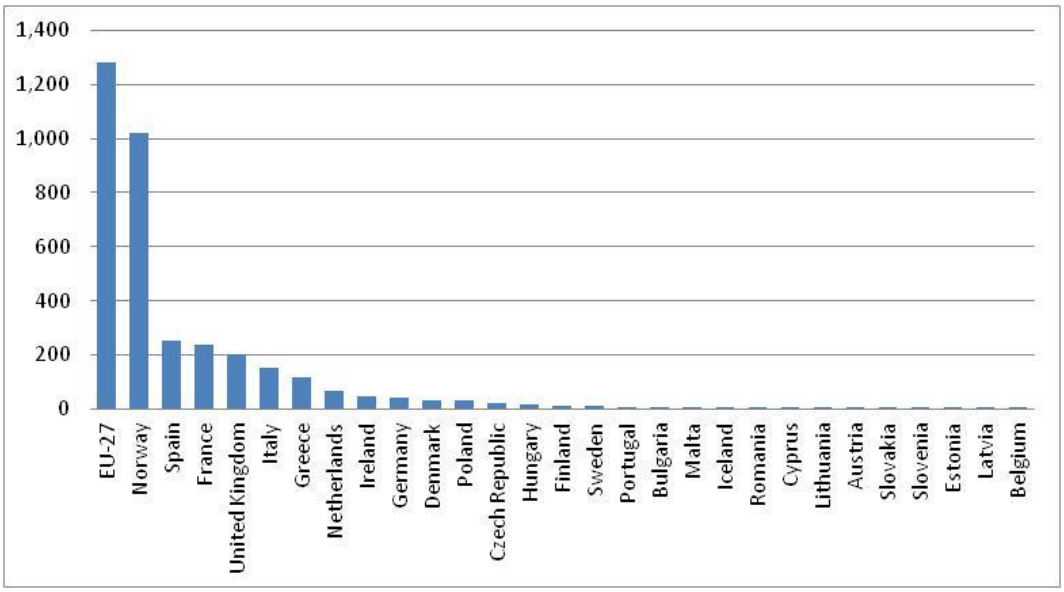
Socio-economic performance of the aquaculture sector

Globally the increase in human population and limited scope to increase the total wild capture fish yield mean that there is likely to be increasing demand for products from EU aquaculture. In addition to the overall picture, the EU is globally the largest net importer of farmed seafood with average per capita consumption of fish across the EU of around 23 kg per year. Some 1.27 million tonnes of farmed seafood products were imported in 2007, four times the volume in 1999 and double the volume in 2004. Available data show a growing gap – estimated at 8 million tonnes – between the level of consumption of seafood in the EU and the volume of captures from fisheries. Aquaculture has been identified as one of the principal means of meeting the deficit in EU seafood demand and supply. The potential for EU aquaculture to meet this deficit is uncertain. While Europe is ranked third in terms of aquaculture production by continent, it is providing only 3.6% of total production[179]. Added to this, EU aquaculture has been relatively stagnant in volume terms; from 2001 to 2008 EU production growth averaged only 0.5% APR compared to 7.5% for all non-EU countries combined. Currently the EU accounts for only 2% of global aquaculture production and 10% of the EU seafood market supply. Aggregate figures however conceal a 20% growth in marine production over the same period. There are currently eight EU countries with annual aquaculture production values over EUR100 million (France, UK, Italy, Greece, Spain, Denmark, Holland and Germany) that together account for 81% of Community production.

The EU has committed to a set of Strategic Guidelines for the sustainable development of EU aquaculture[180] that are intended to support the future development of the sector. As one of the pillars of the EU's Blue Growth Strategy[181] it is a sector that can be expected to receive additional support.

[179] Hall, S. (2011) Blue Frontiers. WorldFish Center
[180] http://ec.europa.eu/fisheries/cfp/aquaculture/official_documents/com_2013_229_en.pdf
[181] COM(2012) 494

Figure 0.30 Aquaculture production in Europe by country in 2010



Support to the sector will help meet the current gap and also to address the expected increase in seafood consumption that is predicted over coming years across the majority of EU Member States[182].

The products from EU aquaculture activities are also in demand in other parts of the world. Export from the EU tends to focus on niche and value-added products (e.g. organic salmon and smoked salmon) and exports only represent a small proportion of the value of imports (estimated at 8% in 2006[183]). However, combined with expected trends in global demand for seafood, this suggests that there is considerable potential for expansion.

Role of SMEs in the aquaculture sector

Most marine biotechnology applications are related to the inputs to aquaculture – seed and feed - with some additional efforts related to disease detection and prevention. Within the aquaculture sector SMEs dominate the bivalve and freshwater aquaculture sectors, including many family owned enterprises. By comparison, intensive marine cage-culture sectors have seen more rapid consolidation as a result of a combination of economies of scale and higher value products[184]. Vertical integration is increasing, but specialisation is more important for high technology activities, especially selective breeding programmes and more advanced food processing. There is a strong role for SMEs in the R&D field, especially as, with the exception of feed companies, the aquaculture companies tend not to have large R&D budgets or capability. As with other industries, marine biotechnology SMEs can be disproportionately affected by red tape, with regulatory and administrative costs up to ten times higher for SMEs than for large companies in the general economy[185].

[182] Failler, P. Future prospects for fish and fishery products. 4. Fish consumption in the European Union in 2015 and 2030. Part 1. European overview. FAO Fisheries Circular. No. 972/4, Part 1. Rome, FAO. 2007. 204p ftp://ftp.fao.org/docrep/fao/010/ah947e/ah947e03.pdf

[183] Framian (2009) Review of the EU aquaculture sector and results of costs and earnings survey. Part 1 of the Definition of data collection needs for aquaculture report. FISH/2006/15

[184] e.g. Bostock et al. (2010)

[185] http://ec.europa.eu/enterprise/policies/sme/business-environment/administrative-burdens/

Products and services offered currently and their future prospects

While the development of the aquaculture sector in Europe has stabilised in terms of production, there is still considerable innovation and effort to address the challenges that have emerged during the expansion of the sector. At the same time, globally aquaculture is a growing industry with high demand for new production and impact mitigation technologies.

There are a range of products and technologies that are currently in production or development that could contribute to the development of the sector in the EU and beyond. The status of aquaculture globally as the fastest growing form of food production in the world, high levels of demand and position of European companies mean that there is significant potential within the sector. While there have been impressive advances made in reducing the use of antibiotics in a number of aquaculture systems – notably salmon – culture of new species, such as cod, is still in need of similar advances. Aquaculture in other parts of the world, e.g. Asia, is still dependent on chemicals and antibiotics to treat disease outbreaks and there is significant potential for technologies that can address this which European companies and researchers may be well placed to assist with.

Feed for aquaculture is dominated by three large European companies and these companies are also well placed to supply aquaculture globally with formulated feeds and with feeds that are based on raw materials other than wild sourced fish oils and meals.

Drivers and barriers of the aquaculture sector

With the pressure on wild fish stocks globally and focus on rebuilding stocks in EU waters together with a global expansion of aquaculture production there is interest in the potential of the sector within the EU. The development of aquaculture within the EU has been identified as offering the potential to generate additional employment and income, in particular within rural regions. Furthermore, it would reduce the large EU fish trade deficit, as 50-60% of fish consumed in the European Union is imported from non-EU countries[186].

Marine aquaculture in the EU has a long history but there have also been recent advances in the production of a number of species (e.g. salmon and sea bass) that have increased significantly the volume and value of production. Marine biotechnology has the potential to make significant contributions to the sector in the quest to increase production, production efficiency and minimise impacts. However, the industry also faces a number of constraints that are beyond the scope of marine biotechnology. One of the most critical of these is in the number of suitable sites that exist that could allow for the expansion of aquaculture activities. Should these constraints be overcome, e.g. through the development of offshore cages, the potential contribution of marine biotechnology will be enhanced.

It should also be noted that aquaculture is an expanding global industry. In salmon farming for example, many of the companies operating in the EU are also engaged in or supplying production facilities in other parts of the world (e.g. New Zealand and Chile). The potential markets for EU marine biotechnology applications are therefore much wider than the EU alone and this is evident from the recent agreements for the delivery of genetically improved salmon eggs to Australis seafood in Chile. European expertise also support the development of aquaculture in many developing countries where there is also likely to be an expanding market for EU marine biotechnology derived products.

[186] Framian (2009)

Currently there is a low level of recognition of the contribution that MB can make to the performance of the sector within policies at the EU level. The main emphasis has been on more traditional technological constraints, competition and regulation and legal constraints[187]. There is a need to ensure within policies that aquaculture development is better embedded in CFP, MSFD, WFD and other policies and that the role of MB is considered within this.

Table 0.19 Drivers of MB in the aquaculture sector

Existing Drivers	Current extent	Drivers evolving in absence of measures	Drivers evolving with successful measures
A growing market	+++	+++	+++
Strong demand for technical innovations	+++	+++	+++
Organic and nature orientated consumer needs	++	++	++
Drive to reduce production costs and increase efficiencies	++	++	+++ ↑
Knowledge about marine living resources	++	++	+++ ↑
Research facilities	++	++	+++ ↑
Highly developed SME landscape	++	++	+++ ↑
Knowledge and technology base	++	++	+++ ↑

+++ strong, ++ medium, + small, ↑supporting drivers

Table 0.20 Barriers of MB in the aquaculture sector

Existing Barriers	Current extent	barriers evolving in absence of measures	barriers evolving with successful measures
Sources of raw materials	++	++	+ ↓
Regulations	++	+++	+ ↓
Recognition of the value of innovation within the sector	++	++	+ ↓
Public perceptions of the risks associated with biotechnology in the sector	++	++	++
Financing, venture capital, high costs of innovative techniques and products	++	++	+ ↓
Recognition within policy of the contribution that MB can make within the sector to improved sustainability	++	++	+ ↓
Recognition of the contribution that MB can make to the competitiveness and productivity of the sector	++	++	+ ↓
Attractiveness of the sector in compared to pharma or medical product sector	+++	+++	++ ↓

+++strong, ++medium, +small, ↓suppressing barriers

[187] e.g. Bostock, J., Murray, F., Muir, J., Telfer, T., Lane, A., Papanikos, N., Papegeorgiou, P. and Alday-Sanz, V. (2009) European aquaculture competitiveness: limitations and possible strategies. Report prepared for the European Parliament's Committee on Fisheries

Other industries (Environmental health)

Marine biotechnology has applications in industry sectors other than health, cosmetics, energy, food, and aquaculture sectors. This study looks at the industrial applications of marine biotechnology, in particular those that have a marine focus, these include environmental protection, depollution (bioremediation) and antifouling, as well as industrial products used in the marine environment, such as underwater bioadhesives. There are a range of enzymes, biopolymers, biomaterials, and other bioactive compounds which are derived from marine organisms that can be used industrial applications. The usefulness of marine derived 'products' stems from their unique properties and functions which are the result of the huge biological, chemical and genetic diversity displayed by marine life and their symbiotic nature, especially those microorganisms found in extreme marine environments (extremophiles).

Value chains specific to other industries

Figure 0.31 Value chains specific to other industries

The specific value chains for industrial products and processes vary depending on the marine resource utilised and the final application. However, the steps of the discovery and research and development stages do not differ significantly from the other industry sectors in that they are very much focused on the collection, cultivation, extraction and analysis that all marine resources are subject to before their potential in an industrial application is realised. Development also involves the up-scaling and commercialisation of products to allow for bulk production and manufacture.

Potential products areas currently in research and development stage

There are a number of product areas that in which enzymes, biopolymers, biomaterials, and other bioactive compounds which have the potential to be utilised in a number of industries and are currently being researched. A selection of these product areas are described below:

Environmental protection and depollution sector (bioremediation)

Anthropogenic activity has led to considerable quantities of contaminants including crude and petroleum oil products, hydrocarbons and halogenated compounds entering marine environments. Researchers have been trying to identify bacteria sourced from microbial populations from the marine environment that can metabolise certain types of hydrocarbons as so could be used to break down pollutants without negatively impacting the marine ecosystem.

Bioremediation can be approached with two methods: bioaugmentation or biostimulation, and the method used depends on the specific case. Bioaugmentation involves the introduction of oil degrading microorganisms to the contaminated area while biostimulation involves the addition of supplemental nutrients to the contaminated area to assist the naturally existing oil degrading microorganisms. Biostimulation is thought to be more effective as, unlike bioaugmentation, it allows for a growth of microorganisms and degrades a larger amount of hydrocarbons[188].

Biosurfactants (BS), bioemulsifiers (BE) and exopolysaccharides (EPs) produced by marine microorganisms are an attractive alternative to synthetic compounds for use in bioremediation as

[188] Radermacher, Matt. "Bioremediation of Marine Oil Spills." *Iowa State University* Available: http://home. eng. iastate. edu/~ tge/ce421-521/matt-r. pdf.

they are environmentally biodegradable, less toxic and are able to undertake specific activity at extreme temperatures, pH and salinity[189]. BS and BEs are ampiphillic compounds containing both a hydrophilic and a hydrophobic moiety which allow for solubilisation of hydrophobic substrates and reductions in surface and interfacial tension thus allowing solids, liquids or gases to mix more readily. Their usefulness in terms of bioremediation is due to a variety of relevant functions including emulsification, foaming, detergency, wetting dispersion, solubilisation of hydrophobic compounds and enhancing microbial growth enhancement[190,191,192.] Table 0.21 shows the different types of BS/BE produced by different organisms and their general, potential applications.

There is currently an FP7 research project[193] being undertaken by institutes around the EU looking at the microbial diversity and ecology of the Mediterranean with the aim to find microbes which can be used as antipollutants. This project is scheduled to be completed in 2014 and may result in effective products for this purpose.

Table 0.21 BS/BE producing microorganisms and their potential applications

Polymer/Compound produced	Marine Microorganisms	Properties	Potential applications
Polymeric biosurfactant/bioemulsifiers	*Acinetobacter sp., Pseudomonas*, *Myroides, Halomonas*, yeast, *Streptomyces, Antarctobacter, Marineobacter*	Effectiveness as emulsifiers that can stabilise oil-in-water interactions. act to lower surface water tension	Oil-recovery. Emulsfying weathered crude oil, They are useful for limestone, titanium, gasoline, crude oil, kerosene, hydrocarbons
Glycolipid surface active molecules (carbohydrates in combination with long-chain aliphatic acids or hydroxyaliphactic acids)	*Alcaligenes sp., Arthrobacter, Alcanivorax borkumensis, Rhodococcus, Halomonas*.	Extensively studied due to a wide range of applications and can be cheap to make through sugar based, cheaper renewable feedstock substrates (Thavasi et al., 2009). Can degrade hydrocarbons. Inhibition of microflaggelate and microalgae growth, surfactant activities, effective interfacial and emulsifying properties, surface active agent, enhance solubility of polycyclic aromatic hydrocarbons and increase degradation rate of hexadecane (Rhodococcus).	Bio-remediation for marine oil spills including solubilisation of PAHs (Polycyclic aromatic hydrocarbon).
Lipopeptide surface active molecules	Bacillus sp., Azotobacter chroococcum,	Antimicrobial and antibacterial activity. Enhance degradation of PAHs by increasing bacterial growth and increasing biosurfactant	Bioremediation through emulsification of marine oil spills.

[189] Thavasi, R., Nambaru, V. R. M. S., Jayalakshmi, S., Balasubramanian, T. & Banat, I. M., 2009, Biosurfactant Production by Azotobacter chroococcum Isolated from the Marine Environment. Mar Biotechnol 11, 551–556 (2009).
[190] Banat, I. M., Makkar, R. S., & Cameotra, S. S., 2000, Potential commercial applications of microbial surfactants. Applied microbiology and biotechnology, 53(5), 495-508.
[191] Kosaric, N., 2001, Biosurfactants and Their Application for Soil Bioremediation. Food Technology Biotechnolgy 39, 295–304
[192] Satpute, S. K., Banat, I. M., Dhakephalkar, P. K., Banpurkar, A. G. & Chopade, B. A., 2010, Biosurfactants, bioemulsifiers and exopolysaccharides from marine microorganisms. Biotechnology Advances 28, 436–450
[193] ULIXES http://www.ulixes.unimi.it/

Polymer/Compound produced	Marine Microorganisms	Properties	Potential applications
		production.	
Phospholipids and fatty acids surface active molecules	Myroides	Good surface active agent	Uncertain.
Glycolipopeptide surface active molecules	Corynebacterium kutscheria	Emulsification of different hydrocarbons	Remediation of hydrocarbon polluted sites
Exopolysaccharides complex surface active polymer		Emulsification and removers of pollutant metals and toxic elements means that they are useful in bioremediation	Oil recovery and additional industrial uses

These compounds are isolated from polluted marine environments after oil spills using several screening methodologies to isolate high and low-molecular weight BS and BE[194]. Biosurfactants produced by these microorganisms are then optimised and comparative studies are then conducted in laboratory conditions to show performance in a wide range of conditions by testing a number of measurements including surface tension/interfacial tension measurement[195]. Private biotech companies and university researchers are typically behind production of novel organisms and trials rely on actual oil spills in order to test effectiveness; Alcanivorax was trialled by a biotech company at the Gulf of Mexico spill with inconclusive results. Biotech companies will be involved in the research, development, consultation and manufacture of these products.

Wastewater treatment

Wastewater treatment is another area of bioremediation that marine microorganisms are utilised in for the removal of toxic metals including lead, cadmium and zinc through chelation[196] from solutions[197]. Microorganisms produce exopolysaccharide (EP) that helps to remove/remediate toxic metal pollution; those isolated from deep-sea thermal vents have been shown to bind and remove these metals, other microorganisms also have a high binding ability towards monovalent and divalent ions or high uronic acid contents which increase EPS affinity for heavy metals.

Chitin and Chitosan, extracted from crustacean such as prawns and crabs, can be used to remove potentially dangerous heavy metal ions from wastewater. Specifically, chitosan composites can be used as adsorbents to remove dyes in wastewater in areas of varying levels of pollution from synthetic dyes[198].

Environmental monitoring – biomarkers and biosensors

Marine cnidarians, such as jellyfish, have auto-illuminating green-fluorescent proteins (GFPs) is increasingly used as a biosensor in research and industry to monitor gene expression[199]. Through fusing a promoter-less reporter gene such as gfp (encoding green-fluorescent protein) with a pollutant-response gene a microbial biosensor is created that will react to specific chemical

[194] Batista, S. B., Mounteer, A. H., Amorim, F. R., & Totola, M. R., 2006, Isolation and characterization of biosurfactant/bioemulsifier-producing bacteria from petroleum contaminated sites. Bioresource Technology, 97(6), 868-875.
[195] Kumar, A. S., Mody, K. & Jha, B., 2007, Evaluation of Biosurfactant/Bioemulsifier Production by a Marine Bacterium. Bull Environ Contam Toxicol 79, 617–621
[196] A particular way that ions and molecules bind to metal ions
[197] Das, P., Mukherjee, S., & Sen, R., 2009, Biosurfactant of marine origin exhibiting heavy metal remediation properties. Bioresource technology, 100(20), 4887-4890.
[198] Wan Ngah, W. S., Teong, L. C. & Hanafiah, M. A. K. M., 2011, Adsorption of dyes and heavy metal ions by chitosan composites: A review. Carbohydrate Polymers 83, 1446–1456
[199] Hötzer, B., Scheu, T., Jung, G. & Castritius, S., 2012, Measurement of the copper concentration in drinking water based on changes of the fluorescence lifetime of the green fluorescent protein. in 8550, 855021–855021–10

compounds or to particular physio-chemical conditions[200]. The resultant biosensor has a variety of potential uses for soil, sediment and water testing.

Specifically, their use has been demonstrated for detecting contamination such as heavy metals and hydrocarbons in ex-situ water and soil environments[201,200]. GFPs can be used in combination with strains of E.Coli as biosensors to deduct heavy metal contamination and changes in physio-chemical conditions in water systems[201].

These biosensors are able to work in an aqueous phase within a buffered medium and represent a cost-effective, compact, portable opportunity for monitoring environmental pollution in in-situ water and soil environments[200]. However, their widespread use as an environment pollution detector is constrained by their performance in harsh environmental conditions and also due to political sensitivities with using genetically engineered microbial biosensors[200].

Few sensors have been developed specifically for marine applications but a number of sensors have relevant analytes. The potential uses of biosensors include the detection of characteristics of eutrophication; organism detection; detection of pollutants; detection of trace metals; detection of contaminants in food; and detection of toxic substances[202].

Further advances within this field include the increased chemical or stress specificity of these reporter genes through fusing with natural regulatory genes which can allow the targeting of specific chemicals or classes/of compounds[200]. In addition, constraints to GFPs usefulness include a relatively slow formation of the “flurophore”, however experimental mutant GFPs have successfully displayed increased stability and intensity. These are now commercially available and their use is expected to increase.

Antifouling

Biofouling is the colonisation of man-made surfaces by microorganisms which can lead to biodeteriation and increased drag on ships which leads to increased fuel consumption. Biofouling has long been considered a problem in shipping and several techniques have been used to combat it starting with copper which was found to have a short effective lifespan as well as being toxic to many forms of marine life. Tributylin (TBT) paints were developed in the 1960s as a replacement for copper paints. TBT worked effectively as an antifoulant but was found to be very damaging to the marine environment and organisms living in it and the continued use of it led to severe contamination of many bays and estuaries particularly those close to shipping ports. Concern over these impacts led to a partial ban on the use of TBT paints by the International Maritime Organization so other solutions were required[203]

A key approach being taken to acquire a solution to biofouling is through the use of marine biotechnology. Natural products with antifouling properties have been identified from marine organisms including seaweed, seagrasses, sponges and soft corals. Strategies adopted by organisms living in the marine environment against fouling can be grouped into four types: chemical, physical, mechanical and behavioural, of which, the first three are of interest for use in biotechnology and have been the basis of research on marine antifoulants and microtexturing of

[200] Shin, H. J., 2011, Genetically engineered microbial biosensors for in situ monitoring of environmental pollution. Applied microbiology and biotechnology, 89(4), 867-877.
[201] Raja, C. E. & Selvam, G. S., 2011, Construction of green fluorescent protein based bacterial biosensor for heavy metal remediation. Int J Environ Sci Technol 8, 793–798
[202] Kroger S, Law RJ. 2005. Biosensors for marine applications. We all need the sea, but does the sea need biosensors? *Biosensors and Bioelectronics*. 20: 1903-1913. Available: http://www.researchgate.net/publication/7992973_Biosensors_for_marine_applications._We_all_need_the_sea_but_does_the_sea_need_biosensors/file/d912f506e9995476fd.pdf.
[203] CSA MarineBiotech, http://www.marinebiotech.eu//

surfaces[204]. Some water-based coatings which use elements of low-toxicity and natural biocides are being developed and are a promising source of natural antifouling compounds[205]

While several potential sources and compounds have been identified, a cost effective solution has yet to be found. Some of the work being carried out currently is summarised below:

- Investigation of methods for immobilising bacteria which have antifouling characteristics and compounds including the marine bacterium *Pseudoalteromonas tunicate;*
- The evaluation of classes of compounds extracted from marine organisms which display biofouling inhibition properties;
- The evaluation of antimicrobial peptides extracted from crustaceans that could prevent biofilim formulation;
- The discovery and evaluation of compounds which can prevent microbial biofilm formulation by impairing the communication systems between bacterial cells;
- The development of biomimetic analogues of mussel adhesive proteins (MAP) which could be used to develop antifouling coatings[206].

Underwater bio-adhesives

Bioadhesives produced by marine organisms are extraordinarily effective and have the potential to be utilised in a number of industrial and biomedical applications. Marine bioadhesives are composed of proteins assembled into functional composites which allows for different structures and functions. Research and development has focused on bioadhesives of mussels and barnacles and their potential applications as biomedical and underwater industrial adhesives. Mussel adhesive proteins (MAPs) are water insoluble, biocompatible bioadhesives that are able to form permanent, strong and flexible bonds with biomolecules and a number of surfaces including glass, Teflon, metal and plastics, thereby making them highly interesting to biotechnological applications. Furthermore, their biodegradable properties make them environmentally friendly. Several mussel adhesive proteins have been identified and characterised from mussels, and extensive biochemical knowledge on mussel adhesions has been accumulated. One common feature of many MAPs studied is the high content of the amino acid 3,4-dihydroxy-L-phenylalanine (DOPA). High DOPA content, small molecular size, protein flexibility, the presence of metal ions, and a high oxidation state enable strong mussel adhesion to surfaces. However, the adhesion mechanism is not fully understood.

Mussel bioadhesives have been researched extensively for their potential application as industrial underwater adhesives, biodegradable water resistant wood adhesives, surface coatings and antifouling polymers. Considerable progress has been made, but the biochemistry of mussel adhesion proteins and adhesion mechanisms have not been fully elucidated. Further identification and characterization of MAPs is required to improve our understanding of their biological roles in adhesion mechanisms and advance the on-going research in novel biomimetics.

Landscape of Marine Biotechnology infrastructures and technologies in other industries

The application of marine biotechnology in industrial products and processes is diverse and therefore involves a wide range of infrastructures and technologies, most of which will be generic to the applications of marine biotechnology in the health, cosmetics, food, energy, and aquaculture industry sectors.

[204] Hellio, Claire, 2010, The potential of marine biotechnology for the development of new antifouling solutions. Journal des Sciences Halieutique et Aquatique, 2. pp. 35-41.
[205] Eguõa, E. and Trueba, A. 2007. Application of marine biotechnology in the production of natural biocides for testing on environmentally innocuous antifouling coatings. *J. Coat. Technol. Res.*, 4(2): 191-202. Available: http://gendocs.ru/docs/13/12995/conv_8/file8.pdf
[206] European Science Foundation (ESF) Marine Board, 2010, Position Paper 15 Marine Biotechnology: A new Vision and Strategy for Europe, http://www.marine.ie/NR/rdonlyres/C076682C-2B32-437C-A781-B2EACBAA6B62/0/ESFMBmarine_biotechnology_paper15LR.pdf

Networks of excellence (NoEs) were established in Europe under the EC's FP6 and have been further developed under FP7 in order to integrate scientific communities and infrastructures needed to conduct interdisciplinary research into issues key to marine biotechnology such marine biodiversity, ecosystem functioning, and marine biology genomics. Several specific research infrastructure initiatives have been implemented and tackle issues such as access to marine resources, access to and use of research vessels and fleets, coordination of research facilities, and the development of new tools. Databases are crucial aspects of marine biotechnology applications in industry. Two such databases are the World Register of Marine Species (WORMS)[207] and the Ocean Biogeographic Information System (OBIS)[208] and their creation involved a huge number of scientists from a large range of institutions across a host of countries. Bioinformatics is a crucial aspect of marine biotechnology and involves the construction of databases on genomes, protein sequences; and complex biological processes. At present the storage capacity of these is becoming an issue as the rate of genomic sequencing increases. Databases can serve as a community resource and can contribute to the comparative analysis of species and annotation of genomes. Model systems encompass the detailed and focused study of model organisms to improve understanding of biochemical processes and identifying pathways for development and production. Whilst only a few model organisms are currently studied they are important for the development of industrial application of marine biotechnology.

The technologies of importance to marine biotechnology are omics, metabolic engineering and systems biology, cultivation and bioengineering. With regards to omics technologies, genomics, metagenomics, and sequencing technologies are the most relevant to marine biotechnology and whilst there has been some advance in recent years, further development is needed in order for the full potential of marine resources to contribute to biotechnology to be fully realised and commercialised. Metabolic engineering and systems biology provide the basis for the production unique compounds as they deliver the link between metabolic pathways and genomics. Cultivation of marine microorganisms is notoriously difficult, and in some cases have proved impossible, but in order to produce bioactive compounds for further research and development specific cultivation techniques and methods are necessary.

Socio-economic performance of other industries

Environmental protection and depollution sector (bioremediation)

Determining market values for industrial products and processes is not straightforward, especially when they relate to environmental protection. Furthermore it is difficult to break down the economic contribution of marine biotechnology beyond specific products. The bioremediation market is difficult to define because the occurrence and discovery of contamination in the marine and terrestrial environment is on-going. A recent analysis[209] predicts that revenues for the marine coatings (including anti-corrosive, anti-fouling and foul-release coatings) industry will jump from USD 5 billion in 2011 to USD 10.2 billion in 2018 as shipowners look for ways to reduce fuel consumption and meet environmental regulations. It reported that companies are investing in developing eco-friendly products such as metal-free, anti-fouling coatings. Furthermore, it is reported[210] that hull fouling can cost cruise vessels up to USD 500 thousand a year due to increased fuel costs. The socio-economic performance will be an area of focus for the sector review going forward.

[207] http://www.marinespecies.org/
[208] http://marine.rutgers.edu/OBIS/
[209] Frost & Sullivan, Strategic Analysis of the Global Market for Marine Coatings, http://www.prnewswire.co.uk/news-releases/need-to-reduce-fuel-consumption-of-ships-drives-demand-for-marine-coatings-says-frost--sullivan-179235141.html
[210] Hull Fouling – the hidden cost, 2012, Eniram, http://shipandbunker.com/news/world/462875-hull-fouling-has-500k-a-year-price-tag

Role of SMEs in other industries

It appears that SMEs and education institutions tend to be the main drivers of research into marine biotechnology products. However, one of the obstacles to the advancement of marine biotechnology is the lack of collaboration and agreement between academia and industry, particularly when applied to approach taken to utilising and protecting promising results and the distribution of IP rights for any results. It is unclear whether particular SMEs will look at a range of potential end products or if they focus on the source materials and compounds found.

Products and services offered currently and their future prospects

The biotechnology sector for other industries is still in its infancy with many products at the research stage but none have been developed for commercial use. Despite promising research results cost effective products for antifouling, *in situ* monitoring, bioadhesives and bioremediation are still a long way off.

Drivers and barriers in other industries

The drivers and barriers vary slightly between the industry sectors but there is commonality. The drivers tend to relate to environmental issues such as increasingly stringent environmental legislation being introduced, the demand for eco-friendly products and an overarching move towards greening industrial processes and products.

The barriers to the widespread application of marine biotechnology to multiple industry sectors and industrial products and processes are many. The cultivation and culture of marine microorganisms is far from easy and impossible in some cases and this has a profound impact on the supply of, for example, bioactive compounds for research and product development. This in turn can cause issues with the bulk production of products for commercial use (i.e. up-scaling). Furthermore, the complexity of marine microorganisms is such that further advances and improvements in biotechnological analytical tools are required, for example, in the areas of screening, expression and other DNA based technologies, and 'omics' approaches. Another barrier that has been identified is the lack of coordination between academic and industry partners at the EU level and a lack of common projects.

Some specific barriers to come of the potential industrial products and processes are detailed below:

Environmental protection and depollution sector (bioremediation)

Marine microorganisms can be difficult to culture in laboratories due to specific conditions required and their production is often limited by low yields (Banat et al., 2000). Further limitations to the usefulness of these products include that oil still often needs to be turned into small droplets for the microbes to consume and petroleum has thousands of components and therefore the required microbial community would be complex. It also depends on the location of the spill as colder, deeper water limits microbial growth.

Antifouling

Progress in this area is slow due to a wide variety of reasons. Progress has been slow due to insufficient funding and a lack of strong incentives for scientists to fully commit to finding a solution to fouling. It is also difficult to reproduce known compounds on a large enough scale for commercial purposes due to the costs and the fact that many compounds are produced in organisms in very low quantities and it is not sustainable to harvest these organisms directly from the marine environment and laboratories often are unable to conduct as many replicates of tests due to the limited supply (Qian et al 2010). Another issue for the development of antifoulants through biotechnology is the fact that the necessary infrastructure for this research, in particular broad-

spectrum bioassay systems in research laboratories. Many laboratories have replied on looking at either microfoulers or macrofoulers and compounds that may work effectively on one of these are often ineffective when applied to the other. There is also a small range of target organisms studied in most research laboratories both in terms of the number of species and the geographical range of these species meaning that compounds identified tend to have a narrow spectrum of antifouling activity.

Underwater bioadhesives

One of the major challenges in mussel adhesive research is the difficulty in extracting and purifying sufficient quantities of MAPs from mussels; the amount of MAPs required for research is considerably high. Recombinant protein expression technologies have been utilised extensively in an attempt to address this issue during the last decade, however, low product yield, difficulties in purification, and impaired functionalities (compared to native proteins) of recombinant mussel proteins have limited their uses in research and practical applications. Development of recombinant technologies to produce MAPs in bulk quantities with functions comparable to mussel MAPs is on-going. Biomimetics has also been used in the research and development of mussel inspired bioadhesives.

Annex 7: Inventory of Marine Research Infrastructures

Research vessels and underwater vehicles

Research vessels and underwater vehicles tend to be operated by or via a public entity and can offer opportunities for regular scientific activities and cruises. Public operators include public research organisations, public administrations (i.e. vessels dedicated to monitoring activities such surveillance and fisheries stock assessment) and navy vessels. Private operators provide chartering opportunities on an ad hoc basis. There also vessels of opportunities (also called ferry boxes) which are merchant vessels or research vessels which collect measurements on a sporadic basis. Research vessels are categorised by size and classified as global, oceanic, regional or local/coastal vessels. There are more than 240 research vessels[211] operated out of European countries, predominantly in the Atlantic Ocean, the Mediterranean Sea, the Baltic Sea and the Black Sea but also in other seas around the world. Table 0.22 presents an inventory of research vessels in Europe.

EUROFLEETS and EUROFLEETS2 are FP7 funded projects which aims enhance coordination between fleets and works towards an alliance of European research fleets[212].

Table 0.22 Inventory of research vessels and underwater equipment in Europe

	Research vessels			Underwater vehicles			
Country and Sea	Global (>65m)	Ocean / regional (<65m, >35m	Local/coastal (<35m)	ROV	AUV	Manned submersible	USV
Norway -Atlantic	1	5	9	4			
Sweden - Baltic	1	5	4	2			
Sweden - Skagerrak			3				
Denmark - Atlantic	1	2	2				
Denmark - Baltic			2				
Iceland - Atlantic	1	1			1		
Germany - Atlantic	5	9	10	4	3	1	
Germany - Baltic		3	2				
Netherlands - Atlantic	3	2	6			1	
Belgium - Atlantic		3		3			
UK - Atlantic	11	2	19	5	4	5	
Ireland - Atlantic	1		2	3			
France - Atlantic	6	1	5	2	2	2	

[211] Data collected from SEAS-ERA Work Package reports D4.1.1, D6.4.1_2, D7.4.1_2 and D8.4.1 which can be found here: http://www.seas-era.eu/np4/19.html

[212] http://www.eurofleets.eu/np4/home.html

	Research vessels			Underwater vehicles			
Country and Sea	Global (>65m)	Ocean / regional (<65m, >35m	Local/coastal (<35m)	ROV	AUV	Manned submersible	USV
France - Med		1	4				
France - other			3				
Spain - Atlantic	4	4	4	2	2		
Spain - Med		2	2				
Spain - mix			3				
Portugal - Med	2	1	8	9	5	1	5
Italy - Med	2	3	11	4	2		4
Malta - Med			1				
Slovenia - Med			1				
Croatia - Med		2	6	1			
Greece - Med		3	3	4		1	
Greece - Black Sea		1	1	3		1	
Cyprus - Med			4				
Turkey - Med		6	4		1	1	
Turkey - Black Sea	1	5	8				
Turkey - mix			2				
Israel - Med			3				
Bulgaria - Black Sea		1	2			1	
Georgia - Black Sea			1				
Romania - Black Sea	1		3				
Russia - Black Sea	7	1		3		4	
Ukraine - Black Sea	1			1			
Sub-total	48	63	138	50	20	18	9
Total	**249**			**97**			

Data compiled from SEAS-ERA SEAS-ERA Work Package reports D4.1.1, D6.4.1_2, D7.4.1_2 and D8.4.1 which can be found here: http://www.seas-era.eu/np4/19.html

Experimental facilities for biology and ecosystem studies

These facilities are subdivided according to their specialised field and consist of marine biology stations with genomics facilities, aquaculture experimental facilities, mesocosm facilities and ecosystems and biodiversity observatories. Of most significance to marine biotechnology are the marine biology stations with genomics facilities which offer the following 'services':

- Access to analytical platforms in relation 'omics' such as genome sequencing, microarray, 2D-gel electrophoresis, gas chromatography and mass spectrometry;
- Access to model marine organisms, culture collections and databases;
- Cultivation of micro- and macro-organisms;
- 'Mining' of genomes and novel molecules;
- Novel knowledge on biological mechanisms and complex disciplines;
- Integration of marine biology with other biological sciences i.e. biomedicine;
- Marine biology stations with genomics facilities produce a range of outputs including: molecular data, gene functions, functional genomics, protein structures, metabolic pathways and cellular, physiological, evolutionary or ecological knowledge.

Ecosystem and biodiversity observatories also support marine biotechnology in their research on biodiversity from genes to ecosystem functioning and the analytical tools used in particular metagenomics. There are some 29 marine biology stations with genomics facilities in Europe[213], an inventory of 24 these is presented in Table 0.23 .

European networks, projects and initiatives have been established for experimental facilities (i.e. research laboratories). With regards to marine biology stations with genomics facilities the most significant of these are ASSEMBLE[214] and the more recently established European Marine Biological Resource Centre (EMBRC)[215], which was established under the European Strategy Forum on Research Infrastructures[216] (ESFRI) and is in its preparatory phase.

Table 0.23 An inventory of marine biology stations with genomics facilities in Europe

Country	Number	Name(s) of marine biology stations with genomic facilities
Norway	1	Sars International Centre for Marine Molecular Biology
Sweden	2	The Sven Lovén Centre for Marine Sciences: Tjärnö.
		The Sven Lovén Centre for Marine Sciences: Kristineberg
Germany	3	Max Planck Institute for Marine Microbiology (MPIMM), Bremen.
		Alfred Wegener Institute (AWI)
		European Molecular Biology Laboratory (EMBL), Heidelberg
UK	4	Scottish Association for Marine Science (SAMS)
		University of St Andrews - Scottish Oceans Institute (SOI)

[213] This figure is taken from SEAS-ERA Work Package report D4.1.1 which can be found here: http://www.seas-era.eu/np4/19.html
[214] http://www.assemblemarine.org/
[215] http://www.embrc.eu/
[216] ESFRI is a strategic instrument created in 2002 by the European Commission and the Member States to support a coherent and strategy-led approach to policy-making on research infrastructures in Europe and to facilitate multilateral initiatives leading to a better use and development of research infrastructures. http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri

Country	Number	Name(s) of marine biology stations with genomic facilities
		Marine Biological Association of the United Kingdom (MBA)
		University of Bangor Wales
Ireland	2	The Marine Institute, Microbial Oceanography Research Unit
		University College of Cork - Aquaculture & Fisheries Development Centre (AFDC)
France	4	Marine Biological Station of Roscoff
		Marine Biological Station of Concarneau - Operated by the MNHN
		Observatoire océanologique - Banyuls-sur-mer
		Observatoire Océanologique - Villefranche sur mer
Spain	3	Marine Biological Station of A Graña
		Molecular biology and genetic laboratory – CEAB - Blanes
		ZOOMAR - Marine Zoology Unit – ICBIBE – Univ. Valencia
Portugal	1	Center for Marine Sciences (CCMAR), Faro
Italy	1	Stazione Zoologica Anton Dohrn, Naples
Slovenia	1	Marine Biology Station (MBS), Piran
Greece	1	Institute of Marine Biology and Genetics (IMBG)
Israel	1	Interuniversity Institute (IUI) for Marine Sciences, Eilat
Total	**24**	

Data compiled from SEAS-ERA SEAS-ERA Work Package reports D4.1.1, D6.4.1_2, D7.4.1_2 and D8.4.1 which can be found here: http://www.seas-era.eu/np4/19.html

Marine data facilities

Marine data facilities play key role in archiving marine data, data management and making this data widely available. Marine data facilities include computing and modelling facilities, data storage and data dissemination. Data storage can be the electronic storage of information i.e. databases or the physical storage of biological samples i.e. biobanks for future retrieval and use. The use of advanced technologies such as metagenomic analyses and deep sequencing is increasingly adding to large marine datasets. Data management infrastructures provide long term storage and access platforms for the exchange of this data and derived parameters and they also act as a quality control check to standardise data. Data management systems are often big and expensive to run however can often overlooked by non-specialists when considering the field of marine biotechnology. The efficient management of both data and metadata requires harmonisation and the implementation of common standards.

There are more than 40 marine data facilities in Europe, not all marine data facilities in Europe deal with the types of data relevant for marine biotechnology, for example some are concerned only with oceanographic or fisheries data. An inventory of marine data facilities is presented in Table 0.24 . This study identified that approximately 16% of marine data facilities in Europe are directly involved in data management and integration for marine biotechnology currently.

A number of networks and initiatives have been established in Europe to ensure the harmonisation and integration of marine data and access to it. Those of interest to marine biotechnology are:

- SEADATANET[217]: the open and operational network of all thematic/regional marine data centres;
- EMODNET[218]: towards an European public service of marine data for all users, access free;
- WISEMarine[219]: a comprehensive and shared European data and information management system for the marine environment;
- ELIXIR[220]: pan-European research infrastructure for biological information funded by FP7.

Table 0.24 Inventory of marine data centres in Europe

Country	Number	Name(s) of marine data providers	**Data Type:** M=Marine O=Oceanographic, F=Fisheries Data, Ma=Maritime
Norway	2	Institute of Marine Research (IMR) (at National level)	M
		Biobank of Arctic Marine Organisms (MarBank)	M
Sweden	1	Swedish Meteorological and Hydrological Institute (SMHI) (at National level)	O
Denmark	1	Marine scientific data centre (M-FDC) Danish Meteorological Institute (DMI) Centre for Ocean and Ice	M
Iceland	1	Maritime research Institute (MRI)	F
Germany	3	BSH	O
		AWI	Ma
		MARUM (PANGAEA)	M
Netherlands	2 (NODC encompasses 8 institutes)	National Oceanographic Data Committee (NODC)	O
		MARIS (private company)	O
Belgium	2	MUMM - Belgian Marine Data Centre (BMDC),	O

[217] http://www.seadatanet.org/
[218] http://www.emodnet.eu/
[219] https://webgate.ec.europa.eu/maritimeforum/category/554
[220] http://www.elixir-europe.org/

Country	Number	Name(s) of marine data providers	Data Type: M=Marine O=Oceanographic, F=Fisheries Data, Ma=Maritime
		Flemish Marine Data and Information Centre (FMDC) - VLIZ	O
UK	1	NERC/BODC (also : NEODC for earth obs. data and BADC for atmospheric data)	M
Ireland	1	Maritime Institute (MI) (incl. 5 data banks)	O
France	8	IFREMER-SISMER (incl. 10 data banks)	O
		IFREMER-CORIOLIS	
		SHOM	
		CLS	
		MERCATOR	
		BRGM	
		CDG/CNRS	
		ACRI-ST	
Spain	5	IEO	O
		UTM-CSIC	O
		UB	M
		IGME	O
		STARLAB	O
Portugal	1	IH (incl. 7 data banks)	O
Italy	9	OGS	O
		ENEA	O
		INGV	O

Country	Number	Name(s) of marine data providers	Data Type: M=Marine O=Oceanographic, F=Fisheries Data, Ma=Maritime
		CNR-IAMC	M
		CNR-ISAC	O
		CNR-ISMAR	O
		JRC-ISPRA	O
		CMCC	O
		USAM	O
Malta	1	UoM	O
Slovenia	1	NIB	O
Croatia	1	IOF	O
Montenegro	1	IMBK	O
Greece	2	HCMR/HNODC	O
		National Observatory of Athens, UoA (NKUA /IASA UAT)	M
Cyprus	1	OC/UCY	O
Turkey	2	METU, TUBITAK-MAM	O
Total	46		

Annex 8: Sub-sector specific barriers

Table 0.25 Sub-sector specific barriers to marine biotechnology

Sub-sector	Product area	Type of barrier/bottleneck	Problems encountered	Stage in value chain
Health	Pharmaceuticals	Testing & Safety	To prove stability, safety and the quality of the molecule testing it through various clinical trials is required; clinical trials are lengthy and expensive. In addition, the process is long (between 15 and 20 years) and expensive (various estimates place the cost between USD 500 million and USD 1 billion)[221].	Product Development
		Technical	Industry-wide preference for technology-intensive discovery.	Discovery & Research
Cosmetics	Functional Ingredients	Industry Requirements (Marketing)	Special marketing of purported properties requires the compilation of reasons for efficacy, sustainability and quality and each of these features need specialised proof, tests and certifications.	Marketing & Selling
	Functional Ingredients	Industry Requirements (Safety)	Prerequisites of following regulations have to be fulfilled and services for this supplied to evaluate product safety.	Marketing & Selling
Food	Nutraceuticals	Knowledge Gaps	Limitations to existing knowledge about prolonged use of compounds and its effect on health.	
		Sustainable Supply	High dependence on import partly due to	Manufacture

[221] de la Calle F., 2007, "Marine Genetic Resources: A Source of New Drugs - The Experience of the Biotechnology Sector" Presentation at the conference "Biodiversity and Genetic Resources of the Deep Sea" - ITLOS, Hamburg. Sep, 29th 2007.

Sub-sector	Product area	Type of barrier/bottleneck	Problems encountered	Stage in value chain
			the high costs associated with cultivation of seaweed in Europe.	
Energy	Biofuels (macroalgae)	Technical, economical and environmental	Supplying macroalgae from open-sea "farms" is reliant on mechanised processes under harsh conditions. Only local species could be used. Adding nutrients is difficult within ecological constraints.	Manufacture
	Biofuels (microalgae)	Extraction	The need for oxygen removal in closed (photo bioreactor) systems and CO2 injection in the process water to stimulate the growth rate; The harvest of the very small organisms; The breakdown of the algae cell to free the produced oil/lipids and conversion of the lipids to diesel or bio kerosene that could safely be used in the market.	Manufacture
	Renewable energy processes	Supply	High cost of cultivation and availability of sites for pilots or mass production.	Manufacture
Aquaculture	All	Market opportunities	Public perceptions of the risks associated with biotechnology in the sector	Marketing & Selling
		Policy	There is a low level of recognition of the contribution that marine biotechnology can make to the performance of the sector within policies at the EU level. Needs to be better embedded in CFP, MSFD, WFD and other policies and that the role of MB is	Discovery & Research

Sub-sector	Product area	Type of barrier/bottleneck	Problems encountered	Stage in value chain
			considered within this.	
Marine Environmental Health	Bioremediation	Environmental concerns	Political sensitivities with using genetically engineered microbial biosensors in the natural environment.	Marketing & Selling
	Bioremediation	Limitations to functionality	Oil needs to be in small droplets for it to work therefore solutions to pollution events often have to be multi-layered which can reduce effectiveness of specific marine microbes.	Manufacturing and Development
	Environmental Sensors	Limitations to functionality	Reduced performance in harsh environmental conditions	
	Antifouling	Functionality	The antifoulant needs to be multi-functional for both microfouling and macrofouling.	Development

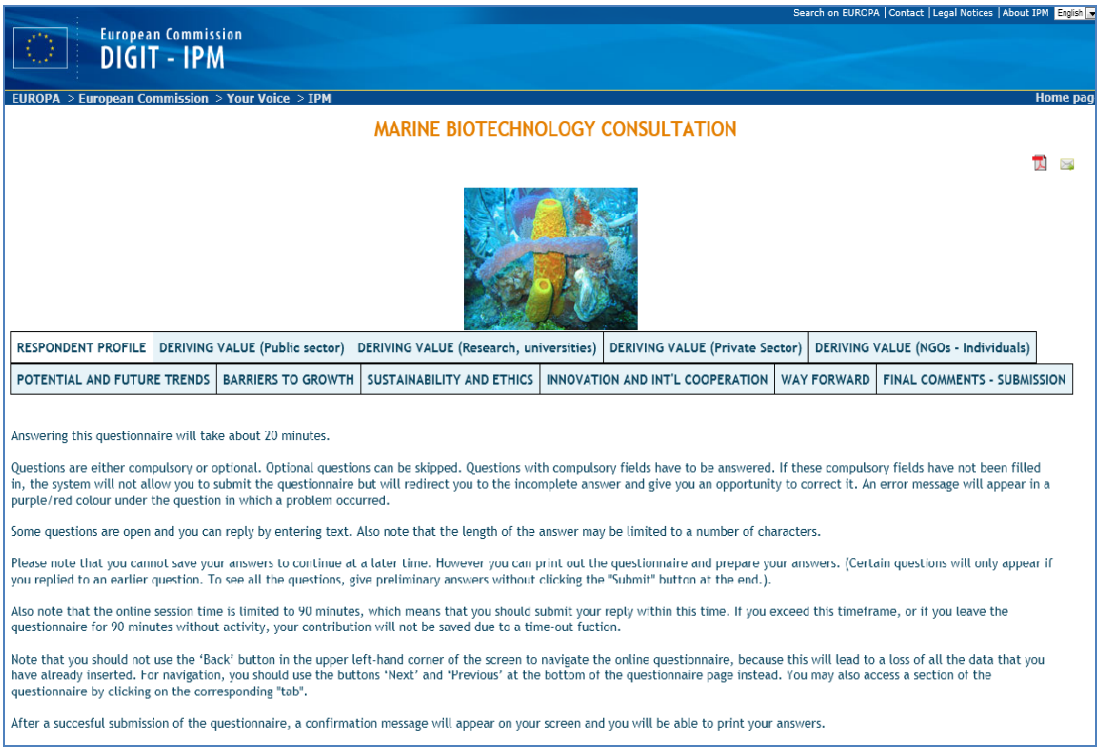
Annex 9: Analysis of the EU's public consultation on Blue Biotechnology

Overview of the consultation

The European Commission launched a public consultation on Blue Biotechnology via the "Your Voice in Europe" website. The consultation was live between the 18th November and the 10th of February.

Questions on the consultation were grouped according to themes e.g. future trends, barriers to growth etc. Additionally private and public organisation, once identifying themselves were offered specific questions relevant for their areas of activities. The questions and the thematic structure of the consultation has been tested on-line by the consortium. The following figure illustrates the opening page of the consultation.

Figure 0.32 Screenshot of the main page for the public consultation



The Blue Biotechnology stakeholder database was used to promote the public consultation. Over 280 stakeholders have been notified via emails about the launch of the consultations, encouraging them to participate.

The study team has used a personalised approach which allowed us to address the individual stakeholders by their name. The mail merger technique has allowed us to derive contact information such as name and email address from the stakeholder database and apply it to a standardised email thereby personalising the message. The contact email has also contained a link to the accreditation letter, provided by the European Commission.

A number of replies have been received from the stakeholders contacted containing either questions regarding the online consultation or information on their projects and possible relations to the EC agenda. The study team has followed up on these individual replies to make sure stakeholders receive the information requested. Furthermore we have disseminated information on these responses to the wider study team.

Responses received

Results and statistics of the public consultation have been downloaded on the 19th of February which has showed 84 responded have filled out the questionnaire. Several stakeholder groups were represented, to the largest extent individuals and research centres have responded. The following table provides an overview on the composition of the respondents.

Table 0.26 Stakeholder Groups

Stakeholder group	Number of responses	% of total
As an individual/private person	25	29.76%
On behalf of a Public Authority	13	15.48%
On behalf of a Civil Society Organisation	0	0.00%
On behalf of a Private Enterprise	13	15.48%
On behalf of an Academic/research institution	23	27.38%
Other	10	11.90%

Based on the above statistics it seems that responses were evenly distributed amongst the main stakeholder groups with an almost equal share of respondents from academia and private enterprises. With regard to the country of origin responses were received from 16 EU Member States and several other countries including Norway, Turkey, Switzerland and Monaco. Stakeholders in France and Germany have provided the highest number of responses, 18 and 10 respectively.

Business operations of respondents

Following on from the generic questions more specific ones followed to establish the business profile of the respondents. Companies and research centres were asked to indicate the thematic field of their activity and the types of products they are developing. The Table below summarises their responses.

Table 0.27 What products and processes you seek develop

Products/processes	Research centres	Private enterprises
Health and wellbeing applications: e.g. Drugs, Neutraceuticals	42.86%	22.62%
Functional foods	28.57%	13.10%
Energy applications e.g. biofuels	20.24%	11.90%
Cosmeceuticals	32.14%	19.05%
Industrial processes: e.g. Fine chemicals/Enzymes/biomaterials	39.29%	15.48%
Environmental applications e.g. Bioremediation, Sensors	32.14%	16.67%

With regard to the sources of the biomaterials both private and public research centres pointed to the Atlantic Ocean, the North Sea and the Mediterranean Sea albeit to varying degrees. The below two tables illustrate the main locations of biosourcing.

Table 0.28 At what depth are the bioresources your work with?

Sources	Research centres	Private enterprises
Atlantic Ocean	45.24%	20.24%
North Sea	19.05%	5.95%
Baltic Sea	11.90%	1.19%
Mediterranean Sea	33.33%	10.71%
Black Sea	5.95%	1.19%
Indian Ocean	14.29%	10.71%
Pacific Ocean	22.62%	8.33%
Other	5.95%	3.57%

Results to the question “at what depth are bioresources found?” indicate that stakeholders are increasingly engage in work at greater depths with 45% of research centres marking benthic and 33% marking the pelagic zones as focal areas of activities. Similarly for private enterprises the benthic and pelagic zones retuned the highest figures 19% and 11% whole the largest number of respondent (34%) did not provide an answer.

The level of depth where bioresourcing takes place is important from the stand point of research infrastructure and financing as greater water depths often require the use of autonomous underwater vehicles (AUVs) or remotely operated vehicles (ROVs), which can increase the costs of research. The following table illustrates the responses of public and private stakeholders regarding the use of the different types of infrastructures.

Table 0.29 What infrastructure do you make use of?

Sources	Research centres	Private enterprises
Laboratories	59.52%	30.95%
Research vessels	38.10%	10.71%
Remotely operated vehicles (ROVs)	14.29%	5.95%
Autonomous underwater vehicles (AUVs)	4.76%	3.57%
E-infrastructure (specify)	19.05%	3.57%
Biobanks	27.38%	8.33%
Screening facilities	30.95%	16.67%
Observation platforms	8.33%	0.00%
Other	3.57%	3.57%
N/A	-	16.67%

Responses indicate that research centres may have more access to state-of-the-art research infrastructure than private enterprises. This could prove to a significant barrier for private companies who wish to commercialise their products. Consequently collaboration and the sharing of available knowledge and infrastructure can be vital. The following questions have explored the potential for collaboration within the sector.

Table 0.30 Who do you collaborate with?

Partners	Research centres	Private enterprises
Other research institutes	60.71%	32.14%
Universities	59.52%	33.33%
Private companies	57.14%	26.19%
Other	5.95%	1.19%

The results show that research centres have an extensive and varied collaboration network. Less widespread are the contacts of the private enterprises especially the inter-company collaborations (26.19%). Together with the lack of access to research infrastructure, the limited collaboration can effectively slow down the sector development and prevent companies from reaching the next milestone in their product development.
Finally questions regarding financing and access to funding have also been posed to the stakeholders.

Table 0.31 How do you currently finance your research/product development?

Sources	Research centres	Private enterprises
Through research councils	36.90%	14.29%
Other public funds	47.62%	21.43%
EU funding	50.00%	21.43%
Private funding	32.14%	17.86%
Other	3.57%	1.19%

Responses indicate that research centres might benefit to a larger extent from the available financial support mechanisms. Based on the stakeholder opinions there seems to be a clear distinction between the ability of the stakeholder groups to access these financing mechanisms. In the case of research council grants and funds this contrast might partially be explained by the somewhat limited collaboration between enterprises and research centres. On the other hand enterprises seem to have experienced limited benefits from EU funding with only 21.43% of the respondents indicating any involvement. In the case of small and medium size enterprises capacity and availability of personnel to handle the administrative strains of grant and tender applications can limit their involvement. Collaboration between enterprises can lead to sharing of tasks which in turn can contribute to a more efficient management of time and capacity.

Perceived barriers to growth

Stakeholders have been asked to rank what they consider to be the main barrier in the commercialisation of products. In both categories a number of barriers have been identified by the European Commission and respondents have been asked to mark their importance on a scale of 1-7 where 1 is the most and 7 is the least important.

Our analysis is twofold, on the one hand we have looked at what respondent have marked as the most significant barrier and in the next stage we have compared the findings with the percentage of responses that have ranked barriers as being 1-4 place. While we do not expect the rankings of barriers to be fundamentally different, however the numbers behind the individual barriers can be stronger, more pronounced if we look at how many stakeholders have ranked a specific challenge amongst the first four.

Table 0.32 Market application: What are the greatest challenges in bringing marine biotechnology applications into the market? (% of responses)

Barriers to market application	Ranked as the most significant barrier (1st place)	Ranked among as an important barrier (1st to 4th place)
Access to finance	27.57%	63.10%
Legal framework (e.g. administrative hurdles related to product development, intellectual	20.24%	47.62%

property rights and ownership barriers)		
High risk involved	7.14%	40.48%
Lack of knowledge (by traditional biotechnology players) about the potential of marine genetic resources for biotechnology applications	5.95%	32.14%
Lack of collaboration including between academic and industrial partners / difficulty in finding partners for collaboration	5.95%	30.95%
Lack of established marine biotechnology value chains or entry points in the already existing ones	2.38%	30.95%
Lack/absence of support mechanisms (e.g. innovation incubators, etc.)	2.38%	28.57%
Capacity shortage (e.g. suitably trained personnel, etc.)	1.29%	21.43%
Lack of visibility of the sector	4.76%	17.86%
Other	1.19%	5.95%

Access to finance has been identified as the most challenging aspect within the sector, followed by legal framework and high risk. All three aspects are marked more significantly when taking into consideration responses placing them onto 2nd to 4th place. The increase in significance is especially pronounced for high risk which was marked by 7% of the respondent as the most important aspect but more than 40% placed it as being among the 4 most important challenges. Meaning over five times as many respondents.

Lack of knowledge and lack of collaborations have also been prominent aspects of sector challenges and as pointed out above, might be interlinked.

The open question has provided stakeholders to identify additional barriers, the following list summarises the most common responses:

- *As with any emerging sector, there are challenges in attracting funds to support early stage developments, particularly where there is a need for further basic research. It appears unlikely that a dedicated marine biotechnology value chain will result: rather existing value chains will absorb marine origin materials;*
- *There is a lack of finance and also a lack of a "bigger" strategic picture;*
- *Lack of collaboration, lack of knowledge by traditional players, lack of support mechanisms, legal frame work and financing are all major problems;*
- *MBT, like modern biotechnologies, needs long product development time (average 10 years) and substantial capital, especially for the development of new drugs (e.g. antibiotics, anti cancer...);*
- *Legal framework: also difficult for the human health sector as is financing of the projects. Risk: The notion of risk is present, especially in the human health sector but no more than in non-marine biotechnology innovation areas;*
- *The lack of framework beyond the national jurisdiction raises questions about ownership, access to the bioresources and the sharing of the benefits to be obtained… Bottlenecks in the marine pharmaceutical pipeline include insufficient funding for basic marine pharmacology and technical challenges for the characterisation of unknown taxa and gene functions (OECD, p.32).*

The following table summarises the responses of stakeholders with regards to challenges in research.

Table 0.33 Research and Innovation: What are the greatest challenges encountered in research?

Barriers to market application	Ranked as the most significant barrier (1st place)	Ranked among as an important barrier (1st to 4th place)
Lack of funding	50.00%	72.62%
Lack of collaboration including between academic and industrial partners / difficulty in finding partners for collaboration	8.33%	63.10%
Research infrastructure	4.76%	59.52%
Capacity shortage	3.57%	40.48%
Legal framework (e.g. administrative hurdles related to product development, intellectual property rights and ownership barriers)	8.33%	39.29%
Lack of access to marine genetic resources or sufficient amounts of marine organisms for downstream biotechnology research and development (e.g. sampling, repositories, biobanks)	5.95%	38.10%
Other	2.38%	4.76%

Similarly to the previous results funding was identified as one of the major obstacles. Lack of collaboration, research infrastructure and capacity shortage have also been marked as key barriers by stakeholders. With regards to collaborations responses provided to the open responses identified a widening base for industry academia partnerships as key to the future development of the sector. The following list provides selected examples for the most frequently reoccurring responses:

- *Early collaboration between industry and academia: Industry-academic partnerships should be encouraged early in the process to support co-development of knowledge and innovations in the market place. This is to ensure that the products of marine biotechnology research are suitable for scaling up to industrial production. Collaboration is needed on an international level (ERA-net Marine Biotech , including third countries;*
- *Three factors influence research in the marine biotech space – the availability of research funds, underdeveloped links between public sector researchers and commercial industry and awareness of major successes delivered/enabled by marine biotech related activity;*
- *…the biggest bottleneck is the shortage of qualified personnel. However, it would be useless to train people without supporting them with access to a research infrastructure…Progress in the field will come from empowering people through training and access to research infrastructure, as well as structures favouring networking.*

Conclusions

A brief overview of the responses given indicates a clear need for a transparent and structured legislative background for the industry. While developing such a legislative background might take considerable resources in terms of both time and capacity from the policy makers the industry is expected to progress further.

While it is clear that infrastructure and expertise are both present in Europe, the expected development of the Blue Biotechnology industry could be facing setbacks caused partially due to the lack of clear definitions and the fragmentations within the sector. Blue Biotechnology, a sector which in itself has a relatively low contribution to the European economy, has strong links to - and been partially developed through research with - the pharmaceutical, the cosmetic and the food industries. A large proportion of research and product development is linked to multinational companies operating in these industries whose overall prospects, future trends and investment potential can result in profoundly different future outlooks for the sub-sectors within Blue Biotechnology.

Furthermore, access to finance and lack of collaborations between public and private actors have been identified as fundamental barriers by the stakeholders. In contrast to research centres and academia, where responses indicate that accessing research grants and other financial support is not seen as a challenge, private enterprises face difficulties to generate the necessary financial background. Moreover, the majority of research centres (57.14%) have identified private enterprises as one of their key partners in research and product development while this was not confirmed in the responses of the companies (with only 26.1% listing research centres as partners). One potential explanation could be that research centres and academia are working together with a set base and a limited number of private partners. This could potentially inhibit the ability of newly established companies to join in on research partnerships, consortiums and access information flow as well as public research financing.

Despite the obstacles an overwhelming 94% of the respondents believe that Blue Biotechnology has a strong potential to grow in the future. In terms of ranking the different sub-sectors, stakeholders consider that health and wellbeing has a *very-high* or *high* potential (84.52%) for future development, with fisheries and aquaculture (70.24%) and energy (57.14%) following closely.

Annex 10: EU Framework Programmes for Research

Table 0.34 Inventory of FP6 projects relating to marine biotechnology

Project*	EC contribution (€)	Coordinating Country	Action type
Fish&Chips	1,599,872	Germany	Specific Targeted Research Project
MARBEF	8,707,000	Netherlands	Network of Excellence
MARINE GENOMICS	10,000,000	France	Network of Excellence
HERMES	14,999,974	UK	Integrated Project
SPONGES	1,441,901	Germany	SMEs-Co-operative research projects
AQUABREEDING	236,614	Italy	Specific support action
AQUAFUNC	177,120	Sweden	Specific support action
BIODIVERSA	2,837,440	France	Coordination action
ERATS	178,683	Sweden	Marie Curie

*Project details are available from Collaborative Working Group on Marine Biotechnology[222]

Table 0.35 Inventory of FP7 projects relating to marine biotechnology

Project*	EC contribution (€)	Coordinating Country	Action type
BAMMBO	2,992,421	Ireland	FP7-KBBE research project
BLUEGENICS	5,999,869	Germany	FP7-KBBE research project
MACUMBA	8,999,948	Netherlands	FP7-KBBE research project
MAREX	5,999,974	Finland	FP7-KBBE research project
POLYMODE	5,999,948	Germany	FP7-KBBE research project
SUNBIOPATH	2,998,182	Belgium	FP7-KBBE research project
MARINE FUNGI	2,999,898	Germany	FP7-KBBE research project
SPLASH	8,942,933	Netherlands	FP7-KBBE research project

[222] Coordinated Working Group on Marine Biotechnology (CWG-MB), 2009, 'Background and recommendations on future actions for integrated marine biotechnology R&D in Europe', http://ec.europa.eu/research/bioeconomy/pdf/cwg-mb_to_kbbenet_report_final.pdf

Project*	EC contribution (€)	Coordinating Country	Action type
BIOCLEAN	2,995,988	Italy	FP7-KBBE research project
SPECIAL	2,991,682	Portugal	FP7-KBBE research project
MAMBA	2,875,245	UK	FP7-KBBE research project
microB3	8,987,491	Germany	FP7-KBBE research project
PharmaSea	9,465,907	UK	FP7-KBBE research project
SEABIOTECH	7,461,716	Belgium	FP7-KBBE research project
Ulixes	2,993,812	Italy	FP7-KBBE research project
Natpharma	809,710	Italy	regpot
Coreshell	856,022	Germany	Marie Curie
MARINEBIOTECH	999,870	Norway	CSA
MARBIOTEC*EU-CN*	680,400	Germany	Marie Curie
BEADS	1,112,388	UK	FP7 SME
ERA NET MB	1,999,838	Norway	coordination action (ERA net)

*Project details are available from European Commission[223]

[223] EC, 2012, Interim Catalogue of Marine related Projects, FP7 - COOPERATION - THEME 2, http://ec.europa.eu/research/bioeconomy/pdf/interim_catalogue_of_marine_projects-2012_en.pdf

Annex 11: National initiatives and clusters

Table 0.36 National initiatives and clusters

Country	Initiative / cluster	Description
France	ALLENVI Groupe Mer	Association
	Biogenouest	Platform
	CapBiotek - Regional Cluster in Biotechnologies in Brittany [16]	Regional clusters
	Atlanpole Blue Cluster - Regional Cluster in Biotechnologies in Pays de la Loire[17]	Regional clusters
	Pole Mer Bretagne - Global economic competitiveness cluster in Brittany[18]	Regional clusters
	Pole Mer PACA - Global economic competitiveness cluster in Provence-Alpes-Côte d'Azur[19]	Regional clusters
	Europole Mer "Blue Network" - an informal coordination structure with about 20 members with one of the focal areas (Axe 1) on marine genomics and blue chemistry (related to biotech)	Regional clusters
Norway	Biotech North: BioTech North is the network organisation for the development of biotechnology in the Tromsø region in North Norway.	Regional clusters
	Mabcent-SFI: Center for research based innovation on bioprospecting in Tromsø where academic research groups and SMBs collaborate on defined research topics for innovation.	Regional clusters
	MarBank: A national marine biobank organising the collection, and structuring of the marine biodiversity for research and industrial development.	Regional clusters
Spain	Spanish Biomass Technology Platform One the priorities of the Strategic Plan of this platform is the production of biofuel from microalgae. [13]	Platform
	PTEPA is the Spanish Platform for Fisheries and Aquaculture Research. This platform has develop a SRA [14]	Platform
	Genoma Spain is a government-supported public foundation devoted to promoting technology development, knowledge transfer and innovative practices, chiefly in the biotechnology sector.	Foundation
UK	The European Centre for Marine Biotechnology aims to be the business incubator of choice for new and emerging marine biotechnology companies in the UK. By establishing a growing cluster of activity and international networks it strives to be the premier site for innovative growth and development within this emerging sector.	Regional clusters
	AB SIG, the Algal Bioenergy Special Interest Group	Association
Belgium	Flemish Marine biotechnology Platform Mariene Biotechnologie Platform Vlaanderen	Platform
	The network Aquacultuur Vlaanderen	Platform
Denmark	The Seaweed Network in Denmark (SND)	Association
Germany	Northern network on marine biotechnology	Association
Iceland	Association of Biotech companies defined by the Federations of Icelandic Industries	Association

Annex 12: EU and regional initiatives and networks

Table 0.37 EU initiatives and networks

Name	Partners	General Description	Website
EU Joint Programming Initiative Healthy and Productive Seas and Oceans (JPI-OCEANS)	JPI Oceans covers all European sea basins with 19 participating countries	JPI-OCEANS is a regional co-ordinated approach to investment which provides a model for resource sharing and the co-creation of knowledge. Its aim is to increase the value of national R&D investments in ocean research in the Europe Union in order to avoid fragmentation and unnecessary duplication of R&D, to look for synergies, and to facilitate different types of co-operation to meet policy objectives and global challenges. It focuses on the development of new bioactive products for health treatments; biotechnology applied to aquaculture; biofuel from marine algae; screening of marine genetic diversity; development of marine biosensors to monitor the environment; and mitigation of human and climate change impacts on the ocean	http://www.jpi-oceans.eu/
European Marine Biological Resource Centre (EMBRC)	13 partners and 7 associate partners	It brings 12 leading marine stations and EMBL together. These institutes study marine organisms (microbes, plants, animals) with the latest technologies to study our seas. EMBRC wishes to give access to these organisms and techniques to the scientific community at large, including universities and industry. EMBRC aims at delivering services to the marine community and increasing numbers of scientists who have turned to marine model organisms to investigate fundamental questions in biology such as: *Provide access to European coastal marine biota and their ecosystems, *Provide an integrated supply of marine model species, for multidisciplinary research, *Offer state-of-the-art research services, *Disseminate knowledge to stakeholders and the general public, *Offer interdisciplinary training in marine biological sciences and marine genomics, *Promote synergies among End-Users (academia and industry) across the life-sciences with the ERA	http://www.embrc.eu/
CSA MarineBiotech	11 partners from 9 European countries.	Part of FP7. Introduction of concrete steps for increasing the networking of research in the field of marine biotechnology in Europe, in order to create synergistic effects in the development of marine biotechnology. The aim of the CSA MarineBiotech project is to lay the foundations for the ERA-NET in marine biotechnology, in order to establish a coordinated European research area in the field of marine biotechnology.	http://www.marinebiotech.eu/

Name	Partners	General Description	Website
The Knowledge Based Bio-Economy Network (KBBE-NET)	EU Member States and associated countries to FP7.	The main role of the KBBE-NET is to support the European Commission and EU Member States to achieve a coordinated approach for the development and implementation of a European research policy related to the Knowledge Based Bio-Economy (KBBE). It acts in coordination with the Standing Committee on Agricultural Research (SCAR). KBBE-NET objectives are: strategic discussion and recommendations for establishing a long-term European Research Agenda (FP7 and beyond) which should allow the building of a European Knowledge Based Bio-Economy; exchange of information between Member States regarding national research policies and mapping of activities, including international cooperation and cooperation between Member States (in relation to launching joint research programmes, common infrastructures, and training programmes as appropriate).	http://ec.europa.eu/research/bioeconomy/policy/coordination/kbbe_net/index_en.htm
European Research Area Network (ERA-NET)		Promote and coordinate collaboration between national and regional research funding organisations and programme administrators (e.g., project sponsors) in strategically important thematic areas at the European level. CSA MarineBiotech project has been working on setting up an ERA-NET in marine biotechnology in Europe. The aim of the ERA-NET in marine biotechnology is to set up a common research infrastructure in the field of marine biotechnology to counteract the fragmentation of the European research area in this field. SEAS-ERA initiative is to coordinate the national and regional R&D programmes in the field of marine and maritime research. This initiative thus also affects the development of marine biotechnology in Europe “ERA Industrial Biotechnology 2: Towards an ERA in Industrial Biotechnology” (ERA-IB-2). The aim of this initiative is to coordinate national and regional funding programmes in industrial biotechnology to increase European competitiveness in this field. In this context, the provision of a platform for long-term collaboration and the setting up of a network on relevant national and regional programmes, projects and strategies relating to industrial biotechnology are important measures. ERASysBio initiative focuses on establishing a network in the field of systems biology, which also includes marine ecosystems. ERA-NET EuroTransBio. This initiative supports small and medium companies (SMEs) in the field of biotechnology and thus also the field of marine biotechnology	http://www.cordis.europa.eu/fp7/coordination/about-era_en.html

Name	Partners	General Description	Website
Eurofleets (Towards an alliance of European Research fleets)	Lead partner: French Research Institute for Exploitation of the Sea	Aims to bring together the European research fleets to enhance their coordination and promote the cost effective use of their facilities.	http://www.eurofleets.eu/np4/home.html
ASSEMBLE (Association of European Marine Biological Laboratories)		Network of marine research stations which provide transnational access to a comprehensive set of coastal marine ecosystems, research vessels, state of the art experimental facilities and a wide variety of marine organisms. Networking activities are performed to enhance interoperability both within and outside of the ASSEMBLE network. This includes organizing workshops as well as establishing a virtual tool-box and a common database for marine organisms. Joint research is conducted to improve the provision of marine biological and/or ecological models with an emphasis on models for marine genomics.	http://www.assemblemarine.org/
EC Expert Group on Marine Research Infrastructure (MRI)	N/A	The MRI Experts group was set up by the European Commission to identify key MRI needs and gaps and to improve governance at EU level.	

Name	Partners	General Description	Website
European Technology Platforms (ETPs)	Various	Industry-led stakeholder fora charged with defining research priorities in a broad range of technological areas. They are characterised by addressing challenging issues for growth, embodying major technological advances in the medium to long term, creating community added-value, involving high research intensity and requiring a European approach. They are driven by industry, compared with ERA-Nets, which are driven by research funding agencies. In the Knowledge-Based Bio-Economy (KBBE) sector, five ETPs of the total 9 are directly or indirectly relevant for marine biotechnology and utilisation of marine bioresources. Five of the ETPs are directly or indirectly relevant for marine biotechnology and the utilisation of marine resources: *Sustainable Chemistry Technology Platform (SusChem TP) for industrial biotechnology *European Biofuels Technology Platform (Biofuels TP) has an Algae fuels task force *European Aquaculture Technology and Innovation Platform (EATIP) *European Technology Platform 'Food for Life' (Food for Life TP) *European Technology Platform 'Plants for the Future' (Plant TP) – many aspects applicable to marine algae *Bio-Economy Technology Platforms (BECOTEPS), an ETP that grouped the biological platforms together, the has produced a final paper The European Bioeconomy in 2030, which is also relevant.	http://cordis.europa.eu/technology-platforms/
EuroMarine	Lead partner: University of Gothenburg, 3 other partners	Integrates three large European marine networks of excellence (EUR-OCEANS, MarBEF, Marine Genomics Europe), that were funded by the Sixth EU Framework Programme for Research and Development, into a EuroMarine Consortium. EuroMarine will provide a rich and diverse source of the best expertise and innovation available in European marine research that can respond rapidly to societal needs, environmental demands, well-being and sustainability. Integration aims to optimise European marine research, in particular in the fields of biodiversity, genomics and ecosystem modelling. This is to be achieved through the advancement of an interdisciplinary approach to research.	http://www.euromarineconsortium.eu/

Name	Partners	General Description	Website
Marine Genomics for Users (MG4U)	7 partners from 6 EU countries	A coordination action which aims to facilitate knowledge transfer, technology transfer, and technology translation between high-throughput marine genomics, industry and society. Marine genomics has enormous potential to improve our lifestyles and prosperity, and to assist with governance and sustainable management of the marine environment. However, many end users of marine genomics knowledge are not yet aware of how marine genomics hold great potential for problem solving and industrial commercial advantage. Valuable knowledge needs to be made accessible and disseminated in user friendly contexts. MG4U aims to spread results from recent and on-going projects in marine genomics and facilitate rapid, efficient knowledge transfer to generate interdisciplinary research capacity in Europe	http://www.mg4u.eu/
EUR-OCEANS Consortium (EOC)	66 + research organisations	EOC ensures the continuity and further integration of member organisations of the former EUR-OCEANS European Network of Excellence (NoE) and other interested marine research organisations. The aim of the EUR-OCEANS Consortium is to favour joint initiatives between key Research Performing Organisations (RPOs) and Research Funding Organisations (RFOs) across Europe, to help the community make significant jumps in marine sciences during the next decades. This is implemented by organising and sponsoring activities which focus on hot topics only and can lead to wider European (FP8, JPI…) projects. These activities include Gordon-like conferences, flagship programmes, foresight workshops and public outreach. The focus of the Consortium is on the impact of climate/global change on marine ecosystems and biogeochemical cycles, and the construction of scenarios relevant to the emerging International Platform on Biodiversity and Ecosystem Services (ipBes).	http://www.eur-oceans.eu/
Marine KIC Initiative	A large number of partners - industry, universities, research institutes and public actors	Aim is to promote the creation of a Knowledge and Innovation Community focusing on the sustainable development of marine resources. This will promote the competiveness of Europe's RTD-based maritime economy through the European Institute of Innovation and Technology (EIT).	http://www.marinekic-initiative.eu/index.php?sp=en&id=home
ERA-NET Marine biotechnology	In preparation	Part of FP7. ERA-NET in marine biotechnology, in order to establish a coordinated European research area in the field of marine biotechnology. It is in its preparatory phase.	www.marinebiotech.eu

Name	Partners	General Description	Website
FP7 - Seventh Framework Programme for Research and Technological Development	EU Member States and associated countries to FP7.	The most important measure taken by the European Union to promote research and development projects. The programme aims to establish Europe as the global leader in research. The focus of this measure is on research programmes that are characterised by transnational collaboration. The programme covers a variety of thematic areas, such as health, energy and transport. Food, agriculture, fisheries and biotechnology are the thematic areas of relevance to marine biotechnology. * Sustainable production and management of biological resources from land, forest, and aquatic environments. * Development and implementation of strategies to support the European bio-economy. * Masterplan Marine Biotechnology Schleswig-Holstein – a regional development strategy * Supporting life sciences and biotechnology for sustainable non-food products. For example, this also includes (marine) resources for energy production	http://cordis.europa.eu/fp7/home_en.html
The European Strategy Forum on Research Infrastructures (ESFRI)		A strategic instrument to develop the scientific integration of Europe and to strengthen its international outreach. The competitive and open access to high quality Research Infrastructures supports and benchmarks the quality of the activities of European scientists, and attracts the best researchers from around the world. Among 38 infrastructures identified in the last roadmap, 3 are distributed marine research infrastructures (Euro-Argo, EMSO, EMBRC) while 4 others have a substantial marine component (ICOS, LIFEWATCH, ECCSEL, SIOS).	

Table 0.38 Regional and trans-regional initiatives and networks

Name	Partners	Source of funding	General Description	Website
Mediterranean Science Commission (CIESM)	23 Member States	Member states	The CIESM is an international partnership with a regional focus which supports a network of several thousand marine researchers who work towards better understanding, monitoring and protecting the Mediterranean Sea using the latest scientific tools. It promotes communication and active cooperation among marine scientists engaged in research on the Mediterranean and the Black Seas. The CIESM has a Committee on Marine Microbiology and Biotechnology whose areas of focus are ecology and biodiversity of marine prokaryotes (Archaea and Bacteria); viruses and hetero - and autotrophic protists (i.e., phytoplankton); microbial food web interactions; microbial pathogens. Furthermore, has a research programme in Marine Economics Research Program operates under the CIESM which encompasses marine genetic resources and has produced a study looking into the economic models of bioprospecting.	http://www.ciesm.org/
SUBMARINER: Sustainable Uses of Baltic Marine Resources	Strong consortium of partners from all Baltic Sea Region countries	Baltic Sea Region Programme 2007 - 2013 Total budget: €3.6 million (€2.8 million from European Regional Development Fund co-finance and €0.8 million are partners' contributions)	The SUBMARINER project has built the road for furthering environmentally friendly and economically appealing innovative uses of marine resources within the Baltic Sea Region, thus contributing toward its aim to become a model region for sustainable sea management. It has done through the production of a Compendium, development of a Roadmap, the implementation of regional development activities and the building of a network of public and private actors. SUBMARINER recognises Blue Biotechnology as a major use of marine resources in the Baltic Sea Region. Within the framework of the SUBMARINER project Norgenta, the life science agency of Hamburg and Schleswig-Holstein, developed a masterplan for marine biotechnology in Schleswig-Holstein.	http://www.submariner-project.eu/

Name	Partners	Source of funding	General Description	Website
SUBMARINER Network	Ministry of Economic Affairs of the Land Schleswig-Holstein together with the Swedish Agency for Marine and Water Management and the Maritime Institute in Gdańsk	membership fee (EWVIB)	Whereas the initial SUBMARINER project (2010–2013) was run with a limited number of project partners under one singular financial framework, the SUBMARINER Network shall bring together an unlimited range of public and private actors and stakeholders from around the BSR countries, in order to further promote and realise activities necessary for using marine resources innovatively and sustainably. The Network shall serve as an umbrella organisation and as a catalyst for a number of initiatives identified as necessary in the SUBMARINER Roadmap. Submariner network will host the blue biotech networking activities in the Baltic region.	http://www.submariner-project.eu/
ScanBalt® fmba	A large number of partners in the Baltic Sea Region	membership fee	ScanBalt® fmba (in short ScanBalt) is the organisation for the Baltic Sea or Nordic-Baltic Region's Health and Bio Economy community, named ScanBalt BioRegion. ScanBalt is a not-for-profit member association for the BSR life science and health communities. They are a mediation, coordination and communication umbrella and platform for the numerous national and regional triple-helix networks of R&D institutes, public authorities and enterprises that together with individual organisations are the members. The ScanBalt BioRegion is a transnational network in the Baltic Sea Region that is composed of regional life science clusters, universities, hospitals, organisations and companies in the life science sector. The ScanBalt BioRegion mission is to become an innovative region and to promote employment, economic growth and advances in the life sciences sector. ScanBalt has set up a transnational network that is made up of private and public stakeholders in the field of marine biotechnology. This network is designed to improve research quality and infrastructure, as well as joint further training and the dissemination of information within marine biotechnology in the Baltic Sea Region	http://www.scanbalt.org/

Name	Partners	Source of funding	General Description	Website
European Society for Marine Biotechnology	A number of academic partners across Europe	membership fee	The ESMB was established in France on 26th April 1995 to promote marine biotechnology in Europe and to promote closer research collaboration between marine biotechnologists. In addition, the development of methods for effective training and education in the field of Marine Biotechnology is being carried out. Was recently (2012) re-established with a new board. ESMB currently has members in 31 countries worldwide, working in all fields related to marine biotechnology. Membership is open to anyone and no membership qualifications are required. Initiated the Journal of marine biotechnology in cooperation with Springer	www.esmb.org
BioMarine	Various companies	company based with strong support of	**BioMarine©** is the only international platform dedicated to marine bio resources, that brings together executives and CEOs from marine ingredients, marine cosmetics, marine nutraceuticals, aquaculture, aquafeed, marine bio energy, pharmaceuticals and clean tech. It is not only the place of meetings and exchanges for professionals in our industry, but above all it is the strategic centre of action and initiatives for key stakeholders in the marine bioresources sectors. Finance, research and industry have learned to use the platform to diversify their cross-sectorial knowledge, strengthen their existing partnerships and build new opportunities.	http://www.biomarine.org/
BioMarine International Clusters Association	In foundation	To be decided	BICA's mission is to be the champion for marine bio resources and their sustainable and innovative utilization. BICA will federate national and regional marine and biomarine clusters, advocate policies that enable the realization of the marine biotechnology's promise for providing breakthrough products to feed the world, clean the environment, and improve health and nutrition. BICA is unique in that it is a conjugation of a strong international business opportunity and an intensely networked set of marine bio-clusters. BICA will structure the biomarine industry and foster economic development by the creation of international business opportunities and partnerships	http://www.biomarine.org/biomarine-international-clusters-association/

Annex 13: Stakeholder Workshop

The stakeholder workshop was held on Tuesday, 11 February 2014 at Hotel BLOOM in Brussels. An agenda and supporting material was prepared and circulated to attendees. The purpose of the stakeholder workshop was to assess the findings from the public consultation, with a focus on the state of play, drivers and barriers, lines of research, main products and services of the Blue Biotech sector. The workshop also included discussion on emerging policy recommendations.

Our invitation approach for the international stakeholder meeting

In line with the request for services, the stakeholder meeting invited a maximum of 20 people as part of the process supporting a Stakeholder consultation. These stakeholders represented the Blue Biotechnology industry including researchers, private enterprises and financiers.

Stakeholder prioritisation

Using the Blue Biotechnology stakeholder database that was created for this study (see Annex 3) stakeholders were prioritised. The stakeholder database was reviewed carefully balancing regional distribution and stakeholder categories. The following criteria were been applied to the selection process:

1. Professions / sector within the marine biotechnology sector, e.g. academic research (further grouped by number of employees), funding agencies, EU and national policy makers, outreach professionals, research infrastructure;
2. Gender, to ensure inclusion of also female opinions on the sector;
3. Function, i.e. we will focus on leading stakeholders, e.g. company directors, lead researchers. However, where appropriate and available, also on the ground (research) staff will be included, to gather a more comprehensive view on the sector;
4. Geographical spread, to incorporate various viewpoints on the sector that may emerge in different national contexts.

Based on these criteria, a long-list of over 40 stakeholders was established and submitted to the Commission for approval. Following approval from the Commission invitations were sent to the first 22 selected participants. Registration was based on a first-come, first serve basis. This encouraged participants to register early ahead of the conference and served as an additional indicator of the interest of participants to attend. The remaining stakeholder on the long-list served as back-up participants in the event that stakeholders from the top 22 could not attend.

Table 0.39 presents the stakeholders who attended the workshop.

Table 0.39 Stakeholder workshop attendees

Country	Organisation	First Name	Surname
EU	EuropaBio	Nathalie	Moll
Belgium	eCOAST Marine Research	Oonagh	McMeel
Belgium	KDM German Marine Research Consortium	Kati	Michalek
Belgium	JPI Oceans / Ifremer	Florence	Coroner
Belgium	Ecorys	Jan Maarten	de Vet
Belgium	Ecorys	Eszter	Kantor
Belgium	Ecorys	Jakub	Gloser
Belgium	Ecorys	Diletta	Zonta

Country	Organisation	First Name	Surname
Denmark	Technical University of Denmark	Torger	Børresen
EU	BioMarine international Clusters Association	Pierre	Erwes
EU	European Commission - DG Research	Garbiñe	Guiu
EU	European Commission - DG Maritime Affairs and Fisheries	Juan	Ronco
EU	European Commission - DG Maritime Affairs and Fisheries	Petra	Sarapatkova
France	French Research Institute for Exploitation of the Sea (IFREMER)	Jean-François	Masset
Germany	Norgenta GmbH, North German Life Science Agency	Julia	Brilling
Germany	S.Pro – sustainable projects GmbH	Angela	Schultz-Zehden
Germany	S.Pro – sustainable projects GmbH	Antje	Labes
Ireland	National University of Ireland, Galway	Ilaria	Nardello
Ireland	AquaTT	Gillian	Marmelstein
Ireland	Marine Institute	Dermot	Hurst
Malta	AQUABIOTECH GROUP	George	D.Mantas
Norway	RCN (Research Council Norway)	Steinar	Bergseth
Portugal	CCMAR, Universidade do Algarve	Deborah M	Power
Spain	PharmaMar	Fernando	de la Calle
Spain	ZELTIA, S.A.	Elena	García Villaescusa
Spain	CETMAR- Marine Technological Center	Silvia	Torres-López
Spain	AIMPLAS	Marti Ferrer	Ferran
The Netherlands	ECN	André	Wortel
UK	BioBridge Ltd UK	Meredith	Lloyd-Evans
UK	MRAG	Ian	Payne
UK	MRAG	Hannah	Norbury
UK	MRAG	Robert	Arthur

Annex 14: Regulatory Review

Introduction

This annex sets out the findings for Task 1.6, which calls for the preparation of a comprehensive description of the legal framework concerning the Blue Biotechnology sector. At the outset it is to be noted that the legal framework in question is complex, extensive and multi-layered in that it involves aspects of international law (the body of law that regulates the relationship between States and other actors recognised under international law), European Union (EU) law and the national or domestic laws of the Member States as well as third countries.

In terms of its scope it includes, in no particular order, aspects of the law of the sea, intellectual property law, contract law, biotechnology law, product sector regulatory law, liability law and last, but not least, the body of law that regulates the acquisition and use of genetic resources. The terms of reference to the Study provide, however, that special attention should be given to: (a) the exploitation and bio prospecting of marine resources in international waters; and (b) access to marine bio-resources data and information.

Moreover, many of the detailed legal and regulatory issues that form part of the legal framework for the Blue Biotechnology sector apply to biotechnology products in general. Thus, for example, the regulatory requirements necessary to obtain approval for the marketing of Blue Biotechnology pharmaceutical products are, in principle, no different to those necessary for the placing on the market of other biotechnology pharmaceutical products. This annex therefore focuses on the issues that are specifically referred to in the terms of reference and which can truly be said to form part of the Blue Biotechnology sector.

This annex is set out in eight parts, including this introduction. In terms of its order it follows the logical path for the development of Blue Biotechnology products from the initial acquisition of genetic resource through and beyond their introduction on to the market. The starting point is the acquisition of the marine genetic material that provides the basic building blocks for marine biotechnology. The legal rules that regulate this topic are the subject of part two.

A key feature of the international legal framework that regulates access to genetic resources is the notion of ‘benefit sharing’: more specifically access to such resources is provided on the basis that the benefits of such access will be shared with the provider country. Benefit sharing, and in particular recent developments in international (and EU) law concerning this topic are considered in part three.

In the case of Blue Biotechnology, as with other biotechnology sectors, the main ‘product’ from natural resources derives from the genetic information that they contain. Such information is protected through a range of intellectual property rights, which are considered in part four. The issue of benefit sharing is next re-visited in part five in connection with intellectual property rights.

The legal framework for the use, manufacturing and marketing of Blue Biotechnology products is considered in part six while liability issues are considered in part seven. Finally a number of conclusions are drawn in part eight.

Access to marine genetic material

As already noted, the starting point for Blue Biotechnology is the acquisition of genetic material from marine genetic resources (which may include organisms, genes and gene products). In terms of international law, as these are marine resources, this issue is subject both to the law of the sea,

the branch of international law that is concerned with all uses and resources of the sea, and to a more recently developed body of international law that specifically regulates access to genetic resources and the sharing of resulting benefits.

The process of searching for and acquiring genetic material for biotechnology purposes is commonly referred to as 'bio-prospecting'. However while this expression is widely used such usage is not consistent. At one end of the scale the expression is used in a manner not dis-similar to, say gold prospecting or uranium prospecting.[224] For example, a note prepared by the Convention on Biological Diversity Secretariat defines bioprospecting as "the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercial products."[225] At the other end of the scale it is used to include a much broader process involving research, development, manufacturing and marketing of products derived from genetic resources.[226]

The key point to note is that there is no internationally agreed definition of the term 'bio-prospecting'. The next question is whether or not this matters. In a sense it does not in that, as will be seen, a relatively comprehensive legal framework now exists at the international level to regulate this topic. On the other hand, though, the term bioprospecting is one that is in relatively common use its ambiguities notwithstanding.

The basic problem, as noted by Scovazzi, is that there is an 'inextricable factual link between marine scientific research (either pure or applied) and bioprospecting. It is impossible to establish a clear-cut distinction between one activity and the other and between one purpose and the other. A research endeavour organized with the intent to increase human knowledge may well result in the discovery of commercially valuable information and *vice versa'*.[227] As will be seen the tension between scientific research and commercial benefit sharing is at the heart of the challenge.

The legal framework created by the Convention on Biological Diversity

The issue of access to genetic resources was first systematically addressed at the level of international law by the Convention on Biological Diversity[228] (CBD) which was adopted at the Earth Summit in Rio de Janeiro in June 1992 and entered into force just over one year later.
There are 193 parties to the CBD including the EU and the Member States.[229]

While the objectives of the CBD also include the conservation of biological diversity and the sustainable use of its components, the issues of biotechnology and access to genetic resources were at the heart of the negotiating process.[230]

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[224] Or, for that, matter for prospecting for minerals on the ocean floor, an issue that is regulated under the law of the sea.
[225] (UNEP/CBD/SBSTTA/8/INF/3/Rev. 1, para. 68). Similarly, New Zealand's Biodiversity Strategy defines bioprospecting as 'the search among biological organisms for commercially valuable compounds, substances or genetic material'.
[226] See or example the definition of bioprospecting in South Africa's National Environmental Management: Biodiversity Act of 2004 as amended:
"bioprospecting", in relating to indigenous biological resources, means any research on, or
development or application of, indigenous biological resources for commercial or industrial exploitation, and includes-
(a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;
(b)the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities;
(c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; or
(d) the trading in and exporting of indigenous biological resources in order to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils;
[227] Scovazzi, T. 'The Concept of Common Heritage of Mankind and the Genetic Resources of the Seabed beyond the Limits of National Jurisdiction' *Agenda Internacional* Año XIV, N° 25, 2007, at page 18.
[228] Convention on Biological Diversity, Nairobi, 22 May 1992. In force 29 December 1993, 31 *International Legal Materials* 822 (1992); <www.biodiv.org>.
[229] See http://www.cbd.int/convention/parties/list/ accessed on 18-1-14. Andorra, the Holy See, South Sudan and the United States of America are not party to the CBD.
[230] Both terms are specifically defined in article XX of the CBD: biotechnology is defined to mean 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use' while genetic resources are defined to mean 'genetic material of actual or potential value'.

In outline the CBD represents a compromise whereby the developing countries with the highest levels of biodiversity agreed to grant access to their genetic resources and to conserve that biodiversity in return for a share of the benefits. A key concern of the developing countries of the South was to stop what was perceived the misappropriation of genetic resources and associated traditional knowledge by companies from the industrialised countries of the North, a process commonly known as 'bio-piracy'.[231] In other words benefit sharing is a fundamental component of the access regime.

In terms of understanding the CBD, the starting point is the recognition that as States have sovereign rights over their natural resources, national governments also have the authority to determine access to their genetic resources in accordance with the applicable national legislation. Such access must be on mutually agreed terms and subject to the prior informed consent (PIC) of the State providing access in accordance with its laws and procedures. Moreover, States must 'endeavor' to create conditions to facilitate access to genetic resources for environmentally sound uses by other parties.[232]

In return, however, each contracting party to the CBD must endeavor to ensure the participation in scientific research of the State providing the resources and must take legislative, administrative or policy measures with the aim of sharing in a fair and equitable manner the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the State that provided those resources.

Moreover article 19, entitled 'handling of biotechnology and the handling of its benefits', requires each contracting party to take legislative, administrative or policy measures to provide for the effective participation in biotechnological research activities of the countries that provide the genetic resources and to promote priority access on a fair and equitable basis to the results and benefits arising from biotechnologies based on genetic resources provided by those countries, especially developing countries.[233] Such access must be on mutually agreed terms.

While these provisions established basic principles for access and benefit sharing (ABS) they provided little operational guidance.

In 2002 the non-binding Bonn Guidelines were adopted by the sixth Conference of the Parties of the CBD to guide both users and providers of genetic resources in the implementation of the ABS provisions of the CBD. The guidelines also provided an indicative list of clauses to be included in mutually agreed terms, and possible monetary and non-monetary benefits. However although these voluntary guidelines were comprehensive, they were not considered to be very effective.

Consequently a decision was taken that the topic of ABS needed to be addressed through the development of a legally binding protocol to the CBD. After eight years of negotiations the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity' (the 'Nagoya Protocol') was adopted on 29 October 2010.

[231] Chiarolla, C., Lapeyre, R., Pirard, R. Biodiversity conservation: *How can the regulation of bioprospecting under the Nagoya Protocol make a difference?* (2013) Studies N°06/13, IDDRI, Paris, France.
[232] Article 15.
[233] The issue of traditional knowledge associated with genetic resources and the rights of communities associated with such knowledge is also an important aspect of ABS but of less relevance to marine biotechnology.

The Nagoya Protocol opened for signature in February 2011 and will enter into force 90 days after the date of deposit of the fiftieth instrument of ratification. To date there have been 28 ratifications. Although the EU and the Member States signed the protocol they have yet to ratify it. Nevertheless the intention is that this will happen shortly.

Before looking in more detail at the Nagoya Protocol, however, it is first necessary to consider the scope of application of the CBD and the regime that it provides for in the terms of the sea and marine genetic resources.

Article 4 of the CBD provides that the convention applies as regards the 'components of biological diversity', which term although not defined is broad enough to include genetic material, in areas within the limits of national jurisdiction. It goes on to provide, however, that the CBD also applies in the case of processes and activities carried out under the jurisdiction or control of a Contracting Party both within and beyond the limits of national jurisdiction.

Moreover, article 22, which is concerned with the relationship between the convention and other international instruments, explicitly provides that the CBD is to be implemented with respect to the marine environment 'consistently with the rights and obligations of States under the law of the sea'. To understand the meaning of these provisions it is therefore necessary to turn next to the law of the sea.

The law of the sea

The law of the sea is the branch of international law that is concerned with all uses and resources of the sea. The cornerstone of the law of the sea is the 1982 United Nations Convention on the Law of the Sea ('UNCLOS')[234] and its two implementing agreements: the Part XI Deep Sea Mining Agreement[235] and the UN Fish Stocks Agreement.[236] UNCLOS entered into force in November 1994 and the EU and all of the Member States are party to it.

The over-arching objective of UNCLOS is to establish a universally accepted, just and equitable legal order - or 'Constitution'[237] - for the oceans that lessens the risk of international conflict and enhances peace and stability in the international community.[238] The development of UNCLOS required a balancing exercise between the competing interests and capacities of States. As with the development of the CBD, the negotiation of UNCLOS took place against competing claims from so-called developed and developing countries both seeking to defend their interests. A major point of contention concerned the rights of States over the mineral resources of the ocean sea bed. However the existence of marine genetic resources there and their possible economic value was unknown at the time. [239] This explains why the issue of marine genetic resources is not expressly addressed in UNCLOS.

Part of the balancing exercise of UNCLOS is provided by the system of maritime zones that it provides for and rules that govern activities that may take place there.[240] Notwithstanding its 'constitutional' aspirations it should be noted that a number of States are not party to UNCLOS

[234] United Nations Convention on the Law of the Sea, Montego Bay, 10 December 1982. In force: 16 November 1994, 1833 *United Nations Treaty Series* 396; <www.un.org/Depts/los>.
[235] Agreement relating to the Implementation of Part XI of the United Nations Convention on the Law of the Sea of 10 December 1982New York, 28 July 1994. In force 28 July 1996, 33 *International Legal Materials* 1309 (1994); <www.un.org/Depts/los>.
[236] Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks New York, 4 August 1995. In force: 11 December 2001, 2167 *United Nations Treaty Series* 3; <www.un.org/Depts/los>.
[237] Remarks by Tommy Koh, Chair of the Third United Nations Conference on the Law of the Sea (UNCLOS III).
[238] See the fifth preambular paragraph UNCLOS.
[239] Bonfanti, A. & Trevisnaut, S. *Intellectual Property Rights Beyond National Jurisdiction: Outlining a Regime for Patenting Products Based on Marine Genetic Resources of the Deep-Sea Bed and High Seas Draft* paper presented at the Third Annual Meeting of the Society for Environmental Law and Economics Amsterdam, June 24-25, 2011 at page 3
[240] In addition to the maritime zones discussed below UNCLOS also contains provisions other types of maritime zone which are not relevant to the discussion.

including the USA.[241] Nevertheless many of its provisions, including those on maritime zones, are generally accepted to be declaratory of customary international law and thus of general application.

Maritime zones under UNCLOS

The starting point for understanding, and for that matter measuring, the maritime zones of a coastal State are the 'baselines', which are to be determined in accordance with UNCLOS.[242] The 'normal' baseline is the low-water line along the coast as marked on large-scale charts officially recognized by the coastal State.[243] However, in some specified circumstances a coastal State may draw a 'straight baseline' such as, for example, across the mouths of rivers and bays.[244]

UNCLOS recognizes that each coastal State has sovereignty over its internal waters which are the waters contained in ports, rivers, estuaries and lagoons that are landward of the baseline.

Moreover, the sovereignty of each coastal State extends beyond its land territory and internal waters to an adjacent belt of sea described as the 'territorial sea'. The maximum breadth of the territorial sea is twelve nautical miles (nm)[245] measured from the baseline. Within the territorial sea the authority of the coastal State is in principle absolute except as restricted by UNCLOS and other rules of international law. The most important restriction included in UNCLOS is the right of 'innocent passage' through the territorial sea, which is enjoyed by ships of all States (article 17).

Beyond its territorial sea a coastal State may claim an exclusive economic zone (EEZ) that can extend up to 200 nm from the baseline. Within its EEZ a coastal State does not enjoy sovereignty as such but a more limited set of "sovereign rights" relating to living and non-living resources and with regard to other activities for the economic exploitation and exploration of its EEZ (such as the production of energy). Article 56(1) states that:

> In the exclusive economic zone, a coastal State has:
> (a) sovereign rights for the purpose of exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the waters superjacent to the seabed and of the seabed and its subsoil, and with regard to other activities for the economic exploitation and exploration of the zone, such as the production of energy from the water, currents and winds;

A coastal State also has the necessary jurisdiction related to these sovereign rights as well as jurisdiction for the establishment and use of artificial islands, installations and structures, marine scientific research and the protection and preservation of the marine environment.[246]

These sovereign rights and jurisdiction conferred upon the coastal State imply the power to regulate the terms of use relating to those activities. On the other hand the coastal State does not enjoy sovereignty in the fullest sense. Article 56(2) of UNCLOS states:

> In exercising its rights and performing its duties under this Convention in the exclusive economic zone, the coastal State shall have due regard to the rights and duties of other States and shall act in a manner compatible with the provisions of this Convention.

In other words coastal State regulatory competence in the EEZ is not plenary, but confined to the matters expressly indicated in UNCLOS in respect of which sovereign rights or jurisdictional powers are granted to a coastal State. Moreover UNCLOS subjects the exercise of this competence to

[241] As at 10 January 2014 there were 166 parties to UNCLOS. See http://www.un.org/199uropa/los/reference_files/status2010.pdf
[242] Article 3 of UNCLOS.
[243] Article 5 of UNCLOS.
[244] Articles 7, 9 and 10 of UNCLOS.
[245] 1 nm = 1,852 metres.
[246] UNCLOS Article 56(1)(b).

various conditions and obligations explicitly foreseen, such as the freedom of navigation of other States' vessels.[247]

Such rights apply for the purpose of 'exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the waters superjacent to the seabed and of the seabed and its subsoil' (article 56) as well as other activities for the economic exploitation of the zone.[248]

Moreover UNCLOS recognises the rights of each coastal State over its adjacent continental shelf, which comprises the seabed and subsoil of the 'submarine areas' beyond the territorial sea and which may extend as far the natural prolongation of the land territory to the outer end of the continental margin or to a distance of 200 nm from the baseline in cases where the outer edge of the continental margin does not extend that far.

In other words some but not all coastal States may be entitled to claim an outer continental shelf that extends beyond 200 nm from the baseline and thus beyond the outer edge of the EEZ. In such cases the coastal State must submit information on its outer limits on the basis of criteria specified in Article 76 of UNCLOS to the Commission on the Limits of the Continental Shelf (CLCS). The limits of the outer continental shelf established by the coastal State 'on the basis of' the recommendations of the CLCS are final and binding (article 78(8)). A number of continental shelf claims around the world have been submitted and are currently outstanding.[249]

As regards its continental shelf each coastal State has 'sovereign rights for the purpose of exploring it and exploiting its natural resources'. Such rights include the exploitation of living organisms belonging to 'sedentary species' (which are defined as organisms, which at the harvestable stage, are either 'immobile, on or under the sea-bed or are unable to move except in constant physical contact with the sea-bed or the subsoil') as well as other activities relating to the seabed and its subsoil such as the extraction of oil and minerals.

Beyond the outer edge of the continental shelf lies the 'Area', defined by UNCLOS as the 'seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction', and which is the subject of Part XI of UNLCOS. No State may claim sovereignty or sovereign rights over any part of the Area or its resources. Instead, all rights in the 'resources' of the Area are 'vested in mankind as a whole' on whose behalf the International Seabed Authority (ISA), established pursuant to UNCLOS, is to act. Further provisions on the functioning of the ISA are set out in the Part XI Deep Sea Mining Agreement.

However, although Part XI does set out a number of generally applicable principles with regard to the conduct of States in relation to the Area including peace, security international cooperation and mutual understanding, the responsibility to ensure compliance and liability for damage, the use of the Area for exclusively peaceful purposes, the focus of Part XI is on the exploration and exploitation the resources of the Area, which are defined in article 133 of UNCLOS as 'all solid, liquid or gaseous mineral resources *in situ* in the Area at or beneath the seabed, including polymetallic nodules'. In other words the focus of Part XI is on the mineral resources of the Area rather than the marine genetic resources found there.

[247] Freedom of navigation in the EEZ is not absolute, but a balancing exercise between the coastal State and the flag State, inasmuch as by UNCLOS Article 58(3) its exercise is subject to due regard to the coastal State's rights and duties and compliance with its laws in so far as they are not incompatible with Part V of the Convention.
[248] It follows too that a coastal State has jurisdiction over the harvest and culture of marine algae within its EEZ as well as its territorial sea.
[249] See http://www.un.org/200uropa/los/clcs_new/commission_submissions.htm

The final maritime zone of relevance to this topic is the area of 'high seas' which include all parts of the sea that do not form part of the EEZ, territorial sea or other maritime zones of coastal States.[250] The high seas are the subject of Part VII of UNCLOS. The provisions of Part VII therefore apply to the airspace, surface waters and water column beyond the outer limit of the EEZ and the seabed and subsoil of that same area. In other words, the UNCLOS regime for the high seas overlaps with its regime for the Area and may overlap with the regime of the outer continental shelf if one is claimed.[251]

All States enjoy the freedoms of the high seas, which include the freedom of overflight, fishing and scientific research. Moreover no State may seek to subject any part of the high seas to its sovereignty.[252] For this reason the high seas, like the Area, are often referred to as an 'area beyond national jurisdiction' or an 'international commons' in which States are not entitled to exercise jurisdiction in a coastal State capacity.[253]

Having examined the UNCLOS provisions on maritime zones it is next appropriate to consider how UNCLOS deals with the issue of marine genetic resources.

UNCLOS and marine genetic resources

In fact, as already mentioned, UNCLOS does not specifically refer to marine genetic resources. The rights and duties of States must instead be understood in terms of more general provisions on the conservation and exploitation of natural resources in general as well as the provisions contained in Part XIII on marine scientific research (which *inter alia* require States to make available knowledge from scientific research and to actively promote the flow the flow of scientific data and information and the transfer of knowledge) and in Part XII, which imposes a number of general duties upon States to protect the marine environment.

In examining the provisions on UNCLOS on these topics it is convenient to distinguish between the legal regime applicable to maritime areas under national jurisdiction (namely internal waters, territorial sea, EEZ and continental shelf) and that applicable to areas beyond national jurisdiction (namely the Area and the high seas).

Areas under national jurisdiction

Although the term 'natural resources' is not actually defined in UNCLOS the all encompassing description of natural resources in Article 56, which includes living or non-living resources, would appear to include marine genetic resources.[254]

It follows therefore that on the basis its sovereignty over its internal waters and territorial sea a coastal State also enjoys sovereignty over the marine genetic resources contained within its internal waters and territorial sea. Similarly the sovereign rights that a coastal State enjoys over the living marine resources contained within its EEZ and on its continental shelf (and extended continental shelf if any) extend to the marine genetic resources found there. In other words genetic resources found within such areas under national jurisdiction (internal waters, territorial sea, EEZ and continental shelf) are subject to the provisions of the CBD and Nagoya Protocol relating to the issue of PIC and benefit sharing.

[250] In other words if a coastal State does not claim an EEZ the waters above its continental shelf may also be considered to form part of the high seas.
[251] For a comprehensive discussion see A.G. Oude Elferink, "The Regime of the Area: Delineating the Scope of Application of the Common Heritage Principle and Freedom of the High Seas", 22 *International Journal of Marine and Coastal Law* 143-176 (2007).
[252] Article 89.
[253] Article 137.
[254] Warner, R.M. 'Protecting the Diversity of the Depths: Environmental Regulation of Bioprospecting and Marine Scientific Research Beyond National Jurisdiction', 22 *Ocean Yearbook* (2008) p. *411.*

In fact the CBD provisions on this topic broadly mirror the provisions in Part XIII of UNCLOS on marine scientific research as regards the need for PIC. Within its EEZ and on its continental shelf, a coastal State has control over marine scientific research – including any research installations or equipment in the marine environment needed for such activities (Articles 60, 80 and 258). Moreover the consent of the coastal State is required for any type of research carried out in these zones. However the coastal State may withhold its consent only under specific conditions. In essence article 246 distinguishes between what may be described as 'applied research' and 'pure research'.

There is a presumption in favour of granting consent for pure research in the EEZ and the CS. Article 246 (3) states that:

> Coastal States shall, in normal circumstances, grant their consent for marine scientific research projects by other States or competent international organizations in their exclusive economic zone or on their continental shelf to be carried out in accordance with this Convention exclusively for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all mankind. To this end, coastal States shall establish rules and procedures ensuring that such consent will not be delayed or denied unreasonably.

Article 246(5), however, goes onto provide that :

> Coastal States may …in their discretion withhold their consent to the conduct of a marine scientific research project of another State or competent international organization in the exclusive economic zone or on the continental shelf of the coastal state if that project:
> (a) is of direct significance for the exploration and exploitation of natural resources, whether living or non-living;
> (b) involves drilling into the continental shelf, the use of explosives or the introduction of harmful substances into the marine environment;
> (c) involves the construction, operation or use of artificial islands, installations and structures referred to in articles 60 and 80;

In other words while in 'normal circumstances' (which pursuant to article 246 (4) may exist even in those cases where there are no diplomatic relations between the researching State and the coastal State) consent for pure research should be given, as regards applied research the coastal State has an almost complete discretion whether or not to grant consent if this research is planned to be conducted in the EEZ and/or on the Continental Shelf. Moreover as regards either types of research activity a coastal State can refuse consent where a researcher has provided inaccurate advance information as to the nature and objective of the project or if the researcher has outstanding obligations to the coastal State from an earlier research project (article 246(5)(d)).

Consent to undertake marine scientific research in the EEZ or on the continental shelf is in any event subject to conditions imposed by the coastal State regarding a range of issues including coastal State participation in the research project, the provision of preliminary reports as well as data and samples, on request, as well as an assessment of such data, also on request (article 249) in addition to any other conditions imposed in coastal State legislation.

While article 255 requires States to endeavour to adopt reasonable legislation and procedures to promote and facilitate marine scientific research beyond their territorial seas and article 252 creates an implied consent regime if the coastal state has not objected to a research project within six months, it is important to note that any dispute over whether a coastal State has improperly withheld consent is not subject to any form of compulsory third-party settlement except compulsory conciliation under Annex V of UNCLOS. Moreover article 297 (2)(b) of UNCLOS provides that the discretion of a coastal State to withhold consent in accordance with article 246(5) may not be called into question. This regime does not contradict the CBD/Nagoya Protocol provisions.

The main problem in terms of understanding the UNCLOS provisions on marine scientific research (which term is not actually defined in the convention) in terms of the acquisition of marine genetic

resources lies in the distinction between pure research and applied research. Although article 251 of UNCLOS calls on States, acting through competent international organisations, to establish general criteria and guidelines to assist States to ascertain the nature and implications of scientific research this task has yet to be completed. More specifically the research cruises that yield marine genetic resources may have a mix of 'pure' and 'applied' research objectives.

It follows, therefore, that in terms of its marine genetic resources each EU coastal Member State has the right to regulate access to its marine genetic resources within its territorial sea, EEZ and on its continental shelf and to regulate marine scientific research within those maritime zones in accordance with its own legislation. However, EU Member States that have yet to claim an EEZ, and several have not[255], cannot regulate the acquisition of marine genetic resources from the water column above the continental shelf.

In the case of access by EU Nationals and vessels to the marine genetic resources of third countries, this is to be regulated by the coastal State concerned in accordance with its own legislation on PIC, environmental impact assessment and, if any, and benefit sharing. The issue of benefit sharing is considered in more detail below.

Two further comments can be made. First of all the ability to identify the scope of areas under national jurisdiction in terms of EEZ and continental shelf implies that the boundaries of such zones are clearly identified. This may not always be the case, particularly in places where contiguous or opposite maritime zone claims have yet to be delineated between the coastal States concerned and as regards outer continental shelf claims.

The second point is that as regards areas that are subject to outer continental shelf claims, the rights of the coastal State apply only as regards the marine genetic resources of 'sedentary species'. Some of the species that inhabit hydrothermal vent communities, seep communities and deep sea sediment such as nematodes and molluscs may fulfill the definition of sedentary species and therefore fall under coastal State jurisdiction. However others, such as the micro-organisms which abound in hydrothermal plumes, do not and access to them will be subject to the regime of the high seas.[256] How this distinction in terms of marine genetic resources is to be made is not entirely clear although extended continental shelf claims cannot, by their nature, include the sea mounts that are particular hotspots of marine genetic diversity.

Areas beyond national jurisdiction

As regards areas beyond national jurisdiction (ABNJ), namely the Area and the high seas, the question of access to marine genetic resources, let alone benefit sharing is not at present effectively addressed under either UNCLOS or the CBD. Put another way, the CBD does not directly apply to genetic resources within such areas (although it does apply to activities under the jurisdiction or control of contracting parties in ABNJ) and the rather broad wording of the provisions in UNCLOS on the freedom of the high seas, tempered only by the rather general provisions on marine scientific research in Part XIII and on the protection and preservation of the marine environment in Part XII provide little guidance on the topic.

Consequently there at present few if any restrictions on access to marine genetic resources in ABNJ or any substantive controls as to how the acquisition of marine genetic resources is to be undertaken.

[255] See *Costs and benefits arising from the establishment of maritime zones in the Mediterranean Sea* Study published 11/07/2013 at http://ec.europa.eu/maritimeaffairs/documentation/studies/study-maritime-zones-in-mediterranean-sea_en.htm
[256] Warner *op cit.*

This has a number of implications. First of all there is a risk of damage to marine biodiversity as a result of the acquisition of marine genetic resources from or near the sea bed (sampling techniques mean that negative impacts in the water column are likely to be negligible). Although unlike a harvesting operation, only very small quantities of such resources are needed for the purposes of gathering marine genetic material, such material may be located within very delicate ecosystems such as hydrothermal vent ecosystems which are hotspots of marine biodiversity.

Second, there is the question of ABS with regard marine genetic resources. In this connection it is necessary to recall that two separate regimes apply: the regime of the high seas, which applies to the surface and water column, and the specific regime of the seabed that applies to the Area.

In terms of the high seas, as already noted, all States enjoy *inter alia* the freedom of navigation, the freedom fishing and the freedom of marine scientific research. However such freedoms are not absolute.[257] They must be exercised by all States with due regard to the interests of other States in their exercise of their freedom of the high seas as well as relevant provisions of UNCLOS including those relating to the conservation and management of living resources (Part VII, section 2), general obligations to protect and preserve the marine environment (Part XII) as well as the regime for marine scientific research (Part XIII). Nevertheless, article 257 clearly provides that all States, irrespective of geographical location, have the right to conduct scientific research 'in the water column beyond the limits of the exclusive economic zone'.

As regards the Area, it will be recalled that in accordance with Part XI a specific regime applies to the exploitation of the (mineral) resources of situated there. However that regime is silent as to the marine genetic resources of the Area. Moreover article 256 clearly indicates that all States have the right, in conformity with Part XI, to conduct scientific research in the Area.

In outline, two basic positions can be taken with regard to the question of ABS in connection with marine genetic resources in ABNJ. Developed countries tend argue that principle of the freedom of the high seas extends to the acquisition and exploitation of the marine genetic resources found in the water column and by extension in the Area given that this issue is not expressly addressed in Part XI. Other countries argue that when the principle of the freedom of the high seas was developed, back in the seventeenth century, no-one had marine bioprospecting in mind and that a 'first come first served' legal regime favours the richer countries that have the resources to fund marine scientific research. Consequently it is argued that the spirit of UNLCOS calls for marine genetic resources in ABNJ to be recognized as forming part of the common heritage of mankind and to be managed in a more equitable manner along the lines of the regime for the mineral resources of the Area.[258] In support of this second argument it is further argued that article 143 (1) provides that marine scientific research in the Area must be carried out 'exclusively for peaceful purposes and for the benefit of mankind as a whole in accordance with Part XIII'. Moreover it is argued that the obligation contained in article 244 of UNCLOS to make available knowledge resulting from marine scientific research is incompatible with the commercial objectives of bioprospecting.[259]

Finally there is the much broader issue of the protection of biodiversity in ABNJ in general including as regards the creation of marine protected areas (MPAs).

In response to concerns over these issues raised in international *fora*, as well as by a range of non-government organisations and researchers, in 2004 the United Nations General Assembly (UNGA) established the 'Ad Hoc Open-ended Informal Working Group to Study Issues Relating to the

[257] Article 87.
[258] Scovazzi *op cit at page* 21.
[259] Warner *op cit.*

Conservation and Sustainable Use of Marine Biological Diversity Beyond Areas of National Jurisdiction', commonly known as the 'BBNJ Working Group'.[260]

Since then the BBNJ has held a series of meetings (in 2006, 2008, 2010, 2011, 2012 and 2013) during the course of which various options to fill the existing 'normative gap' have been discussed. A number of alternative proposals have been canvassed as to how this should be done in terms both of ABS and the protection of the marine environment. These include amending the CBD, the adoption of a further protocol on ABS in ABNJ under the auspices of the CBD, the adoption of a separate stand-alone agreement on biodiversity in ABNJ (with its own new international organization to be responsible for enforcement) and the negotiation and adoption of an additional implementing agreement (IA) on these topics under the framework of UNCLOS. Moreover in order to ensure progress it was agreed at the Rio+20 Summit that States would decide by the end of the 69th session of the UNGA (August 2015) whether or not to launch the negotiations for the conclusion of an UNCLOS IA. The EU has been heavily involved in this process since 2006 and was instrumental in building in 2011 a consensus within the BBNJ Working Group with the G77 group of developing countries and China that the issue of marine genetic resources in ABNJ should form part of a negotiating 'package' that would also address MPAs, EIA and capacity building/technology transfer.

Nevertheless many questions remain not only as to whether an IA will be developed but also as to its content and the procedure whereby this may take place. And a key question in all of this concerns the issue of benefit sharing and in particular whether or not the benefits of marine genetic resources obtained from ABNJ should accrue (directly or indirectly) to the States concerned or to mankind as a whole. But what is really meant by benefit sharing?

Benefit sharing

As already noted, the rather vague provisions on ABS in the CBD have been supplemented by the more detailed arrangements contained in the Nagoya Protocol. The European Commission played an active role in the negotiation of the text in respect of matters falling within EU competence.

The objective of the Nagoya Protocol, which applies only to genetic resources over which States exercise sovereign rights, is the fair and equitable sharing of the benefits arising from the utilization of genetic resources which expression is defined to mean the conducting of research and development of the 'genetic and/or biochemical composition of genetic resources, including through the application of biotechnology' as defined in the CBD.

Article 5 re-emphasizes the fair and equitable sharing of the benefits arising out of the utilization of genetic resources as well as their subsequent application and commercialisation, while article 6 sets out the minimum requirements for access and PIC including making provision for a formal permit or equivalent confirming that PIC has been granted as well as setting out clear rules and procedures for requiring and establishing mutually agreed terms.

Apart from canvassing the need for a global multilateral benefit-sharing mechanism relating to genetic resources that occur in transboundary situations or which it is not possible grant or obtain PIC[261], the Nagoya Protocol also requires each contracting Party to establish a national focal point and national competent authority and also provides for the creation of an ABS 'Clearing House' and information centre. A key provision is article 15 which requires each contracting Party to take appropriate, effective and proportionate legislative and other measures to ensure that genetic resources (including their derivatives) utilized within its jurisdiction have been accessed in accordance with PIC and that 'mutually agreed terms have been established as required by the

[260] The BBNJ was established pursuant to United Nations General Assembly Resolution 59/24 of 17 November 2004.
[261] In other words such a protocol could conceivably apply to marine genetic resources obtained from ABNJ.

domestic ABS legislation or regulatory requirements of the other Party'.

A range of different types of benefits are described in Annex I of the Nagoya Protocol. These include monetary benefits (such as access/sample fees, milestone payments, the payment of royalties and licence fees in the case of commercialisation, research funding, joint ownership of intellectual property rights) and non-monetary benefits (such as the sharing of research and development results, collaboration, cooperation and contribution in scientific research and product development, capacity strengthening for technology transfer, training and directed research).

In this connection it is important to note that the Nagoya Protocol effectively sets up a mechanism for bilateral benefit sharing rather than the multilateral benefit sharing mechanisms contained in other instruments such as the FAO-sponsored International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the benefit sharing provisions on deep sea bed mineral resources provided for in Part XI of UNCLOS and the Part XI Agreement.

Although, as mentioned above, the Nagoya Protocol has yet to enter into force its imminent ratification by the EU and Member States means is anticipated that this will happen sometime during the course of 2014. In order to be permit the EU and Member States to be able to ratify and implement the Nagoya Protocol a draft regulation (the 'draft ABS regulation') was prepared by the European Commission and has recently completed the legislative proceuder in the European Parliament.[262] It is anticipated that the draft ABS regulation enter into force in May 2014.[263]

The key obligation contained in the draft ABS Regulaiotn is in article 4 which imposes a duty on users (defined as a natural or legal person using genetic resource…') to exercise due diligence to ascertain that genetic resources were accessed in accordance with applicable ABS legislation or regulatory requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms. Moreover users must take active steps as regards acquiring and sharing information on the resources and the Member States must monitor user compliance to ensure the correct application of article 4.

The draft ABS regulation will only apply to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol. In other words it will not apply to resources already contained in collections or gene banks at that date and nor will it apply to marine genetic resources obtained from ABNJ.

Before evaluating in more detail the nature of benefit sharing in the context of Blue Biotechnology, it is first necessary to briefly examine the nature of kinds of benefit that may be derived from marine genetic resources: after all with the exception of harvested products such as algae, the value of such resources derives from the knowledge or information that they provide.

As noted above, the Nagoya Protocol lists a number of different types of monetary and non-monetary benefits. While the sharing of non-monetary benefits (such as research and development results, capacity strengthening for technology transfer, training and directed research etc.) are relatively easy to understand at the conceptual level (even if in practice the sharing element may remain difficult to practically implement) a more important question is how economic benefits are to be derived from what are often very small quantities of marine genetic resources. The simple answer is that the economic value of such resources derives from the knowledge or information that they provide. The economic value of such knowledge or information derives from intellectual

[262] Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.
[263] The comments that follow are based on the version of the draft regulation published on the European Commission's website at http://ec.europa.eu/environment/biodiversity/international/abs/index_en.htm

property rights.

Intellectual property rights

Intellectual property rights (IPR) confer protection on the creators of knowledge or information by giving them property rights over their creations. Such property rights relate to the items of information or knowledge that can be incorporated in tangible objects in an unlimited number of copies (and not to those objects or copies as such).

IPR are usually divided into two categories: (1) industrial property, which includes patents for inventions, trademarks and industrial designs; and (2) copyright, which includes literary and artistic creations such as books and films as well as technology-based works such as computer programs and databases. IPR are usually also subject to certain limitations, such as a limited duration in time in the case of copyright and patents.

While IPRs invariably play an important role throughout the Blue Biotechnology development and marketing cycle (in terms, for example, of the trademark protection of biotech products) in terms of ABS the most relevant IPR are copyright/database rights and patents.

Intellectual property (IP) law is a complex area of law which derives primarily from national legislation although as will be seen a number of international instruments seek to harmonise approaches to IPR and their cross-border recognition and treatment. It follows that IP legislation varies from country to country in accordance with the applicable national IP policy (which may in turn vary from time to time reflecting technical and economic priorities).

Within the EU a certain amount of harmonization has been achieved through the introduction of the unitary patent regime as well as specific legislation on copyright/database rights both of which are considered in more detail below.

At the level of international law the principal international organisation concerned with IP issues is the World Intellectual Property Organisation (WIPO), which administers a number of international agreements concerned with IP. Moreover mention must be made of the Trade Related Intellectual Property Agreement[264] (TRIPS) concluded under the auspices of the World Trade Organisation (WTO). TRIPS requires States that are members of the WTO to provide minimum standards of protection of a wide range of IPRs.

Copyright/database rights

The relevance of copyright/database rights to Blue Biotechnology arises as follows. The analysis and assessment of the genetic capabilities of marine organisms involves the sequencing of their genome and annotation of the genes. This process of genomic and metagenomic analyses coupled with deep sequencing generates large datasets from resources acquired from marine environments. Specific bioinformatics resources and tools have been developed in order to try and maximize the capacity to analyze the resulting vast datasets.

Such datasets are subject to, and protected by, copyright. Copyright arises automatically and without formality upon creation of the work, generally once it is fixed in some material (reproducible) form. Databases (in any form) can also benefit from copyright protection. Copyright protection will be accorded to databases that 'by reason of the selection or arrangement of their contents' constitute the author's own intellectual creation[265] (i.e. concept of originality). The copyright protection does not extend to the data contained in the database (which may however be subject to copyright in its own right) but rather to the manner in which the data are organized and presented.

[264] Annex 1C to the Agreement establishing the WTO (Marrakesh, 15 April 1994).
[265] Article 3 (1) of the Database Directive.

The *author* of the database is the natural person(s) who created the database or (where national legislation permits it) the legal person designated as the rightholder by that legislation (e.g. the employer of the database creator). **In addition, or alternatively, there may be a "*sui generis* database right" protecting the content of the database (irrespective whether there has been creativity in its arrangement), provided that there has been a substantial (q**ualitative and/or quantitative) **investment in obtaining, verifying or presenting the material.**

The *sui generis* database right should protect the maker of the database against the unauthorised extraction and/or re-utilisation of the whole or a substantial part of the database. In essence, the *sui generis* right aims to protect the investment of time, money and effort incurred by database producers in relation to non-original (in terms of intellectual creativity) databases. The *sui generis* right applies irrespective of the eligibility of the database (or of its contents) for protection by (ordinary) copyright or other rights.

In terms of copyright/database rights there are generally two types of rights under copyright: (i) economic rights (which allow the author to derive financial benefits from the use of his works by others); and (ii) moral rights (which allow the author to take certain actions in order to preserve the personal link between himself and the work).

Databases containing genomic or metagenomic data may therefore be protected by both copyright (if they are intellectual creations in terms of their arrangement or selection of the data) and/or by the *sui generis* database right (if they are the product of a substantial investment in obtaining, verifying or presenting the data).

International harmonisation of copyright law has been achieved to a certain extent through, *inter alia*, the minimum standards set out by the Berne Convention[266], TRIPS, the WIPO Copyright Treaty of 20 December 1996 and, within the EU, through a number of copyright-related Directives, including the Directive 96/9/EC of 11 March 1996 on the legal protection of databases (the 'Database Directive'[267]) and Directive 2001/29/EC of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (the 'Copyright Harmonisation Directive')[268]. It should nevertheless be noted that, although subject to both international and EC law, the subsistence and enforcement of copyright will mainly occur at the national level.

Patents

Patents protect the rights of inventors. Simply put, a patent is the right granted to an inventor by a national or regional patent office (*e.g.* the European Patent Office in Munich), which allows the inventor to exclude anyone else from commercially exploiting the invention for a limited period (generally 20 years).

As already noted, patents are usually created at the level of national law which will therefore determine the extent to which biotechnology inventions may receive patent protection although as with copyright, there are harmonising legal instruments at: (i) international level, namely the Paris Convention for the Protection of Industrial Property of 20 March 1883, as revised at Stockholm on 14 July 1967 (the Paris Convention) and the Patent Cooperation Treaty, Washington, 19 June 1970, (the PCT) which makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an international patent application; and (ii) European Economic Area (EEA) level in the form of the European Patent Convention (Munich) 1973, as

[266] Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886, as revised.
[267] *OJ* L 77/20 of 27 March 1996.
[268] *OJ* L 167/10 of 22 June 2001.

revised (the EPC).[269] Moreover in December 2013 the European Parliament approved the 'EU patent package', which provides for a unitary EU patent, language regime and unified EU patent court.

The general requirements for patentability at European level are set out in the EPC, which states that European patents should be 'granted for any new inventions, in all fields of technology which are susceptible of industrial application, which are new and which involve an inventive step'. Similar tests for patentability are found in other jurisdictions[270].

That biotech inventions may be subject to patents is clear established at the EU level by Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions[271] which provides in article 3(1) that new inventions that involve an inventive step and which are susceptible of industrial application are patentable 'even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used'. Article 3(2) goes on to provide that; '(b)iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'. Under Article 6 of the directive, inventions are to be considered un-patentable where their commercial exploitation would be contrary to public order or morality.

Patent law is obviously fundamental to the development of the Blue Biotechnology sector: without patent protection the enormous costs and effort required for the creation of biotech products could not be justified. New genes, proteins and processes resulting from research and development may all be subject to patent protection provided they meet the necessary criteria for patentabilty.

As noted above, patents like other types of IPR are subject to certain limitations in terms, for example, of their duration. In Europe, the United States and Japan patents typically last for 20 years from the date of application. Moreover as part of the patent application process an inventor must adequately disclose the patented invention to the public.

Nevertheless patent law also raises a number of issues as regards biotechnology in general and Blue Biotechnology in particular. First of all there is the question as to precisely what may be patented in terms of sequenced genomes.

Secondly as patents are a form of property right the owner may chose to use them - or not. The deliberate acquisition of patents can therefore be used to block competitors in a particular field. Moreover in some biotechnology sectors, although apparently not at present in the marine biotechnology sector, the sheer number of patents issued with regard to genomic information has created what are known as 'patent thickets', which in turn have the potential to hinder future research. The next question to consider, therefore, is the basis on which IPR may be used.

The licensing and use of IPR

Again as IPR are, above all, a form of property right the owner of an IPR has the exclusive right to authorise third parties to use that right, usually through some form of contractual licensing agreement as well as the right to sell or otherwise assign that right.

Copyright owners will usually not 'sell' their copyright as such (*i.e*. transfer their property rights), licence the use of the copyrighted material. In relation to copyright, licensing means that the owner

[269] The EPC sets out the patentability requirements for all Member States, but patent enforcement remains a matter for national law.
[270] As reflected by Article 27 of TRIPs, which provides that 'patents shall be available for any inventions, whether products or processes, in all field of technology, provided that they are new, involve an inventive step and are capable of industrial application'.
[271] OJ L 213, 30.7.1998, p. 13

of the copyright retains ownership but authorises a third party (on an exclusive or non-exclusive basis) to carry out certain acts covered by his economic rights, generally for a specific period of time and for a specific purpose which is defined in the licence agreement. Depending on the purpose (commercial or otherwise), such use may be subject to payment. The extent to which, say a laboratory, authorises the use or re-use of data in respect of which it holds copyright/database rights will depend on its own specific IPR (data) policy. Similar observations apply as regards database rights.

Commercial considerations will determine the extent to which patents are sold or their use licensed. For example in the context of the Blue Biotechnology a patent may be sold to a manufacturer which will then become the sole provider of the product that is covered by the patent. Alternatively a patent holder may license the patent to others for appropriate payment. This may be in the form of an exclusive licence (whereby a licence is granted only to one party) or a non-exclusive licence (whereby a licence is granted to more than one party).

While IPR are a key means of promoting innovation, and although patent laws do typically contain certain exceptions allowing use for research[272], policies with regard to licensing the use of IPR can also slow the pace of research depending on the conditions imposed and also the level of the fee demanded. Moreover even if the owners of IPR are amendable to licensing the transaction costs can be high particularly if negotiations are lengthy.
However these and other issues relating to the impacts of IPR on innovation (both positive and negative) are of general application to the biotechnology sector as a whole and are not specific to the Blue Biotechnology sector as such.

One specific area of potential tension as regards IPR and the Blue Biotechnology sector does exist, however, and that concerns the relationship between IPR and marine genetic resources obtained from ABNJ. More specifically, article 244 of UNCLOS imposes a duty on States to make available for publication and dissemination knowledge resulting from marine scientific research. The article goes on to provide that States must 'actively promote the flow of scientific knowledge resulting from marine scientific research…'. These provisions raise two specific questions. First of all, as mentioned above, the commercial imperative to keep information derived from marine genetic resources confidential both to protect if from potential competitors and to satisfy the need for novelty in terms of patent applications sits ill with the duty to promote knowledge flows. Second, the grant of a patent may further hinder such flows. While this may seem, at first sight, like an academic point the fact is that negotiations with regard to the marine genetic resources in ABNJ remain very much open. Consequently it is a point that is likely to be taken by developing countries, thereby contributing to legal uncertainty.

Benefit sharing revisited

So the next question is how to link IPR back to the issue of benefit sharing and the Nagoya Protocol? The key point to note is that the knowledge and information that may be derived from marine genetic resources, and which is subject to IPR, will generally pass through a number of quite distinct stages of use, as it were, before any substantive economic benefits can be realised and shared.

Of course there are many ways in which knowledge and information flow but to take a roughly typical example the following scenario may envisaged.

[272] See Chiarolla, C., Lapeyre, R., Pirard, R. Biodiversity conservation: *How can the regulation of bioprospecting under the Nagoya Protocol make a difference?* (2013) Studies N°06/13, IDDRI, Paris, France. A research exemption is an exception to the exclusive rights granted by a patent that allows researchers to undertake experiments on the patented invention with the view to discovering unknown effects or making improvements on the invention without the prior consent of the patent holder.

Marine genetic resources are planned to be acquired in the EEZ of a third country, country A, during the course of a research cruise organised by research institutions from country B. The cruise is undertaken on a research vessel registered in country B and which therefore flies the flag of country B.

Before the vessel can enter the waters of country A in order to commence marine scientific research, the prior informed consent of country A, as the coastal State, must be obtained in accordance with the requirements of UNCLOS as outlined in section 2.2.4 above. Such permission is usually negotiated and obtained at the diplomatic level between the two States concerned.

At the same time, the person or research institution that will actually seek to acquire marine genetic resources from within the EEZ of country A during the course of the cruise, will need to conclude an ABS agreement with the organisation in country A that is formally authorised to do so (a research cruise may have a number of distinct activities apart from the collection of marine genetic resources, undertaken by different research bodies represented on board). It is to be hoped that the Nagoya Protocol procedure will streamline this process: experience pre-Nagoya suggests that even identifying the correct body in the provider country with whom to conclude an ABS agreement is difficult.

Because of the high costs involved, the acquisition of marine genetic resources is typically publicly funded both in terms of the costs of mounting a research cruise and as regards the public research institution undertaking the work.

Going back to the hypothetical scenario, the genetic resources are collected by a public research institute from country B and taken back to that country where they are placed in a bio-bank run by the institute. Further possible sub-scenarios may then arise. The research institute may begin the process of genomic analysis and placing the results in a database. It may also as part of the ABS agreement with country A provide all of the raw data to that country as well as, for example, training its scientists.

Another researcher in country B may request some of the data in the database for research purposes (or may alternatively request a sample form the bio-bank on the basis of a material transfer agreement).

The data (or the sample) may be provided on a free of charge basis through a licensing agreement that requires the open access to any research results and the recognition of the moral rights (in the case of a dataset) of the original laboratory.

Where the situation starts to get complicated is where the knowledge and information supplied are used to claim patents either by the second laboratory or by an SME linked to it. Of course simply obtaining a patent does not in itself yield any direct commercial benefit. Such commercial benefits, if any, may arise only many years later after a specific product has been developed and successfully placed on the market. By this stage the IPR in the original genetic resources subject to the ABS agreement may have passed through several stages (ie from copyright to patent) and from several different ‘users’ (ie from research laboratory to SME to large corporation) whether by way of assignment or transfer.

Of course in theory a well-designed ABS agreement should be able to anticipate such scenarios and address what third parties should be subsequently allowed to do with the material and knowledge. However it may well be the case that a ‘come back’ clause will be necessary such that

if there is a change in the use of the material the consent from the (authorised) organisation in the provider country is obtained.

Obviously pending the entry into force of the Nagoya Protocol it is impossible to evaluate how the system envisaged will actually work. Nevertheless is seems reasonably clear that it will be a challenging process, not only in terms of concluding ABS agreements but more particularly in terms of sharing of economic benefits with the country from which genetic resources were obtained, country A in this scenario, given the potentially long chain of actors and actions between the genetic samples and the final product.

The key point to note here is that in terms of marine biotechnology the party that concludes the ABS agreement will in most cases not be the person who is able to successfully exploit the economic benefits of the genetic material. In theory of course the mechanism foreseen in the draft ABS regulation, that of a contractual link back to the original ABS agreement should work.

The challenge will be more practical in terms not only of managing the contractual chain but also in terms of locating the precise source of genetic material used in inventions that are subject to patent applications, which may be sourced from gene banks or from different physical locations (for example from ABNJ as well as areas under national jurisdiction).

A key point to note in this respect is that while practice may vary from country to country patent legislation typically does not require the source of genetic materials to be identified in the course of a patent application. The adoption of the Nagoya Protocol has seen repeated calls from developing countries have sought to argue for this point to be regulated through an instrument adopted within the auspices of the WIPO or TRIPs.

Finally in terms of ABS relating to marine genetic resources acquired in ABNJ the current situation is one of potential uncertainty. In terms of future legal obligations as regards benefit sharing much may depend on the outcome of the negotiations currently under way at the UN. However if the example of the regime for seabed mining in the area provided for in Part XI of UNCLOS is any indication it seems likely the rights and interests of IPR relating to marine genetic resources sourced in ABNJ will be respected.

Use, manufacturing and marketing

Before Blue Biotechnology products can be placed on the market they are typically subject to a range of regulatory approvals that depend on the type of product in question such as pharmaceuticals, cosmetics and food. However such regulatory approvals are of general application and as such are not focussed only on the marine biotechnology sector. For example, while Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients,[273] specifically refers to foods and food ingredients consisting of or isolated from microorganisms or algae it also applies to a range of other novel foods and ingredients. In other words the fact Blue Biotechnology products are sourced from marine genetic resources does not matter: they are treated the same as other products including other types of biotechnology products. The same observation applies to the legislation applicable to pharmaceutical products[274]and cosmetic products[275].

[273] (OJ L 43, 14.2.1997, p. 1)
[274] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1); Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).
[275] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

Similar observations apply if Blue Biotechnology products are classified as genetically modified organisms (GMOs): the same regulatory framework applies as regards their deliberate release to the environment and/or placing on the market as for other types of biotechnology products.[276]

In terms of manufacturing too Blue Biotechnology products are subject to the same restrictions on emissions and environmental standards as other types of product.[277]

Liability

A feature of the Blue Biotechnology sector is that it pertains not only to products based on genetic materials sourced from the marine environment but also on products that are used in the marine environment. This raises a final issue in terms of potential accidental harm caused by such products at sea in terms for example of the deliberate release of GMOs for such purposes as pollution abatement and anti-fouling.

Article 196 imposes a duty on States 'to prevent, reduce and control pollution of the marine environment resulting from the use of technologies under their jurisdiction or control, or the intentional or accidental introduction of species, alien or new, to a particular part of the marine environment, which may cause significant and harmful changes thereto'. The wording of this article would seem to be potentially broad enough to include GMOs if these are classified as a technology. However the fact remains that marine biotechnology was not considered during the development of UNCLOS.

At the international level the issue of liability for damage caused by GMOs was addressed in 2000 in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the 'Cartagena Protocol'). The Protocol applies to the 'transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.[278] However, while the Cartagena Protocol and the subsequent Nagoya – Kuala Lumpur Supplementary Protocol On Liability And Redress To The Cartagena Protocol On Biosafety[279] apply to transboundary movements, both intentional and unintentional, as well as on liability for resulting environmental harm, their overall focus would appear to be on terrestrial boundaries and it is not entirely clear how they would apply to eventual harm caused by the deliberate release of GMOs to the sea.

At the EU level the scope of the liability regime created by the EU Environmental Liability Directive[280] includes environmental harm arising from the use of GMOs the issue of the deliberate release of GMOs to the sea is also not specifically regulated at present.

[276] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17/04/2001, p. 1).
[277] In terms for example of Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).
[278] Article 4.
[279] 16 October 2010.
[280] Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004, p. 56).

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