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Marine Biotechnology

European Commission public consultation (November 2013)

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Vlaams instituut voor de zee

Flanders Marine Institute VLIZ

Policy-informing brief

Introduction Note

Flanders Marine Institute (VLIZ) participates in public consultations of the European Commission on specific marine policy issues. Such consultations help the European Commission to collect and use the views of a broad range of stakeholders in shaping its discussions, in generating new policies, and in improving existing ones. VLIZ provides summaries of its responses to these consultations in the form of policy-informing briefs (PIBs).

The content of VLIZ policy-informing briefs combines expert scientific opinion with objective data and information. For this purpose, VLIZ draws on the expertise of coastal and marine scientists within its national and international network of marine research.

Policy-informing briefs reflect the impartial and objective position of VLIZ and are motivated by the basic principles of sustainable development and an ecosystem based approach, as endorsed by the European Integrated Maritime Policy and the principles of integrated coastal zone management.

More information about the core business, principles and terms of reference of the VLIZ: http://www.vliz.be/en/mission.

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CONTENT

GENERAL CONTEXT ON MARINE BIOTECHNOLOGY

Marine biotechnology has the potential to help in addressing some of today's greatest challenges, including those relating to health, food supply, environmental sustainability, energy security and others. At the same time the introduction of new high value added products and processes into the market can stimulate economic growth, leading to the creation of new high-quality jobs. This is why this nascent industry has been highlighted as one of the five blue growth focus areas in the Communication from the European Commission on "Blue Growth: opportunities for marine and maritime sustainable growth", adopted on 13 September 2012.

Marine ecosystems are much more biologically diverse than terrestrial ecosystems, yet they have been so far explored and exploited to a much lesser extent. As the research technologies advance, however, we are increasingly able to access valuable marine resources. The incredible diversity of marine life can translate into a wide range of useful applications. Marine Biotechnology can be defined as the use of marine bioresources as the target or source of biotechnical applications. Enhancing aquaculture productivity through containment and rearing technology is an example of the former, more established applications of biotechnology. Modern applications include for example the derivation of drugs from marine sponges, fuel from microalgae and environmental monitoring technologies.

Cutting-edge innovative applications of marine biotechnology currently only takes the form of a niche market of high value added products and processes. However, some suggest that there is a strong potential for it to grow and develop further to become an important contribution to smart, inclusive and sustainable growth in Europe. In this context, the European Commission may develop an impact assessment study, which would explore the potential of the marine biotechnology sector into detail, propose possible options to facilitate the development of the sector and analyse their corresponding social, environmental and economic impacts and inform further policy steps.

To produce this document, Flanders Marine Institute (VLIZ) worked closely together with the Federal Public Service Health, Food chain safety and Environment (FPS Health) and the Belgian Science Policy Office (Belspo), concerning the achievements and potential growth for the marine biotechnology sector. FPS Health and Belspo responded separately to the consultation providing input from a governmental point of view whereas VLIZ provided in its response input from a scientific point of view. Where relevant, information of the other party was included in the response. All parties agreed on the response to the consultation that is summarized below.

Quantification and potential growth

VLIZ, FPS Health and Belspo are of the opinion that marine biotechnology has a strong potential to grow in the future. In particular, marine biotechnology applications in the areas of health and well-being (e.g. pharmaceuticals, nutraceuticals and cosmetics), food (e.g. fisheries and aquaculture) and environment (e.g. remediation, environmental monitoring) could have high growth potential in financial terms, whereas the potential growth for energy applications is believed to be rather low. Yet, there is little information available allowing the quantification of this potential growth.

It should be noted that the research field of blue marine biotechnology is still in full development and various barriers still exist to develop, test and commercialize scientific findings. Therefore, at this moment, it is not possible to indicate the growth potential of the different application areas. From a government policy point of view, it is important to stimulate research in a wide range of "marine biotech fields". Given the vastness of the marine environment and the increased use of the marine area, development in "remote sensing" in the broad sense (environmental monitoring, safety, surveillance, …) may have a specific potential for growth. On the other hand, given the vast number of species, yet undescribed from the deep sea, there is a potential for the use of these "genetic resources' for the development of marine-derived molecules exploitable by industry including enzymes, biopolymers and biomaterials. For example, microalgae form an important alternative feed in aquaculture and can also be produced as an alternative source of omega-3 fatty acids (as opposed to fish-oil derived omega-3 FA), thus reducing the pressure on the already over-exploited fish stock.

For the general biotechnology sector of Belgium, following information is available for 2011: there are 350 biotechnology firms (i.e. using biotechnology to produce goods or services and/or to perform biotechnology R&D) of which 127 (i.e. 36%) firms devote at least 75% of their production of goods and services, or R&D to biotechnology (OECD, 2013b). Without being able to give precise numbers, the share of marine biotechnology within this general biotechnology sector in Belgium is currently limited to very limited. Projects and networks in which Belgian institutes are involved, are amongst others: PharmaSea, Microalgae, Special chemicals, MicroB3, Vlaams Algenplatform and Marien Biotechnologie platform Vlaanderen. A list of other international projects involving marine biotechnology activities can be found in the following database: http://www.marinebiotech.eu/projects?module=project&show=search. The framework of this project database has been developed under the FP7 Coordination and Support Action on Marine Biotechnology, CSA MARINEBIOTECH

(October 2011-March 2013) and will be further expanded during the ERA-MarineBiotech (December 2013-November 2017).

For general considerations on the growth of marine biotechnology on EU level, the EMB Position Paper 15 (2010) states that marine biotechnology can not only create jobs and wealth, but that it can also contribute to the development of greener, smarter economies, central components of the new Europe 2020 Strategy. In OECD (2013b) the economic contribution of the oceans is calculated for the United Kingdom, Canada and the United States. However, a global estimation is not yet possible.

Considering the global market for marine biotechnology, the EMB Position Paper 15 (2010) states that: " the global market for Marine Biotechnology products and processes is currently estimated at € 2.8 billion (in 2010) with a cumulative annual growth rate of 4-5%. Less conservative estimates predict an annual growth in the sector of up to 10-12% in the coming years, revealing the huge potential and high expectations for further development of the Marine Biotechnology sector at a global scale."

The value of a few markets is estimated in the publication from OECD (2013b):

- Pharmaceutical products:
  - sponge, *Cryptotethya crypta*: compounds with anti-viral (Ara-A) and anti-leukemic (Ara-C) properties which have an annual market of USD 50-100 million;
  - soft coral, *Pseudoterigorgia elisabethae*: bioproducts used in skin care and cosmetics lines which are currently worth USD 3-4 million a year.

- Biotechnology:
  - Taq polymerase and other synthetic polymerases with similar properties is now used in biotechnology laboratories worldwide and represents a considerable market: sales of Taq DNA polymerase in Europe alone were USD 26 million in 1991 (Roberts, 1992) and had an initial estimated annual market of USD 50-100 million. The market for DNA polymerases is now believed to be in the order of USD 500 million a year.

- Fish and shellfish: the contribution of marine biotechnology to production and market value is not known.

- Biomass-related markets:
  - Seaweed-derived polysaccharides (including those derived from agar, alginates and carrageenan) have mature and

relatively stable markets: 86 000 tonnes and USD 1 018 billion in 2010 (Bixler and Porse, 2010).

- Globally the markets for chitin and chitosan (both largely marine-derived) are worth USD 481 million and are dwarfed by the market for chitin and chitosan derivatives (e.g. glucosamine) which are forecast to reach USD 63 billion and USD 21.4 billion, respectively, by 2015.
- The market for functional foods and natural products, including dietary supplements, natural and organic foods and beverages, functional foods and beverages, and natural and organic personal care and household products, was estimated at USD 270 billion in 2008 and is forecast to grow at around 6% through 2015. Again, with a few notable exceptions, it is difficult to separate out the fraction derived from marine bioresources.
- The global market for marine and algae oil omega-3 ingredients, estimated at USD 244 million in 2009, is forecast to reach USD 476-664 million by 2015 (based on estimated annual growth rates of 10.9% to 17.3%).
- Markets & Markets has also forecasted that the aquaculture feed market will grow with 11.7% from 2013 to 2018, becoming a 1.2 billion$ market. Algae are a more sustainable alternative to fish meal for this application and the growth of this market only confirms the great potential of algae culture.

In OECD (2013b) it is stated that some believe that the potential of marine biotechnology is equal to that of land-based biotechnology, but that the field is too young to be measured by economic output indicators and should be measured using R&D and innovation.

Benefits

Benefits of the marine biotechnology development from a private, national and regional perspective are described in the key highlights of the CSA MarineBiotech Public Report (2013):

• Sharing knowledge between researchers and private companies.

• The early involvement of firms in research projects creates the potential to develop a market focus or a utility aspect.

• Achieving a diversity of participation and a balance of regional representation.

• Capturing new disciplinary expertise and competencies, opening access to infrastructures and drawing from specific regional experiences in marine biotechnology.

• Efforts that give greater focus to areas where Europe has already established unique competencies, or by exploiting natural resources that offer exceptional potential and opportunities for member states are likely to offer long-term success. The impact of this approach, particularly where opportunities are relevant to economic and societal challenges is considered to be of greater value, than a purely scientific oriented one. Successful implementation of the strategy will require a joint effort with active support and involvement from all relevant stakeholders. Europe needs to mobilise the necessary support in terms of funding, human resources and research infrastructures, and to secure the engagement of all of the relevant actors. These actors include the science community, the private sector (e.g. individual companies, associations and technology platforms) policy makers and advisors at national and European level, national strategy and programme developers and managers, and ultimately the public at large. As each actor has an important responsibility to bring forward key elements of the strategy, mobilising, in a coordinated way, this diverse range of actors will be critical.

Economic impact

According to VLIZ, FPS Health and Belspo the development of marine biotechnology has a positive impact on the bioeconomy by creating jobs throughout the value chain from academic positions to positions in industry. It is also expected to affect many value-added sectors: pharmaceuticals, food, industrial processing, nutraceuticals, etc. (OECD, 2013b). The application of new genomic knowledge and technologies in aquaculture can create new job opportunities, both in the coastal and non-coastal populations. It could also create a shift from more traditional jobs.

In addition, VLIZ, FPS Health and Belspo believe that there is also a significant potential for exports from the EU to third countries. Marine biotechnology can help to address global challenges related to food, fuel security, population health and sustainable industrial and environmental processes. However, developing countries face challenges for accessing new technologies and financial capital, for example in the field of molecular aquaculture, which is especially important in the context of the growing consumption of animal protein, expected to double in the first half of this century (OECD, 2013b). The different rate at which these technologies are developing in different countries could potentially limit the productivity gains and sustainability of the progress in these domains. Therefore it is advised to anticipate by allowing/facilitating third countries to participate in the "EU marine biotech research arena" and by exporting advanced technologies and products to third countries.

Marketing

VLIZ, FPS Health and Belspo consider the greatest barriers for bringing marine biotechnology applications into the market to be the lack of a legal framework, the lack of collaboration (including between academic and industrial partners / difficulty in finding partners for collaboration) and access to finance.

The lack of a framework beyond the national jurisdiction raises questions about ownership, access to the bioresources and the sharing of the benefits to be obtained. If no clear governance framework is in operation, progresses in marine biotechnology are likely to be delayed or sustainable use of bioresources is at risk.

Other potential challenges for the marketing of biotechnology applications are believed to be the lack of knowledge (by traditional biotechnology players) about the potential of marine genetic resources for biotechnology applications and the lack of established marine biotechnology value chains or entry points in the already existing ones. The complexity of marine ecosystems and the comparative lack of in-depth knowledge of marine bioresources and their interaction with ecosystems implies that precautions should be taken for the sustainable use of those resources and their ecosystem services. Great attention to scientific research should be made to protect the shared resources of the interconnected world's oceans. 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, 2013b). The main challenges facing pharmaceutical discovery from marine bioresources are linked to: legal aspects (secure access to marine resources, property rights and intellectual property); quality of marine resources (identification and variability); technology (screening of active compounds and dereplication, preventing repeated rediscovery); and structural costs of drug discovery from natural products and especially marine products (EMB Position Paper 15, 2010).

VLIZ, FPS Health and Belspo also suggest that an increase in visibility of the sector could also enhance the marketing of marine biotechnology applications.

Finally, the involved risks, the availability of support mechanisms (e.g. innovation incubators, etc.) and the available capacity (e.g. suitably trained personnel, etc.) are believed to pose less of a challenge for the marketing of marine biotechnology applications, at this time.

Research innovations

According to VLIZ, FPS Health and Belspo the greatest challenges encountered in research are the lack of collaboration, a lack of funding (regional, national and EU-level) and complexities of obtaining funds. 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-MarineBiotech), including third countries. Also, limited access to research infrastructure (e.g. research vessels, laboratories) could pose a barrier to research.

Finally, VLIZ, FPS Health and Belspo are of the opinion that available capacity (e.g. suitably trained personnel, etc.), legal frameworks (e.g. unclear intellectual property) and access to marine genetic resources or sufficient amounts of marine organisms for downstream biotechnology research and development (e.g. sampling, repositories, biobanks, rights, patenting rules, etc.) pose less of a challenge to innovative research, at this time.

SUSTAINABILITY AND ETHICS

Environmental impact

VLIZ, FPS Health, Belspo consider bioprospecting in a delicate ecosystem to have potential negative environmental impacts. In situ activities are likely to introduce (unfamiliar, heightened) light, noise, change of water temperature, pollution, debris, biological contamination and overexploitation. Extraction of samples can also have an influence on life cycle, characteristics, distribution and population. This concern may increase when there is a cumulative impact suffered by the source organism, for example: krill is not only being harvested, but also suffers from reduced sea ice, leading to cumulative pressure on the species. In general, bioprospection is limited to sampling, which requires the extraction of relatively small amounts of material. Research indicates that such sampling may not have a large impact on the fragile organism or delicate ecosystem the sample is collected from. Bioprospection and biodiversity conservation need to go hand in hand, as the former benefits from the latter. However, repeated collection, when a species has shown biotechnological potential and value, may require greater quantities and may raise the likelihood of environmental impact. On top of this, at this stage, very little is known about marine ecosystems and species – especially deep sea ecosystems and extremophiles – and it is this uncertainty which warrants the application of the precautionary approach (UNEP, 2013).

VLIZ, FPS Health, Belspo also acknowledge the positive impacts of marine biotechnology on the environment. Microalgae, for example, form an important alternative feed in aquaculture and can also be produced as an alternative source of omega-3 fatty acids (as opposed to fish-oil derived omega-3 FA), thus reducing the pressure on the already over-exploited fish stock. Another example put forward is algal biofuel production that can reduce environmental pressure as

the source does not compete with food production like other biofuels. In addition, the cultivation of microalgae has a smaller physical footprint and carbon- or nitrogen-rich waste gas streams provide an opportunity to biofix greenhouse gases.

Marine biotechnology can help to ensure the sustainable use of biomass through the development of new culture, production and processing techniques and practices (OECD, 2013b). Moreover, marine biotechnology can also provide a means of monitoring and even remediating the marine environment through biosensor and bioremediation applications. Since 2001, rapid biological and biotechnological progress has resulted in a more efficient and environmentally responsible aquaculture and a greater diversity of marine food products. (EMB Position Paper 15, 2010)

Social impact

According to VLIZ, FPS Health and Belspo, the impact of bioprospecting on marine ecosystems is not to that extent that it would influence other sectors, such as fisheries or that it would influence coastal populations. There is, on the other hand, already interaction between other users of the marine environment and researchers, who often use existing cruises as means of transportation for their research. Public-private cooperation is in that sense relevant. As we live in a more globalized world now and taking into account that marine biotechnology will encompass the entire marine part of the world, the impact will be of benefit to coastal populations but most important to the users of the marine space. The OECD (2013b) recognizes the bioeconomy as a political priority because of its tremendous potential for economic growth and social benefits. It considers that the bioeconomy will allow US citizens to live longer, healthier lives, reduce national dependence on oil, address key environmental challenges, transform manufacturing processes, and increase the productivity and scope of the agricultural sector while creating new jobs and industries. Marine biotechnology can make an important contribution to the bioeconomy through the development of innovative products and processes, the creation of jobs and the building or greening of a number of industries and sectors.

The development of marine biotechnology will have an impact on the population as a result of the products that are produced. Marine biotechnology has led to the development and production of a number of pharmaceuticals, nutraceuticals, nutrition supplements, cleaning products, other consumer products. It is also important to consider the non-market value of the oceans, e.g. the environmental (ecosystem services) and recreational value that can be derived from the ocean, and to recognize how these are affected, positively and negatively, by marine biotechnology applications. This affects the entire population on earth.

Ethical issues

VLIZ, FPS Health and Belspo are of the opinion that there are no adequate arrangements in place to ensure an equitable distribution of the benefits of marine biotechnology.

They refer to the OECD (2013b) which states that marine biodiscovery is already taking place in the open ocean and the international seabed, marine areas beyond the limits of national jurisdiction, and is expected to increase. The CBD (Convention on Biological Diversity) and Nagoya Protocol only apply to the continental shelves and exclusive economic zones (EEZs) of their contracting parties, and therefore do not address marine genetic resources obtained from these areas. At present, such resources are accessible to anyone for any purpose. There is no formal obligation to share benefits with the international community, although the United Nations Convention on the Law of the Sea (UNCLOS) does have provisions on international co-operation and the exchange of results with respect to marine scientific research in these areas. While it is important to reach a shared understanding of "countries providing genetic resources" and "local" providers and a better understanding of the role and value of traditional knowledge, particularly to ensure legal certainty in the discovery and development of marine bioresources, the equitable development of marine genetic resources in areas beyond national jurisdictions may provide even greater challenges. New governance frameworks should be put in place to deal with these issues. UNCLOS was adopted at a time when the international community was unaware of marine genetic resources and their potential and although it has provisions for metallic/gaseous/… substances, it is silent on living genetic resources. UNCLOS's general rules on activities at sea (such as a duty to preserve the marine environment) are obviously applicable to bioprospecting in areas beyond national jurisdiction, but there are no provisions on benefit sharing. This is why Belgium and the EU have been arguing for the start of negotiations of an additional protocol to the UNCLOS (an "Implementing Agreement for biodiversity in areas beyond national jurisdiction") within the relevant UN working group and in other high level fora (such as Rio+20). This Implementing Agreement would, amongst others, create a system where biodiversity is protected and preserved and where access and benefit sharing is regulated. This system needs to be balanced in such a way that genuine needs of the developing world are met (for example: capacity-building for experts and scientists from developing countries, transfer of technology, database of activities, fair system of patenting,…), but investments from other States, as well as private entities are not hazarded.

'Open innovation'

VLIZ, FPS Health and Belspo believe that 'open innovation', i.e. innovating with partners by sharing risk and sharing reward, is possible. Moreover, effective partnerships will play a large role in developing marine biotechnology and in translating new scientific and technological knowledge into social and economic benefits. Successful innovation will require partnership with stakeholders throughout the innovation cycle: suppliers, consumers, competitors, private R&D firms, universities and higher education institutions, and government and public research institutes. It will be important to understand the types of partnerships that facilitate innovation and the mechanisms that are effective for initiating and supporting them (OECD, 2013b). Incentives or other support may be required to encourage academics and other actors in basic research to participate in the full innovation cycle up to commercialisation. To achieve an appropriate balance between basic and applied research in advancing marine biotechnology will also require business models for developing and producing marine biotechnology products and services that ensure the right incentives and support (OECD, 2013b). It is advised to anticipate by allowing/facilitating third countries to participate in the "EU marine biotech research arena" and by exporting advanced technologies and products to third countries.

Models and initiatives for knowledge sharing

With regards to potential collaborative models and types of initiatives for knowledge sharing, VLIZ, FPS Health and Belspo refer to OECD (2013b): "some forms of collaboration are listed which have proven successful for some sectors in facilitating knowledge sharing: collaborative research, university-industry research centres, contract research and academic consulting. Other examples are: platforms, public-private partnership and collaboration with SME's (Small and Medium Enterprises). A good example is the Marine Biotech Platform of Flanders (in Dutch: Marien Biotechnologie Platform Vlaanderen, website: http://www.mariene-biotechnologie.be/). This Platform forms a network of industrial and scientific partners with the aim of increasing the visibility of marine biotechnology so that it can contribute to the general recognition of the research and may lead to improved cooperation and the promotion of interdisciplinarity. VLIZ performs a facilitating role. In addition, VLIZ collects relevant information (contact database, project database, job vacancies, events,…) and publishes these on the website and through a LinkedIn group.

The formation of dedicated clusters

VLIZ, FPS Health and Belspo see the formation of dedicated clusters, i.e. geographic concentration of interconnected businesses, suppliers, and associated institutions in a particular field, as beneficial for the development of marine biotechnology.

They refer to the OECD Innovation Strategy that recognises the impact that fully functioning knowledge networks can have on the efficiency and effectiveness of the innovation process, both stimulating innovation and improving its efficiency by reducing transaction costs. As marine biotechnology becomes a focus of investment and innovation strategies, it will be important to ensure that mechanisms are in place to generate, share and give value to knowledge in order to enable innovation. Given the global nature of marine bioresources, it will also be useful to consider international, transboundary approaches that can help to drive innovation in R&D infrastructure (OECD, 2013b). Marine biotechnology funding programmes and initiatives are already established of which some examples are: EU Joint Programming initiatives (JPI Oceans, …); EU ERA-NET (ERA-MarineBiotech, …); Regional partnerships (CIESM, KAUST,…); European infrastructures for example the European marine biological centre (EMBRC): a research infrastructure for exploring the secrets of marine organisms, open to all European researchers. This consortium will deliver services to the marine science community, local SMEs and industrial companies by facilitating access to marine organisms, their environment and the expertise associated with their study. Marine biotechnology funding programmes and initiatives should be promoted in the future to increase the value of international partnerships and investment for fostering knowledge development. This is also highlighted in the EMB Position Paper 15 (2010), which recommends to:

- stimulate the development of research strategies and programmes for Marine Biotechnology research and align these at the national, regional and pan-European level.
- create a European Marine Biotechnology Institute or Centre, at least virtual, charged with developing Europe's Marine Biotechnology research capabilities through a range of collaborative actions including establishing and operating the European Marine Biotechnology Portal.
- develop a coherent European Marine Biotechnology RTD policy to strengthen the integration at EU level of Marine Biotechnology research and corresponding infrastructures, among others through a future Framework Programme support action or a dedicated ERA-NET.
- strengthen common European platforms in the field of omics research which include corresponding bioinformatics and e-infrastructures and the development of centres for systems biology and synthetic genomics, recognising that Marine Biotechnology draws from a wide range of multi-disciplinary research outputs and tools.

- develop high level European Marine Biotechnology research programmes taking an industry-academia collaborative and multidisciplinary scientific approach in the thematic areas of Food, Energy, Health, Environment and Industrial Products and Processes.

Infrastructure sharing

VLIZ, FPS Health and Belspo suggest some opportunities for infrastructure sharing and how these could be developed:

- omics science (genomics, transcriptomics, proteomics and metabolomics) and related technologies have rapidly made great improvements over the last decade. Marine organisms can now be examined more quickly and in greater detail than ever before, by for instance the use of metagenomic analysis. Also the cost is dropping rapidly by the advances in new technologies. OECD (2013b) reports a new infrastructure bottleneck that threatens to limit the rate at which its benefits can be realised. Moreover, exploration and sampling are still difficult in areas of environmental extremes which offer great potential for discovering organisms with novel functionalities. International cooperation is needed to deal with the technically difficult, expensive and very risky cruises. Upgraded infrastructure is needed, with new model, culture systems and bioinformatics-based tools to visualise and analyse genomics and other types of data. Platforms such as databases and biobanks provide an excellent focus for collaboration and the open sharing of data and data products.

- Databases are an important tool assembling and sharing different types of information. Especially for the study of marine bioresources and biodiversity, databases are an integral part allowing an inventory of the different aspects within marine biotechnology. Support should be given to the development of databases, as established in the ERA-MarineBiotech (http://www.marinebiotech.eu/component/imis/?module=institute) and the Marine Biotechnology platform Flanders (http://www.mariene-biotechnologie.be/mariene-biotechnologie-in-vlaanderen).

- The challenge to keep databases up to date implies that access to networks of stations, seagoing platforms and observatories is required and this could be obtained by the execution of international cooperation projects. Great effort should also be made into making these databases publicly accessible, ensuring high quality and providing international awareness and cooperation and synergies.

- Additional value could be found in databases which are developed by cooperation between researchers in research institutes, universities and

industry. Meanwhile, sharing of shiptime on research vessels (like the EUROFLEETS project), exchange of specific equipment, provide/exchange of access to research stations or labs with large infrastructure (like Interact project) need to be continued. On an academic level, the Ghent University created an interdisciplinary consortium called Marine@UGent (the UGent Marine Sciences Center of Excellence), to promote and facilitate the collaboration between 30 research groups from 6 faculties and with Flanders Marine Institute. Marine@UGent members also perform research in the marine biotechnology sector. Marine biotech can also take profit of the platforms that have already been built for the red, green and white biotech.

Data ownership and intellectual property issues

Industry has often access to databases developed with public funding, however the converse is rarely executed. VLIZ, FPS Health and Belspo believe that consideration should be given to incentives for industry and scientists to work together in this area. If there is no competitive disadvantage of sharing private data, this should be done directly after monitoring. The assigning authority must oblige the contractor to collect data during the contracting phase and give a compensation for this effort. In this way the same datasets can be used for different purposes and overlap of monitoring surveys can be avoided. Data collected with public money should be publically available. This data sharing gives everybody the possibility to do their own data assessments. Databases should be designed to summarize the information regarding gathered data, to allow efficient use of scientific data and avoid research duplication.

International cooperation with third (non-EU) countries

VLIZ, FPS Health and Belspo believe there is a scope for international cooperation with third (non-EU) countries. International cooperation with third countries is needed, especially with developing coastal countries that lack the scientific and technological capacity to explore and develop resources. Otherwise further investment by capacity-rich countries will create further inequities, which can be illustrated with the current marine gene patents. The OECD (2013b) summarizes a search of the patent division of GenBank from 1999-2009 which identified 677 international claims of marine gene patents. These patents originated from only 31 of the world's 194 countries. Some 90% of these patents belonged to just ten countries which account for only 20% of the world coastline. Cooperation with research centra in China can provide win-win situations for the study of their "large-scale marine bioremediation" activities in the coastal area of the Shandong province. China is also investing in R&D for Blue BioEconomy activities. Furthermore, marine biotechnology/biodiscovery activities could be a theme for trans-Atlantic cooperation between EU and US/Canada. On the other hand this is

also a topic where cooperation with developing countries is possible (capacity building, knowledge/technological transfer, ...).

WAY FORWARD

Public intervention

VLIZ, FPS Health and Belspo believe there is a scope for the EU to support the emerging marine biotechnology sector with additional measures. Specific funding programs for university-industry partnerships could be supported to accelerate the creation and application of knowledge. Knowledge exchange events could be organised to foster constructive dialogues between academic researchers and industry. Support should be given to the central European information portal which was established in the CSA MarineBiotech project, financed under the FP7 programme. This one-stop-shop for state-of-the-art reports on novel discoveries and success stories, challenges and opportunities will be updated within the ERA-MarineBiotech and continuation beyond this project should be ensured (http://www.marinebiotech.eu/wiki).

Other recommendations to support the emerging marine biotechnology sector are highlighted in the EMB Position Paper 15 (2010), advising to:

- initiate a series of Marine Biotechnology demonstration projects that target the utilisation of marine materials in defined sectors.
- 1d) Develop promotional and education support materials that highlight the potential and the successes of European Marine Biotechnology research.
- significantly improve technology transfer pathways, strengthen the basis for proactive, mutually beneficial interaction and collaboration between academic research and industry and secure access and fair and equitable benefit sharing of marine genetic resources.
- better adapt future FP financial rules and Grant Agreements to ensure SMEs are attracted to participate in a way that maximises the reward and minimises economic risks.
- establish completely new mechanisms and policies to circumvent the high risk of investments in critical novel drugs developed from marine bioresources, in particular for the development of new antibiotics of marine origin.
- harmonise the property rights and procedures for the protection of intellectual property for marine derived products at European level but with a global relevance. Develop new European protocols to facilitate the publication of academic research results whilst protecting, through innovative procedures, the intellectual property on new discoveries.

- develop a common European position on the simplification and harmonisation of regulations on access and fair and equitable benefit sharing from the exploitation of marine genetic resources taking into account three 'territories': inside Europe; outside Europe and international waters.
- conduct a survey of industry stakeholders to guide research towards applications and processes to address current industry needs.

VLIZ, FPS Health and Belspo believe that public engagement at the national/regional level will be necessary to stimulate development of marine biotechnology and to advance the policy agenda. It will be important to have an ongoing, inclusive dialogue on the opportunities offered by marine biotechnology and their environmental implications, and for this dialogue to take place at regional, national and international levels. The goals of economic productivity and wealth creation need to be seen in terms of the cultural and social well-being and not only of coastal populations but of the entire world (OECD, 2013b).

Research and innovation

According to VLIZ, FPS Health and Belspo effective partnerships will play a large role in developing marine biotechnology and in translating new scientific and technological knowledge into social and economic benefits. Successful innovation will require partnership with stakeholders throughout the innovation cycle: suppliers, consumers, competitors, private R&D firms, universities and higher education institutions, and government and public research institutes. It will be important to understand the types of partnerships that facilitate innovation and the mechanisms that are effective for initiating and supporting them. Other recommendations are highlighted in the EMB Position Paper 15 (2010), advising to:

- improve training and education to support Marine Biotechnology in Europe.
- assure that appropriate biotechnology modules are included in all bio-science undergraduate educational programmes.
- initiate actions that will ensure the participation of researchers from non-marine backgrounds in Marine Biotechnology, thus ensuring that a growing pool of exceptional research talent is available to the Marine Biotechnology sector.
- organise regular trainings or summer schools on Marine Biotechnology subjects supported, for example, by the EU Framework Programme.
- create a European School or Course on Marine Biotechnology (virtual and distributed) and a European PhD programme on Marine Biotechnology both of which need to include business and entrepreneurship training as standard.

In addition, VLIZ, FPS Health and Belspo recommend open communication and collaboration in the framework of international programmes or communication events to prevent the duplication of efforts. Focused and effective international dialogue will be needed to address hurdles such as development of indicators, R&D infrastructure and sustainable development of marine resources. Dialogue at national and regional level among end users, regulators, the private sector and researchers will also be important for innovation in marine biotechnology and its applications.

With regards to identifying training that is needed to develop necessary skilled scientists/labour, VLIZ, FPS Health and Belspo refer to the EMB Position Paper 15 (2010): "to promote Marine Biotechnological innovation, training of the next generation of scientists is critical. They must have more interdisciplinary expertise and use tools from various disciplines to address questions related to marine organisms and to solve problems posed by the marine environment". This statement is not specific to marine biotechnology; in fact the future of life sciences in the 21st century will depend upon the ability of scientists to develop interdisciplinary projects embracing skills and concepts from, for example, phylogeny, mathematics, chemistry, and the physical, engineering, computational and social sciences. The challenge for the development of the Marine Biotechnology sector is to ensure that undergraduate and graduate training programmes related to marine sciences include adequate training in biotechnology.

For the international coordination of the marine biotechnology sector VLIZ, FPS Health and Belspo believe that JPI Oceans could play role as a strategic coordination mechanism with other non-EU countries. They also refer to the CSA MarineBiotech Deliverable D3.6 (2013): In spite of the significant progress at various fronts, numerous challenges remain. One of the main challenges will be to keep stock of all the developments currently taking place and ensure appropriate levels of alignment, and integration where required, of the interests, strategies, programmes and activities at the local, sub-national regional, national, macro-regional (sea basin level), pan-European and international level. How to position blue biotechnology in the complicated and dynamic landscape of other biotech fields (notably industrial (white) biotech, health [red] biotech and agricultural research (green) biotech), the numerous relevant research and coordination projects (including the ERA-MarineBiotech and other ERA-NETs), infrastructures, the Joint Programming Initiative on Healthy Seas and Oceans etc.

Market introduction

For suggestions on how to facilitate the interaction between science, industry and society, VLIZ, FPS Health and Belspo refer to the key highlights of the CSA MarineBiotech Public Report (2013): Successful implementation of the strategy will require a joint effort with active support and involvement from all relevant

stakeholders. Europe needs to mobilise the necessary support in terms of funding, human resources and research infrastructures, and to secure the engagement of all of the relevant actors. These actors include the science community, the private sector (e.g. individual companies, associations and technology platforms) policy makers and advisors at national and European level, national strategy and programme developers and managers, and ultimately the public at large. As each actor has an important responsibility to bring forward key elements of the strategy, mobilising, in a coordinated way, this diverse range of actors will be critical.

The rate of conversion of research findings into market applications is lower in Europe compared to other parts of the world. To bridge the gap between research and innovation VLIZ, FPS Health and Belspo suggest the 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. They also refer to the key highlights of the CSA MarineBiotech Public Report (2013): a common problem, to which ERA-NETs offer a solution, is enabling research that a single country could not undertake. The synergies from such interaction could be of interest to firms in the private sector, since access to a broader skill base is possible and there is a scale effect that enhances credibility of the project. However, within such projects, some firms may prefer to remain anonymous for competitive reasons. Irrespective of their duration, it is essential that projects remain clearly focused on specific deliverables. Open ended or vague projects offer little to attract the involvement of firms. A challenge remains, concerning where or what areas to focus upon. Processes which involve firms in setting goals for ERA-NET projects are preferable to those which fail to include firms, since they are more likely to include a commercial perspective. The early involvement of firms in research projects creates the potential to develop a market focus or a utility aspect.

In order to use economic data and information (parameters/indicators) to (i) allow a more objective market/trend analysis to assess the size and development of the sector and (ii) to assess the return on (public) investment in the sector, VLIZ, FPS Health and Belspo propose input indicators in the OECD Scientific and Technological Indicators Database. This database lists a number of input indicators related to R&D, such as gross domestic expenditure on research and experimental development (GERD) and financing patterns, to measure the output of scientific and technological activities. In particular, it contains three proxy indicators for innovation that could be useful in this regard: patents, the technology balance of payments and trade in R&D intensive industries. Also the Marine Biotechnology Working Group of the Marine Board (European Science Foundation) attempted to map indicators of success and found that it was very difficult, and in some cases impossible, to obtain the necessary information. The working group was able to measure some key parameters of scientific outputs: funds and manpower devoted to marine research and technological development;

scientific publications and their impact (citations); European patents by marine science and technology sectors; and information on the objectives, current status and results of various research and technological development initiatives and programmes, both at national and European level. However, information pertaining to businesses and economic outputs was hard or expensive to obtain and difficult to interpret (OECD, 2013b).

Ethics and sustainability

In order to avoid negative environmental and social impacts VLIZ, FPS Health and Belspo suggest following measures to be taken at EU level:

- create a clear legal framework, both at the global level (ex: through an UNCLOS Implementing Agreement, through the ratification of the Nagoya Protocol,…), as at EU level. A legal framework concerning environmental indicators which could contribute to effective resource management and protection protocols could be further developed.
- apply the precautionary approach.
- have a clear procedure for environmental impact assessments, incl. consequences when the impacts are thought to be negative.
- support initiatives that categorize marine biotechnology and research, such as the joint Belgian, UNEP database on bioprospection in Antarctica (http://www.bioprospector.org/bioprospector/antarctica/home.action)
- develop and support initiatives for the transition to a more sustainable and resilient society

Suggestions for biological, geological, chemical and physical indicators that characterise the health of coastal waters, the nature of pollutants and their relation to human activities and urban concentration are being made in OECD (2013b). Further work is required to:

  - define and analyse the policy value of relevant quantitative indicators.
  - identify existing primary science and technology indicators and socioeconomic data on a sectoral and national basis.
  - analyse the validity and relevance of such indicators and data for policy development, such as a demonstration of sustainable development options adapted to regions.
  - synthesise existing indicators with a view to developing international indicators, including benchmarking of indicators and practice.
  - publish and disseminate regular reports on the state of the ocean and on marine activities based on these indicators.

A coordinated approach to the conversation, sustainable use and sharing of the benefits of marine biodiversity, should be considered using the most efficient tool. Other useful tools related to the marine environment that should be considered are the Aichi Targets.

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