NORWEGIAN MINISTRY
OF EDUCATION AND RESEARCH

Strategy 2011-2020

National Strategy for Biotechnology

For the future of value creation, health and the environment

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Contents

Preface

This document presents the Government's strategy for biotechnology. The strategy has its origin in the Government's white paper on research, Climate for Research, (Report No. 30 (2008-2009) to the Storting) which states that a balanced strategy for basic research, industry-oriented research, innovation activity and commercialisation in the field of biotechnology is to be developed.[1] The Ministry of Education and Research, the Ministry of Health and Care Services, the Ministry of Agriculture and Food, the Ministry of Fisheries and Coastal Affairs, the Ministry of Trade and Industry, and the Ministry of the Environment have drawn up this strategy in cooperation with the Research Council of Norway and Innovation Norway. The effort has been headed by the Ministry of Education and Research.

A variety of stakeholders have contributed to the strategy. A kick-off conference was organised in 2010, and a conference focusing on ethics and biotechnology was held in early 2011. In addition, dialogue meetings have been held between key players in educational and research institutions, the health trusts, trade and industry, and organisations and individuals with expertise in environmental and ethical questions related to biotechnology.

This strategy charts out a course for Norwegian efforts in the field of biotechnology from 2011 to 2020. Biotechnology has the potential to solve many of the major global challenges of our time. New, environment-friendly, biotechnology-based industrial processes will help to reduce pollution. The application of biotechnology to aquaculture and agriculture will lead to more reliable access to safe food for the world's growing population. New, innovative health services will improve medical treatment options while reducing the negative effects of medication. Increased investment in biotechnology–related activity will also enhance the competitiveness of Norwegian trade and industry and help to maintain employment levels.

But there are risks involved as well. We must be mindful that developments in biotechnology are taking place more rapidly than ever. We must not begin using new technology before its ramifications have been adequately assessed.

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Minister of Research and Higher Education

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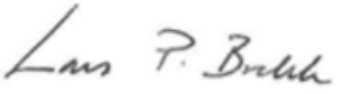

Lars Peder Brekk
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Minister of Fisheries and Coastal Affairs

1. www.government.no/upload/KD/Vedlegg/Forskning/climate_for_research_final.pdf

Summary

Some of the greatest challenges we face are related to the anticipated increase in the global population by two billion people in the next 20–30 years. All of these people require food, water, energy, and health services, and it is expected that they will have a higher standard of living than what the world's poor has today. These needs must be met in a sustainable, environment-friendly manner. Biotechnology paves the way to many new opportunities for meeting these challenges.

Biotechnology is often referred to as an enabling technology along the lines of ICT and nanotechnology, and throughout the world major resources are being used to develop biotechnology and apply biotechnological processes in many areas of society. This is partly due to the assumption that this technology will lead to more accurate methods of prevention and treatment for humans and animals, safer and more effective plant and food production, and more environment- and climate-friendly industrial and energy processes. Norway has an obligation to take part in and contribute to the expansion of the global knowledge pool. This is especially crucial for our ability to make independent, informed choices about the use of biotechnological tools. Biotechnology is being used in an increasing number of activities, and there is every reason to believe that this trend will only escalate.

The Norwegian Government provides a framework for the development of biotechnology in Norway by drawing up regulations, providing support to advisory bodies such as the Norwegian Biotechnology Advisory Board, and by allocating funding for research, development and infrastructure.

This strategy calls for a continued investment in research, development, and commercialisation of biotechnology and a commitment to ensuring that biotechnology is applied in a variety of sectors across Norway. To achieve this, Norway must have an up-to-date statutory framework, and must ensure close cooperation between research and technology communities and those who will be applying the knowledge, as well as close cooperation between the research communities and society at large.

This strategy is based on dialogue with and input from a variety of players. It also builds on a broad knowledge base developed nationally as well as internationally. Both the EU and the OECD have recently implemented initiatives in which biotechnology plays a key role. The Research Council of Norway has analysed the state-of-the-art for Norwegian biotechnological research and development activity as part of the process of establishing the new research programme for biotechnology in innovation (BIOTEK2012 process). The Research Council has also conducted an evaluation of the large-scale Programme for Functional Genomics (FUGE).

Biotechnology has many areas of application, and it is essential that this technology is further developed in an open dialogue with society. The knowledge base shows that the ethical, legal and other social aspects of the development of biotechnology need to be integrated more clearly in projects, programmes

and initiatives that support biotechnological research and development activities. These aspects must not be peripheral to technological development, but rather central to it.

During the past 10 years, substantial government funding has been allocated to research, development and infrastructure measures related to biotechnology. The FUGE programme alone has provided NOK 1.6 billion in funding for research and development activities in the period from 2002 to 2012. In addition, other funding sources, especially the research institutions and health trusts, have given priority to biotechnological research and related subjects. All of these efforts have boosted Norwegian biotechnology to a competent international level, with several research groups of high international calibre. Nonetheless, Norway must continue its efforts to maintain and enhance the quality of Norwegian biotechnology research. There is still a need to further develop basic expertise and to strengthen selected fields. Norway must also continue to support the unique national cooperative technology platforms and distribution of tasks that have been established in this area.

Analyses show that Norwegian biotechnological research and development activities need to have a stronger international orientation. Vast resources are being allocated to this area of technology throughout the world, and it is crucial that Norway establishes international networks and gains new inspiration from abroad. Norway needs to become more visible in the international arena and seek a greater degree of cooperation with the best international environments. This applies to the research communities at universities, university colleges, and health trusts as well as to trade and industry.

Analyses also show that the academic environments could cooperate more effectively with other users of biotechnology. Knowledge environments should seek partnerships with trade and industry, and public policy instruments should stimulate Norwegian trade and industry to participate in biotechnological research and development activities. By the same token, trade and industry has a responsibility to take advantage of international developments in biotechnology. Norwegian research and development activities in biotechnology receive a larger share of public funding than many other research fields, and industry needs to increase its own contribution in the long term.

Efforts to create a better basis for greater use of biotechnological tools in existing companies and industries must be supplemented by activities to stimulate the establishment of new companies based on biotechnology. In general, commercialisation of biotechnology-based products is a capital intensive, time-consuming process with a high investment risk, although different product types and branches of industry have their own distinctive features. To facilitate commercialisation and industrial development, it is important to understand these differences. The Industrial Development Corporation of Norway (SIVA), Innovation Norway, and the Research Council of Norway must cooperate closely on how to target the funding instruments.

Norwegian efforts in biotechnology need to become more targeted. The application of biotechnology in the aquaculture industry may form the basis for increased value creation, in which marine organisms, raw materials or chemical compounds from the marine environment are incorporated into production processes. A transition to industrial processes based on biotechnological principles may give rise to environment-friendly alternatives that produce fewer by-products and use less energy and water. Research and development activities based on biotechnology have the potential to improve production along the entire value chain in the land-based primary industries. Increasingly, medicines and diagnostic tools are being developed and produced using biotechnological methods.

To realise this potential, this strategy identifies four thematic focus areas in which biotechnology can play a role in addressing social challenges and where Norway has national competitive advantages:

- aquaculture, seafood, and management of the marine environment
- land-based food and biomass production
- environment-friendly industrial processes and products
- health, health services and health-related industries

The state-of-the-art overview shows that although biotechnology will open new doors in many sectors in the future, the ability and willingness to use and develop these opportunities differ among the various sectors. The amount and target of public funding instruments will therefore vary between the different thematic focus areas. The public research and innovation agencies Research Council of Norway, Innovation Norway, and SIVA will play a key role in designing the specific measures under each thematic focus area. It must also be taken into account that some thematic areas will have a greater need for long-term, basic research and competence-building.

Biotechnology is cross-sectoral by nature. The Government's efforts in the area of biotechnology are therefore funded through a number of instruments, some of which are general and others of which are targeted towards individual sectors or topics. In the national budget for 2012 the Government proposes an annual allocation of NOK 89.5 million beginning in 2012 to continue the strategic activities in biotechnology through the Research Council of Norway. Furthermore, the Government proposes a large budget increase in 2012 to give a major boost to the open competitive arena for excellence in research, and emphasises that this support must also be targeted towards further efforts in biotechnology. In addition, the Government proposes an allocation of NOK 110 million for the period 2011–2016 to go to funding for human biobanks and health registries. This will provide support for research and development activities aimed at improving health and the health services.

1 Vision for Norwegian biotechnology

The Government's vision
Norway will employ cross-sectoral research, expertise and cooperation to exploit the potential of biotechnology in a responsible manner in order to strengthen value creation, improve health and safeguard the environment.

Eight focus areas
To lay a foundation that will enable Norwegian biotechnology to realise this vision within the next decade, the Government will give priority to eight focus areas - four thematic areas and four cross-cutting areas.

The cross-cutting focus areas are designed to ensure that Norway possesses the high-level expertise needed to apply and utilise biotechnology knowledge in a responsible manner. The interaction between the cross-cutting and thematic focus areas forms a cross-sectoral basis for an innovative, competitive Norwegian industrial sector. The strategy thus establishes a framework for ensuring that there is support for interdisciplinary and cross-sectoral projects within initiatives and programmes in the field.

Activities targeted towards promoting education, research and competence-building; providing optimal conditions for industrial development and innovation; enhancing internationalisation; and ensuring adequate consideration of the ethical and social aspects of biotechnology, will be crucial to ensuring the success of efforts within the thematic focus areas.

Internationally, progress in biotechnological research and development is occurring rapidly and as an integral part of research in the biosciences and other mathematics and natural science fields as well as the medical sciences. Norway therefore needs a sufficiently broad-based biotechnology-related research community in order to absorb new innovations and to meet the new challenges arising from technological development.

Projects in the biomedical industry often originate in academic research, and are developed through small start-up companies until industrial partnerships are established in later phases of the projects. In comparison, projects in industrial biotechnology originate more often in established companies to fulfil their need for new processes or products. The activity in each area must therefore be adapted to the various needs and distinctive features of each sector. Interdisciplinary and cross-sectoral cooperation will be important for deriving the greatest benefit from the resources.

Of the thematic focus areas, it is biotechnological research and innovation within health, health services and health-related industries that have been best developed in scientific and structural terms. Biotechnology maintains a relatively strong position in the marine and agriculture-based area. Industrial biotechnology, however, remains an underdeveloped area of research and industry in Norway which will require a more long-term re-ordering of priorities within Norwegian biotechnology efforts. It is important to establish a framework that promotes the development of biotechnology-related practices that are aligned with the fundamental uncertainty associated with radical new technologies. The precautionary principle presupposes responsible actions on the part of the government, organisations, and individuals. Development must take place in an open dialogue with society.

Publicly-funded infrastructure and new knowledge must be made accessible and used in ed-

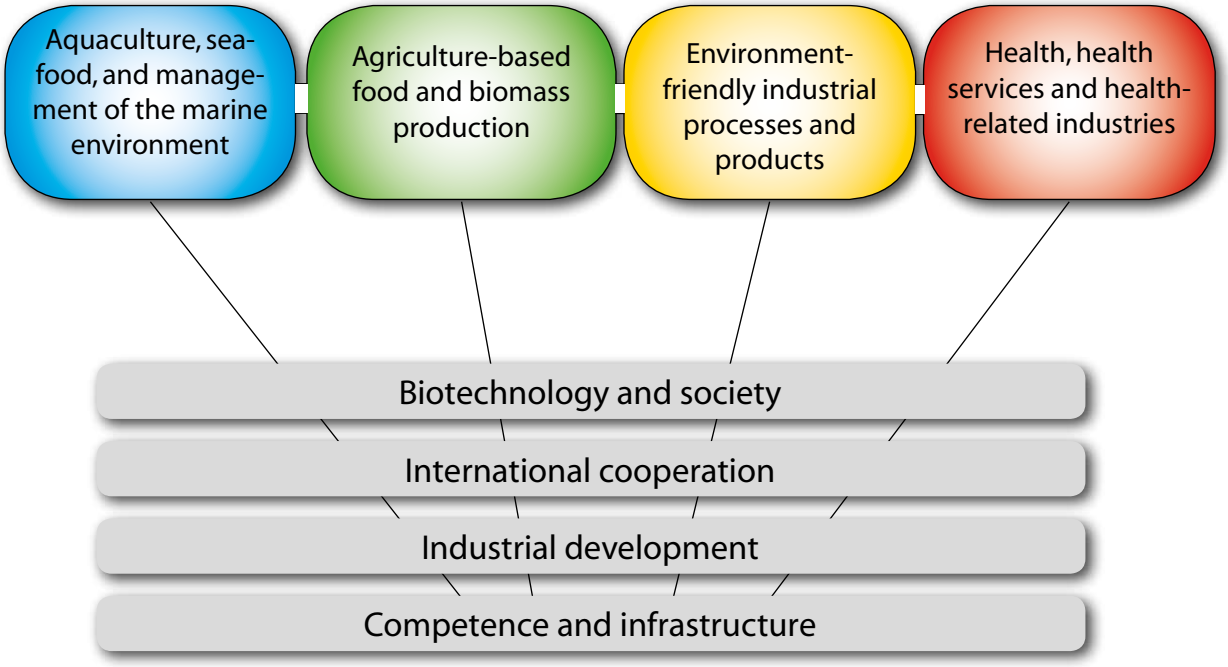


Figure 1.1 Four thematic and four cross-cutting focus areas of Norwegian biotechnology. Cross-sectoral cooperation between the thematic focus areas is essential.

ucation, research, public administration and public service production, as well as by the business sector. New biotechnology activities must further improve the framework for collaboration between industry and the research community.

A state-of-the-art overview shows that biotechnology is a significant field of research in Norway. The capacity as well as the quality of Norwegian biotechnology research has improved during the past decade, due in part to the Research Council of Norway's Programme on Functional Genomics (FUGE). It is an objective to continue this development through greater investment at the institutions and through various funding instruments that support world-class research and build capacity in strategically important areas in both public and private enterprises.

Biotechnological research obtains a larger share of its funding from the public sector than many other research areas. R&D statistics and figures from the SkatteFUNN Tax Incentive Scheme show that biotechnology R&D is conducted within a variety of industries, but that many more companies could make use of biotechnological tools.[2] In the long term industry needs to increase its share of biotechnology R&D.

Statistics show that there are major geographic differences in R&D activity. The specialist scientific communities should act as national resource centres, serving as partners to companies and research groups throughout Norway. Likewise, public instruments should lay the basis for productive dialogue with various players when initiatives are being designed.

2. SkatteFUNN is a tax incentive scheme designed to increase investment in research and development by industry.

The overall public investment in Norwegian biotechnology research is largely a result of internal strategic priorities at universities, university colleges, and health trusts. Given the anticipated significance of biotechnology in the future, this prioritisation is expected to continue. Public funding of biotechnology R&D is currently targeted towards medicine and the health sciences. The institutions need to direct more resources towards the three other thematic areas in this strategy, and public policy instruments should facilitate this.

2 A technology that creates new opportunities

In this strategy the term "biotechnology" is defined as the application of science and technology to living organisms as well as to parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.[3] The term encompasses research, competence-building, and application of the many types of biotechnology.

Biosciences, also referred to as life sciences, include biological and biomedical sciences and research on biological material, such as microorganisms, plants, animal and humans, in related disciplines. Many areas of biotechnology fall under the biosciences. Other areas of biotechnology fall under non-biological subject fields such as information technology or process technology (figure 2.1).

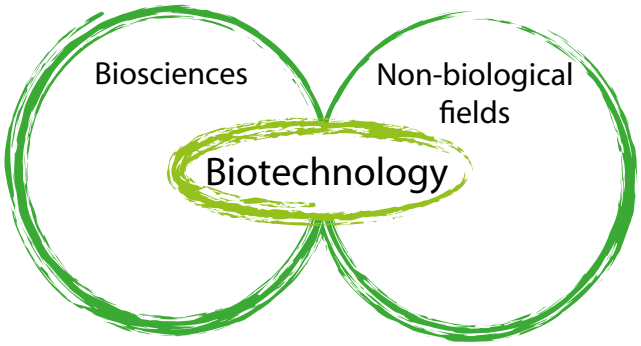


Figure 2.1 Biotechnology is utilised in the biosciences as well as in fields not related to biology.

Similarly, the biotechnology industry comprises only a portion of the activities that fall under the international umbrella of life sciences, which also encompasses activities within medical-technical equipment and the chemical-based pharmaceutical industry.

Biotechnology as an enabling technology

Like ICT and nanotechnology, biotechnology is an enabling technology that has great potential to foster innovation, industrial development and enhanced competitiveness. There are many areas of application, and biotechnology is used by a wide array of actors in sectors such as agriculture, aquaculture, health and industry.

Just as ICT has changed most areas of modern society, so too may biotechnology, along with ICT and other enabling technologies such as nanotechnology, pave the way for new methods and areas of application that cannot be foreseen today.

In some cases, biotechnology constitutes the main element in an industrial process or a key technology in a service, such as diagnostics. In other cases, biotechnology is not an integral part of production, but is nonetheless crucial for the research and development activity underlying the products and production processes. Norwegian aquaculture is an example of an industry in which modern, biotechnological methods have played a critical role in areas such as vaccines, breeding programmes and feed development.

3. The OECD uses the same definition.

Biotechnology as a research method

Modern biotechnology achieved its first breakthrough with the development of gene technology and the establishment of model systems in cells and animals, which among other things made it possible to conduct cancer research on everything from yeast cells to mice. Biotechnology is based on a wide range of foundational subjects focusing on the biosciences as well as mathematics, the natural sciences and medical sciences. Researchers in many fields employ biotechnological knowledge and methods to address issues ranging from basic biomedical research via research on primary production, energy and the environment to process development in new and existing industries.

The ability to sequence entire genomes from humans and many animals, plants and microorganisms has paved the way for functional genomics research. This research uses the huge amount of data obtained from genomes to study biological processes and building blocks in a new way. The ultimate goal of functional genomics is to explore the interaction between genes to learn more about the traits of living organisms. Rather than studying the functioning of individual genes, researchers are employing new methods to study the complex interaction between vast numbers of genes occurring within living organisms at any given point in time. Advancements in bioinformatics have made such studies possible.

Biotechnology for the individual person

The use of biotechnology may enable the development of new, more environment-friendly products, healthier and safer food, and better medical treatment options. However, biotechnology, like most other technologies, poses potential dangers that society must guard against. An up-to-date regulatory framework for biotechnology is therefore crucial.

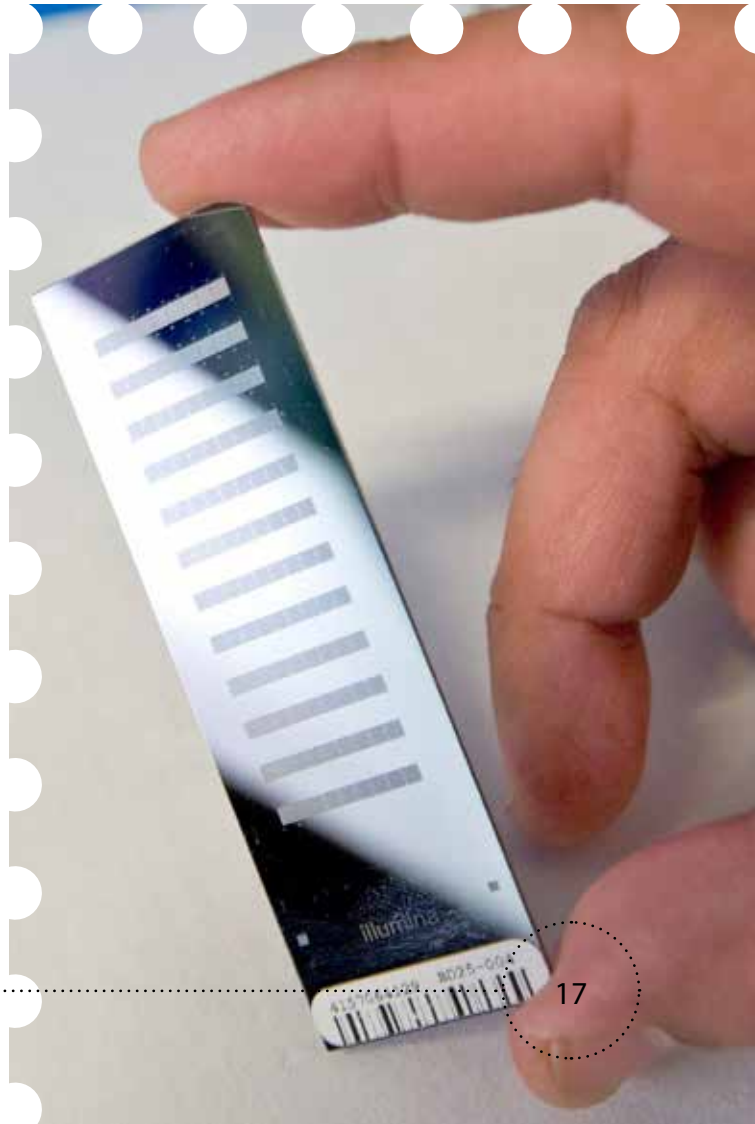
Biotechnology raises fundamental questions about what constitutes life, which for many puts this technology in a unique position. Ethical principles, freedom of personal choice in health care and considerations related to personal privacy may conflict with more overarching societal or research interests. Such questions must be addressed with independent health and environmental risk research and research on the ethical, legal and social aspects of biotechnology. It is important to promote a public debate on how biotechnology should be developed, applied and regulated.

The biotechnology that enabled the aquaculture industry to evolve.

Today's aquaculture industry would not have been possible without modern biotechnology. Knowledge and methodology were developed early on to understand the various traits of fish species, to develop vaccines and to gain insight into fish biology as a basis for developing a more sustainable industry.

The prevalence of bacterial infections in the late 1980s led to unacceptably high use of antibiotics in the early years of the aquaculture industry. However, through the application of modern biotechnology the industry, in cooperation with research institutions, pioneered efforts to develop effective fish vaccines that have helped to reduce the use of antibiotics.

Modern biotechnology has also been applied in salmon breeding. Researchers have found areas of genetic material which are vital to the salmon's ability to resist certain diseases that cause losses for the aquaculture industry. A blood test may indicate whether the broodfish have this trait without the need to test their offspring, as was previously the case. Roe that leads to disease-resistant fish can thus be produced. Norwegian researchers have taken the initiative to map the genome of salmon, salmon lice and cod. This has given Norway an international advantage with regard to understanding the biology of farmed fish and developing a sustainable aquaculture industry that benefits from modern biotechnology.



3 Thematic focus areas

3.1 Criteria

The Government will give priority to areas in which there is convergence between national competitive advantages or major social challenges and the opportunities inherent in biotechnology. The criteria for determining the thematic focus areas are that they are to:

- build on national advantages, such as expertise and infrastructure, natural resources, and industrial strength found throughout the entire country;
- have good market potential;
- be of great benefit to society, nationally or internationally;
- be developed in dialogue with society.

The selected thematic focus areas are wide-ranging and reflect the generic nature of biotechnology. However, the development and application of biotechnology do not have the same scope in all four areas. They will therefore differ with regard to their potential for further development.

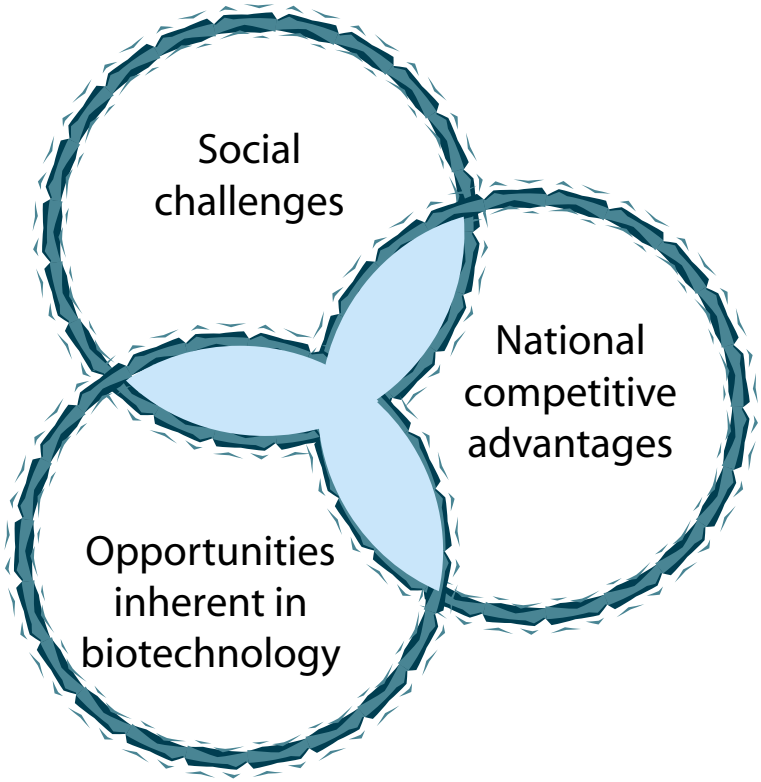
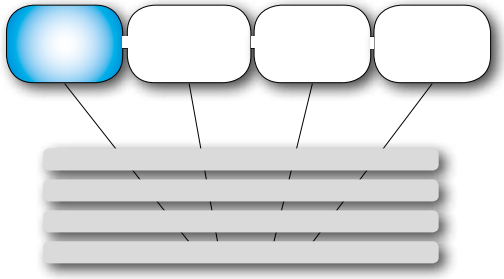


Figure 3.1 Interface between the opportunities inherent in biotechnology, social challenges and national competitive advantages.



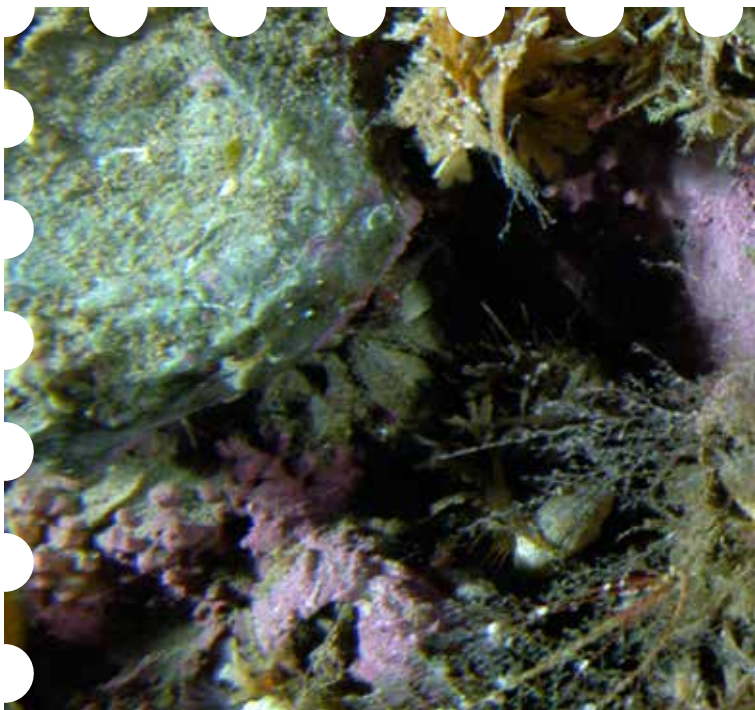
3.2 Aquaculture, seafood, and management of the marine environment

Marine resources are essential to Norwegian value creation and employment. It is therefore likely that marine resources will constitute a large part of the Norwegian bioeconomy in the future. Norway is the world's second largest exporter of seafood, and the industry had a turnover of more than NOK 50 billion in 2010.

Norway's sea area is seven times as large as its land area. The production potential of the oceans remains untapped in many areas, and the sea may play a key role in providing future access to safe, healthy food, renewable energy, health, and welfare. The provision of safe, healthy seafood products of high quality is a stated policy objective, and biotechnology has a central role to play in these efforts in the years to come. Increased use of by-products and new conservation methods can generate new opportunities within existing industries, while marine bioprospecting activities may lead to the emergence of new products.

At the same time, climate change and increased pressure on the environment poses a threat to the sustainability of the marine and coastal areas. These are important considerations that must be addressed, and knowledge from biotechnology may increase insight into both the potential and the limitations of the marine environment.

Increased use of biotechnology in these areas will promote value creation by boosting advancements in existing industries and generating new industries whose production processes incorporate marine organisms, raw materials or chemical compounds from the marine environment. Norway will also work to be a leader in developing and utilising knowledge related to sound resource management and the design of an appropriate statutory framework. The application of biotechnology methodology must be developed in a dialogue with civil society and the public administration, and within a framework that ensures safe, healthy seafood and environmentally sustainable development in the marine sphere. It is crucial that Norway seeks an international role in the development of marine biotechnology not only to secure its competitiveness, but also to enhance its reputation in an area in which the country, as a marine nation, is expected to be a leader.



Activities in the area of aquaculture, seafood, and management of the marine environment are to be targeted towards:

- safe and healthy seafood and new food products based on marine resources;
- good fish health and welfare;
- motivating companies to utilise and develop environment-friendly biotechnological solutions and production methods;
- the application of new knowledge from the genomes of relevant aquaculture species and parasites;
- utilisation of marine biomass and residual raw materials , e.g. as new sources of marine feed;
- cultivation and use of marine biomass, such as kelp, for producing sustainable bioenergy;
- marine bioprospecting in keeping with the national strategy set out for that field;
- sound infrastructure for marine research and international cooperation.

The strong international position of the Norwegian aquaculture industry today is due to research and industrial development carried out over many years and targeted towards achieving better selective breeding programmes, developing feed, and solving problems related to fish health. Norway will work to maintain its leading international position in aquaculture, and biotechnological research will play an important role in ensuring safe, healthy seafood and creating new food products from marine resources.

The sustainable management of marine resources requires basic competence in biology and knowledge of marine ecosystems and how they are affected by climate change. Knowledge about marine resources other than those found in fisheries and aquaculture is important. The aquaculture industry is facing increasing demands for environmentally sustainable methods at all stages of production. Dialogue within society is needed to foster understanding and acceptance of the importance of safeguarding sustainability in the marine area. Biotechnology can provide tools for environmental monitoring, e.g. to track escaped farmed fish, confirm species identity, measure breeding parameters, and identify non-native species. Environmental monitoring will serve as the basis for the assessment of environmental impact of the aquaculture industry.

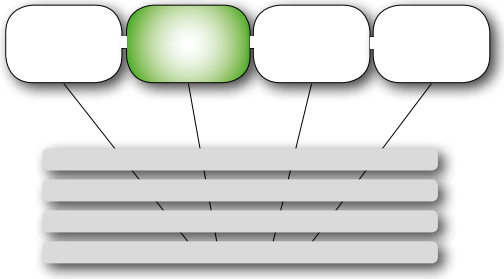
The aquaculture industry is now entering a new phase in which knowledge about the genetics of fish and other organisms provides the basis for achieving sustainable production and value creation. Norway plays a leading role in mapping the genome of commercially important species such as salmon and cod, as well as the genome of salmon lice. When the genomic sequence for these species is available, a new phase will begin in which this information must form the basis for knowledge-building and innovations for the industry.

In Norway, almost all residual raw materials from the aquaculture industry are used, whereas only 40 per cent of by-products from the white fish and pelagic fish industries are used. Biotechnology can be used to promote value creation through better use of residual raw materials than is the case today. The by-products contain substances such as valuable proteins, fatty acids, and antioxidants which are already being developed into commercial products. Continued research and development is needed to realise the full potential of this field.

Seaweed is currently being used for products in the areas of health care, nutrition, feed and specialty chemicals. The Norwegian coast is well-suited as an environment for seaweed and kelp, and several species of kelp bind carbon more efficiently than the tropical rainforest. The cultivation of seaweed, kelp and single-celled algae as the basis for high-value products is of interest and should be further developed. Assuming that the biological and technological challenges posed by seaweed and algae production can be overcome, Norway has a unique basis for hosting this type of knowledge and technology-intensive industry. The Government presented a national strategy for marine bioprospecting in September 2009, and this is now being followed up. Bioprospecting activities hold great potential for the development of commercially attractive products in the food, feed, health care and energy sectors. Institutions in the Tromsø region play a central role in the Government's focus on marine bioprospecting, but strong research communities have been established in other parts of the country as well.

Marbank in Tromsø will be further developed as a national marine biobank. Marbank will maintain a complete overview of the marine biological material collected in Norway. The aim is to make this material known both nationally and internationally to ensure that it is easily accessible for use in further research and commercialisation.

Good infrastructure for marine research and development activity and stronger international cooperation will be important for further developing Norway's leading position in the marine sector.



3.3 Agriculture-based food and biomass production

Research and development based on biotechnology has great potential for improving primary production along the entire land-based value chain. In this sector biotechnology is not only used as a tool for industrial development and increased food production, but also for meeting major social challenges such as climate change and the prevention of lifestyle diseases.

Plant health is the most important factor for crop size in plant production, and has a major impact on the quality and safety of food. Climate change and more international trade are posing new challenges to animal and plant health. Biotechnology, such as technology based on molecular markers, makes it possible to achieve more efficient selection and production. Agricultural greenhouse gas emissions relating to land use, livestock farming, and fertilisation illustrate the need for new, sustainable innovations.

What is needed is a broad approach involving fundamental competence-building, innovation measures, and advisory services for industry and the public administration. There is a particular need for research and innovation aimed at ensuring quality, food safety and food security, also in the face of climate change.[4]

Activities in the area of agriculture-based food and biomass production are to be targeted towards:

- competence-building and basic research;
- food security and food production, with focus on resource efficiency, plant disease, and sustainable production with less environmental impact;
- animal and plant breeding, including biobanks and bioprospecting;
- animal health;
- motivating companies to begin using and developing biotechnological solutions;
- innovation in the production of food, feed and fertiliser to achieve healthier and safer end-products, higher productivity, and better use of feed and alternative raw materials;
- use of biomass, such as wood, fibres, and offal, through application of biocatalytic processes and other biotechnology.

The food industry is Norway's second largest industry, and employs 46 500 people. The industry had a turnover of NOK 173 billion in 2009. Despite Norway's wide-ranging and dynamic land-based food industry, the new opportunities for growth and innovation implicit in the application of biotechnology have been under-utilised. In a high-cost country such as Norway, research-based innovation is especially important for ensuring continued national production through improving the industry's competitiveness. The Norwegian food industry needs to increase its biotechnology expertise and expand cooperation with the knowledge communities.

The Norwegian agriculture and food sector has a long tradition of cooperation between the government authorities, industry players, and knowledge communities on the production of knowledge through research and development activity. These networks will also

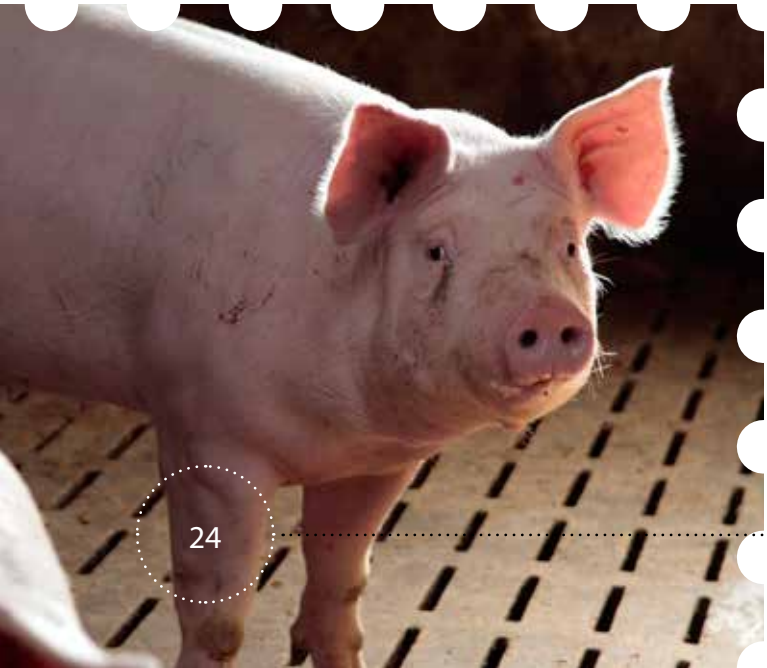
4 Food safety refers to a food supply safe from hazards and adverse effects, while food security refers to the secure supply of food.

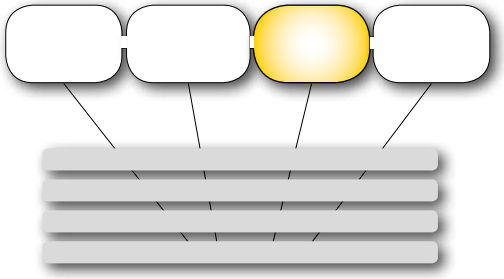
provide a good arena for dialogue, information and discussion regarding the opportunities and challenges arising from the use of biotechnological knowledge and methodology. At the same time, it is vital to achieve greater cooperation between agriculture and other sectors in order to promote the exchange of knowledge, technology, and ideas.

Public and private players are facing much the same knowledge challenges. The Government's task of ensuring safe food, animal health, animal welfare, plant health, and genetic resources comprises a key component of the research for the public administration. Social science research will also provide knowledge on the role of agriculture in these areas. Both research conducted in Norway and research-based knowledge obtained from other countries will form the basis for policy development and management. Such research may also strengthen the foundation for dealing with issues related to approval of genetically modified products, including genetically modified organisms, for use in agriculture or in relation to the import of genetically modified food and feed.

To ensure that a larger proportion of the resources and energy is renewable, it is necessary to achieve better use of biomass such as wood, fibre, and animal by-products. Biotechnological innovations can be used to increase the efficiency and profitability of using renewable biomass. Waste timber and other types of biomass from forestry and agriculture should, as far as possible, be developed into high-value products. For example, valuable products (biochemicals, biomaterials and so on) may be extracted using new methods for processing and refining timber before the residual materials are used as a source of energy. Biotechnology, enzyme technology, and advanced fermentation processes form the basis for new uses of all types of biological material and residual raw materials.

Within agriculture and forestry, the Hamar–Ås cluster is emerging as a dynamic industrial development environment in areas such as breeding, biobanks, biomass, seeds and plants. The high level of expertise built up in recent years through participation in international projects on genome sequencing of livestock and plants will help to ensure that industrial development continues. A relevant growth area is the development of fish feed. Another is the development of new ingredients and bioactive compounds in food believed to have positive health effects, known as "functional food".





3.4 Environment-friendly industrial processes and products

Industrial biotechnology refers to the use of biological principles in the industrial production of substances such as chemicals, enzymes, materials and bioenergy. Biotechnology may lead to new products and production processes in a variety of different sectors, such as food and feed, medicines, fine chemicals, cosmetics, textiles, paper and wood processing, polymers, plastic products, and energy. In addition, a transition to biotechnological processes can represent an environment-friendly alternative which produces fewer by-products and reduces consumption of energy and water. The OECD and the EU expect that industrial biotechnology will be of great economic and social significance.

Biorefining will be essential in replacing petroleum as the primary raw material in the chemical industry. Today nearly all production of plastics is petroleum-based. Plastics alone represent a large, global market, and the OECD expects rapid growth in environment-friendly bioplastics between now and 2050.

Its high level of biotechnological expertise, industrial traditions, and unexploited biomass resources place Norway in a good position to take on a prominent role in industrial biotechnology. Priority will be given to encouraging existing industries to increase their investments in research and development on biotechnological processes. Biotechnological research communities that link the chemical industry's need for raw materials with different types of biomass from agriculture and the marine sector may greatly increase the potential for value creation. A good dialogue between the research communities and industry to identify research needs and to determine how to target related activities is essential for industrial development.

Activities in the area of environment-friendly industrial processes and products are to be targeted towards:

- fostering cooperation between companies and research communities on discovery of new enzymes and ingredients connected to marine bioprospecting;
- promoting sustainable use of Norwegian biomass through integrated biorefineries;
- expanding expertise and research on important tools within industrial biotechnology, such as enzymes, micro-organisms, microbial systems, systems biology, and synthetic biology;
- developing expertise and research on biotechnological process technology, such as biocatalysis and industrial fermentation;
- gradually establishing infrastructure for demonstration and upscaling of biotechnological processes;
- participation in international projects which support the development of industrial biotechnology.

Internationally, biofuel is a key area in industrial biotechnology that has attracted political attention due to climate goals and the need for increased energy security. Thus, research on biofuel is receiving substantial public funding in many countries, and the industry is subsidised through taxes, laws and regulations. Today, second and third generation biofuels are being produced on the basis of biomass that does not affect the food markets. Examples of this are wood, straw, offal, marine residual raw materials as well as seaweed and kelp. Biorefining and industrial biotechnology will be important in the coming years, when much of the current petroleum-based industrial production will gradually be forced to shift to production based on raw materials derived from renewable biomass.

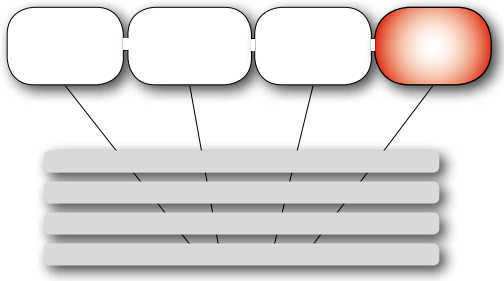
Today Norway is a leader in biorefining of wood thanks to the activities of Borregaard and other wood processing companies. Norway also holds a strong position in the refining of marine oils and ingredients from marine raw materials. Nevertheless, the potential to develop more advanced products based on new biotechnological methods and research in both areas remains great.

Biotechnological innovations in the medical sector are often based on academic research. For industrial biotechnology, however, many innovations are instead created within established industries that invest in new areas or in more environment-friendly processes. The public research and innovation agencies must give consideration to how they can stimulate such investments, and whether risk sharing is necessary in a mobilisation phase.

It is important to further develop Norway's strong position within biorefining of wood and straw. In the long term, it is likely that new niche markets will emerge based on the use of plants in the production of fine chemicals or bioactive compounds. Cultivation of seaweed, kelp and single-celled algae as a basis for feed, fine chemicals, and energy also represents an opportunity to develop new industries. Norway already has long experience with the industrial utilisation of kelp for use in foodstuffs and medicine, among other things.

Even though Norway has several competitive research communities within industrial biotechnology, especially in the independent research institute sector, the industrial application of biotechnology is new and immature. Long-term, basic and strategic research is needed to develop the knowledge base. In order to fully exploit the potential of industrial biotechnology and biorefining, it will be particularly important to increase expertise in the areas of microbiology, biocatalysis, systems biology, and fermentation processes. New knowledge about the composition and function of genetic material and a better understanding of microorganisms' functioning through a systems biology approach will be vital in this context. Similarly, synthetic biology is expected to lead to new possibilities for industrially sustainable processes.

Industrial biotechnology is especially dependent on an interdisciplinary approach. Fermentation and other industrial processes must be developed in close cooperation with various engineering disciplines. Pilot and demonstration installations are necessary to establish new, industrial-scale processes. These entail large investment costs which can represent a major burden, especially for young biotechnology companies. Therefore, it is important to establish cooperation between various sectors and encourage investments through cooperation between public and private enterprises. Oil and gas should be viewed as a valuable, non-renewable, and steadily decreasing resource which may be difficult to fully replace in many contexts and which will continue to be of great importance in the future. Use of biotechnology also has the potential to increase the degree of recovery, to refine oil and gas in a more environment-friendly way and to yield new products. Biotechnology in industrial processes is applied primarily in closed and controlled processes using enzymes and microorganisms, thus reducing the risk of unwanted pollution. Furthermore, the health risk can be controlled by taking necessary precautions. Industrial biotechnology thus may present fewer social and regulatory challenges than other biotechnology-based areas of application. One of the aims of using biotechnology in industrial processes is to make production more sustainable and reduce the environmental impact. There is currently a lack of recognised methods and indicators for assessing sustainability. Reliable indicators and internationally recognised standards and methods for life-cycle assessment -are needed to enable both consumers and governments to assess the degree to which biobased products and processes are sustainable.



3.5 Health, health services and health-related industries

Increasingly, medicines and diagnostic tools are being developed and produced using biotechnological methods. New forms of treatment based on biotechnology research, such as the use of stem cells and gene therapy, are approaching clinical application. Biotechnology also provides opportunities for better public health and reduced public expenditures through a more targeted, customised focus on prevention, early diagnosis, and treatment using biotechnological methods.

Nutrition and diet comprise one of the major global challenges and represent a crucial factor in public health, also in wealthy countries such as Norway. Diet greatly affects the risk of chronic disease such as diabetes.

For many years Norway has been investing in infrastructure and research groups in health-related biotechnology. Continued investment is needed if Norway is to sustain the high quality of research in health-related biotechnology. It is also necessary to place greater emphasis on the application of biotechnology in the health services when this will have added value.

Activities in the area of health, health services and health-related industries are to be targeted towards:

- basic biotechnological research, competence-building, and the application of biotechnology in translational research, clinical research, prevention, and innovation in the health sector;
- infrastructure for and expertise in clinical trials of new biotechnological diagnostics and treatments through clinical trial units and national and international networks for clinical trial treatment;
- biotechnological research relevant to understanding the connection between food and health;
- biotechnological research and innovation for diagnostics, patient treatment, and innovation in the health sector;
- infrastructure for health registries and biobanks to support biotechnological research and development for improvements in health and health services;
- better understanding of the regulatory framework that promotes the use of health-related biotechnological innovations and provides support for potential industrial activity in the area.

The health services need to establish a better foundation for integrating biotechnology into diagnostics and patient treatment based on profitability assessments. Norway has basic and clinical research communities of high international quality. These must increase their cooperation, both with other academic fields and with other sectors and technology environments, in order to develop new ideas, technology, and knowledge. In particular, the research communities should work in close collaboration with the growing biotechnology industry.

Norway has strong traditions within epidemiological research. Large collections of medical samples (biobanks) and associated registries of information on health conditions and disease have been compiled, and there is much to be gained from expanding the links between these. The significance of these research resources has increased due to new methods of analysis and new knowledge of the connection between genetics and disease. The Research Council of Norway was commissioned by the Ministry of Education and Research and the Ministry of Health and Care Services to propose measures for more efficient use of human biobanks, health registries, and health surveys, for both research and commercial purposes.[5] As a result, a new research programme for human biobanks and health data has been established. This will lead to an increase of NOK 110 million in total for this purpose in the period 2011–2016.

Commercial utilisation of the biobanks is possible and desirable, given the focus on

5 *Potensial for kommersiell utnyttelse av humane biobanker* ("The potential for commercial utilisation of human biobanks"), Research Council of Norway, 2009. Gode biobanker – bedre helse ("Good biobanks – better health"), Research Council of Norway, 2009.

the framework set out in the Act relating to biobanks as well as considerations regarding personal protection and informed consent on which the biobanks are based. Most importantly, however, the biobanks must be further developed to improve patient treatment through a better understanding of the causes of disease.

The human body's ability to fight disease and benefit from medicine is largely determined by individual genetic variations. Therefore, the quality of medical treatment for both hereditary and more widespread disease may be improved by adapting the treatment and medication to the patient's genetic profile. Using this personalised approach to medicine, it is possible to prevent unnecessary treatment of patients in cases when a particular medication does not work, and to reduce the degree of side effects by sorting out in advance the patients with greater individual risks. At the same time, this approach raises new ethical issues which are discussed in the chapter on biotechnology and society.

To ensure that research and innovation in health-related biotechnology, and personalised medicine in particular, is beneficial to the patients, it is important to cooperate and build interdisciplinary bridges between basic research, clinical practice and treatment. This research (known as translational research) requires high-quality infrastructure and trial units. National and international cooperation is needed to implement large-scale clinical studies, and this is to be given priority. International cooperation can also give Norwegian patients increased access to new treatments by way of testing in clinical studies.

An emerging international trend is for large pharmaceutical companies to reduce their own internal research and instead purchase new technology from external research communities. This gives innovative biotechnology companies the opportunity to introduce their own products to an international market. This is also the case for companies in countries such as Norway which lack large domestic pharmaceutical industry locomotives.

Developments in the past decade have shown that investment in Norway's best research communities may help to spawn promising biotechnology companies that attract investors and international industry partners. Commercialisation of health-related biotechnology is resource-intensive, and it will be necessary to strengthen commercial and industrial expertise and continue existing funding schemes that contribute capital to the commercialisation process. Norwegian research and innovation communities within health-related biotechnology do not make adequate use of the funding schemes under the EU Framework Programmes. To achieve this, national funding schemes must be linked more closely to the existing international arenas.

Major funding has been allocated through the Programme for Functional Genomics (FUGE) and other infrastructure initiatives to develop research infrastructure for sequencing and genome analysis. This is an important foundation for further biotechnological research within medicine and the health sciences.

For clinical practice, the development of biomarkers will be an important contribution to public health and disease prevention. An important resource in this respect are health surveys, in particular the Nord-Trøndelag Health Survey (HUNT), which has followed a large population group over almost 30 years, and can thus compare disease development based on both genetic and environmental factors. Biobank Norway will be key in the efforts to coordinate Norwegian biobanks. Biobank Norway is a consortium that is creating a national infrastructure to combine Norwegian population-based and clinical biobanks under a single umbrella.

Nutritional research is pivotal to society, and research efforts should be directed towards increasing knowledge about the significance of food and diet for disease and health. New knowledge developed using biotechnology could give better and more nuanced, knowledge-based, and individualised nutrition advice to the public, leading to better public health. It may also promote value creation through innovative product development and healthy foodstuffs and meals. Increased cooperation and coordination between research communities in the areas of food and health is necessary for developing the fields further. Modern biotechnology may also help to improve the quality of drinking water.

Efforts in the field of molecular epidemiology related to both treatment and nutrition are crucial for ensuring that Norway is prepared to participate in international developments in medical genetics. The application of biotechnology in this field may also create opportunities for scientific, technological and equipment-related collaboration with veterinary medicine, livestock breeding (including aquaculture), and bioprospecting, and these opportunities should be seized. However, in the field of human medicine it is important that this research is coordinated with research on the social, ethical, and psychological ramifications of increased knowledge of individual predispositions.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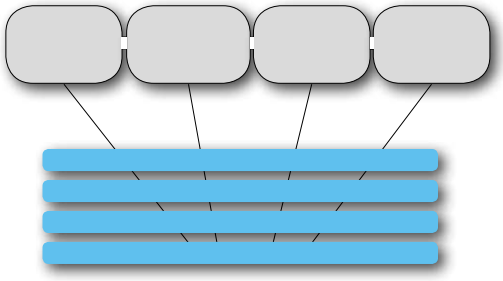
4 Cross-cutting focus areas



4.1 Biotechnology and society

Expectations are high that the use of biotechnology will yield major benefits for society, such as better health and a cleaner environment. However, uncertainties also exist about the risk of unintended harm to human health and the environment, and potential conflict with ethical norms or other unwanted, social consequences. It is therefore important to encourage a fundamental debate on the desired use of biotechnology for society as a whole and for certain groups in particular. A central question is what risks and uncertainties, and potential benefits, are associated with the use of alternative technology as compared to doing nothing. Social dialogue, value choices, and identification of new knowledge needs are required to understand and manage the role of biotechnology in society as a whole.

The public must be encouraged to participate in the debate on the implications and consequences of biotechnology for production, society, the environment, and daily life. Research that explores and analyses the ethical, legal, financial, and social aspects of the application of biotechnology is needed. The results from such research and other relevant basic research should be incorporated into the basis for decision-making, and the research communities must contribute in the public debate.

Activities in the area of biotechnology and society are to be targeted towards:

- integration of research on ethical, legal, and social aspects in technology initiatives;
- basic research in the humanities, social sciences and law on perspectives related to biotechnology;
- independent research on biosafety, risk, and other types of uncertainties;
- social dialogue and user participation related to the use of biotechnology.

In many cases, research on the ethical, legal, and social aspects of biotechnology is best approached through integration with technological research. Such integration must be considered when new initiatives or projects are designed by public research and innovation agencies or researchers. At the same time, it is important to ensure the existence of strong research communities which, independent of time-limited research programmes, can conduct broad-based, critical research on the application of biotechnology. The research communities must participate actively in defining relevant research questions on the relationship between biotechnology and society, and developing measures that address the knowledge needs in cooperation with the public research and innovation agencies.

Increased use of biotechnology creates the need to develop new methods, models, and services that may be used to assess the risk and safety aspects of the application of biotechnology. Norwegian specialist research communities have a high level of expertise, enjoy the trust of the international community, and are independent from manufacturers

and other stakeholders; this gives them an advantage that must be used.

Greater knowledge about the connection between heredity dispositions, lifestyle, and disease raises new ethical and societal questions. One example of this is personalised medicine, which raises questions about privacy protection, the right to treatment, costs, and expectations of the health sector. Personalised medicine may lead to more effective treatment with fewer serious side effects. At the same time, it can be challenging to communicate that a treatment cannot be used due to the patient's genetic profile, for example. These issues require knowledge development, effective dissemination of information, and public debate. It is also important to have a dynamic regulatory framework that supports stated societal objectives.

Synthetic biology is a new field within biotechnology which has produced the first examples of life forms engineered in the laboratory. Research on synthetic biology is to be prioritised; at the same time, however, the Government and research communities are responsible for ensuring that this knowledge is applied safely, on the basis of existing knowledge and thorough risk assessments.

Biotechnology research must be developed in cooperation between the research community and society. It is important to promote interdisciplinary and cross-sectoral research, as well as cooperation between research communities, industry, the public administration, and society, in order to ensure that biotechnology develops in a direction and manner that is in keeping with the needs and desires of people and society at large. Issues related to individuals' rights and wishes must be balanced with society's ethical norms, shared priorities, and cost considerations.

The most important legislation regulating the use of modern biotechnology in Norway includes the Act relating to the application of biotechnology in human medicine, etc. (Biotechnology Act) and the Act relating to the production and use of genetically modified organisms, etc. (Gene Technology Act). The Biotechnology Act is under review by the Ministry of Health and Care Services. Research

within the medical and health sciences field that falls within the scope of the Biotechnology Act is also regulated by the Act on medical and health research (Health Research Act). Use of biotechnology in land-based and marine production is regulated in the Act relating to food production and food safety, etc. (Food Act), the Act relating to the welfare of animals, and the Gene Technology Act. The need for amendment of the Gene Technology Act is assessed on an ongoing basis, viewed in light of new, biotechnological techniques and the development of synthetic biology, among other things. Patenting of biochemical inventions is regulated under the Patents Act.

The EU directive regulating the deliberate release into the environment of genetically modified organisms (Directive 2001/18/EC) is now incorporated into the Norwegian statutory framework. The directive states that products consisting of or containing genetically modified organisms may only be sold following the approval of an application with specific assessment of the risks to health and the environment. However, an adaption to the EEA agreement allows Norway to ban the sale of a genetically modified organism with reference to Norwegian legislation (the Gene Technology Act).

EU's regulation on genetically modified food and feed from 2003 (Regulation (EC) 1829/2003) has not yet been implemented in Norway. Pending this process, Norway has established national regulations under the Food Act that cover derived, processed, non-germinated, genetically modified food and feed and that include requirements relating to labelling and approval.

The Government is drawing up regulations to the Marine Resources Act and the Nature Diversity Act on access to and the fair distribution of genetic material which create predictability for the use of Norwegian genetic material within an environmentally responsible framework. Norway has also entered into internationally binding environmental conventions to preserve the earth's biological diversity. One of the most important of these is the Convention on Biological Diversity (CBD), which came into effect in 1993, and covers the preservation and sustainable use of biological diversity. The Cartagena Protocol on Biosafety, passed in 2000, is the first protocol under the convention. Its goal is to ensure the safe transport, handling and use of genetically modified organisms. The protocol is legally binding for the parties and aims to protect biological diversity against the potentially damaging effects from genetically modified organisms. The protocol is especially important in connection with the international trade of genetically modified organisms. The protocol states that countries have a responsibility to establish the legal framework, capacity, and expertise needed to assess the import and release of genetically modified organisms.

The Codex Alimentarius Commission is an organisation under the World Health Organization (WHO) and the UN's Food and Agriculture Organization (FAO), which develops international food standards. The objective of Codex, of which Norway is a member, is to protect consumers' health and ensure fair practice in the international food trade. Codex has developed guidelines for genetically modified food with regard to risk assessment, labelling requirements and analysis methodology, and Norway has played an important role in the development of these. Standards developed in Codex come into play in any trade disputes in WTO.

The legal framework must be kept up-to-date and safeguard a variety of interests and rights if initiatives relating to biotechnology are to succeed. Research will be helpful in compiling an overview of Norwegian needs and options, as well as international developments in legislation in the area.

Great advances have been made in biotechnology and gene technology in the past 20 years. A number of public agencies which have partially overlapping mandates and which provide input and conduct assessments in the field have been established. It is important to assess whether the organisation of this system is optimal.

Public bodies in the area of biotechnology

Parallel with the rapid developments in biotechnology in the past 20 years, many public bodies and institutions have been established to serve in an advisory capacity and offer assessments in the field.

- The Norwegian Biotechnology Advisory Board (1991) is an independent advisory body appointed by the Government as stipulated in the Gene Technology Act and the Biotechnology Act. The board advises the Norwegian authorities on issues related to biotechnology and provides information to the general public and the public administration. The board also promotes debate on the social and ethical consequences of the use of modern biotechnology.
- The Norwegian Board of Technology (1999) is an independent body that identifies key technological challenges and promotes a broad, public debate on the opportunities and ramifications of new technology for society and the individual. The board provides input to the Storting and other authorities on choices of technology and helps to ensure that as many actors as possible are able to voice their positions on critical technological issues.
- The Norwegian Scientific Committee for Food Safety (2004) conducts independent risk assessments in the areas of food safety, animal health, animal welfare, plant health and cosmetics. It also conducts health and environmental risk assessments of genetically modified organisms and derived, processed, non-germinating, genetically modified foodstuffs and feed ingredients on commission from the health and environmental authorities.
- The Regional Committees for Medical and Health Research Ethics (1985, REC) assess whether research projects are being conducted in accordance with accepted ethical norms. The committees must pre-approve medical and health-related research projects and research biobanks. The seven committees conduct their activities pursuant to the Act on ethics and integrity in research and the Act on medical and health research (the Health Research Act), and are comprised of specialists, lay representatives and representatives of patient groups. The members are appointed by the Ministry of Education and Research for a four-year term.
- The National Committee for Medical and Health Research Ethics (1990) is an advisory and coordinating body for the seven Regional Committees for Medical and Health Research Ethics. The national committee also serves as the body of appeals in relation to projects reviewed by the regional committees.
- The National Committee for Research Ethics in Science and Technology (1990) has given special focus to biotechnology and genetic engineering since it was launched.

4.2 International cooperation

International cooperation with prominent biotechnology players is essential to ensure high-quality research, innovation, and value creation. Such cooperation will provide the Norwegian biotechnology communities with access to new knowledge and advanced infrastructure, thereby ensuring their scientific development in the forefront of the field. At the same time, Norwegian researchers need to stand out as attractive, international partners, who can contribute to the international knowledge pool.

In general, Norwegian research communities must position themselves better in relation to the leading communities, and cooperation with such communities must be an important criterion when selecting which research and innovation projects are to be awarded funding.

Activities in the area of international collaboration are to be targeted towards:

- encouraging researchers and companies to establish long-term cooperation with leading, international biotechnology communities;
- promoting cooperation with the leading communities within the framework of Nordic and European cooperation and in bilateral cooperation agreements;
- increasing participation in the EU's research and innovation programmes;
- improving coordination of national and European activities;
- establishing a national infrastructure that is aligned with European infrastructure.

International cooperation in biotechnology is initiated by individual researchers, institutions, companies or the public research and innovation agencies. It is important both to strengthen existing cooperation of this type, and to encourage the establishment of new relations with the best research communities internationally.

Norwegian biotechnology groups must succeed in obtaining considerably more resources from the EU Framework Programmes than they do today. In particular, Norway needs to take active part in the EU's mobility and cooperation programmes under the European Research Council (ERC) and in programmes for industry (e.g. Eurostars). Norwegian biotechnology companies must become better qualified to seek funding through the European research cooperation than is the case today. It is a key task for the public research and innovations agencies to create a better framework for this. Other Nordic countries have more developed biotechnological industries than Norway, and these may be good partners for small and medium-sized Norwegian companies or health trusts.

Increasingly, European cooperation activities are moving in the direction of combining national funding with funding under the Framework Programme. The purpose is to achieve better coordination of research and innovation activities in Europe. Norway will be an active participant in various European initiatives, such as the European Strategy Forum on Research Infrastructures, Joint Programming Initiatives and Joint Technology Initiatives, based on a thorough assessment of strategic and capacity-related considerations. Norway is a member of the European Molecular Biology Laboratory (EMBL), which is one of the most important European institutions for life sciences and biotechnological research. Better use should be made of this membership, and Norwegian research communities must give higher priority to researcher exchange and collaboration with EMBL.

Bilateral agreements provide an important context for promoting research and development activity. It is increasingly important to remain cognisant of the ways in which such agreements can be used to help Norway to find new partners for biotechnology cooperation, outside as well as inside Europe, particularly with regard to development of industry-oriented technology. The bilateral cooperation with the USA is of special importance to Norwegian biotechnology. Cooperation with countries such as Brazil holds great potential as well. Brazil is investing heavily in industrial biotechnology, and may become an important strategic partner for Norway.

4.3 Industrial development

It is through the development of new or improved products and services in particular that the potential inherent in biotechnology can come to benefit society. Biotechnology will be instrumental in enhancing the competitiveness of many of Norway's most important industries and may generate new industrial opportunities nationwide.

A central objective of the Government's strategy for biotechnology is to lay the research-oriented foundation for innovation and industrial development. Activities are also to help to build cooperative relationships at the national and international level that strengthen and support the individual measures. The markets for biotechnology companies are international, and participation in international projects and networks will facilitate access to these markets. Research communities must work more closely together with industry to lay the foundation for long-term, sustainable value creation. This may be achieved by promoting the establishment of new, viable companies and increasing investments in biotechnology research and development within established industries.

Activities in the area of industrial development are to be targeted towards:

- encouraging industry to conduct research on, develop and utilise new biotechnological solutions that can enhance profitability;
- motivating industry to utilise biotechnology solutions that yield environmental benefits;
- creating a framework for R&D activity, proof-of-concept for technology, and commercialisation through integrated policy instruments;
- encouraging cooperation between various industries and sectors to ensure that biotechnological expertise is utilised across a variety of areas;
- ensuring preparation by Innovation Norway and the Research Council of Norway of regular, industry-specific analyses of the market potential of and challenges facing biotechnology;
- strengthening the cooperation between industry, public administration, health trusts, and research and investor communities.

The development of biotechnological projects towards a final product or service can be a long and costly process. Furthermore, in order to realise biotechnology's potential for industrial development, it is necessary to understand the underlying characteristics of each sector and to develop a sound knowledge base with regard to the potential as well as the bottlenecks in the individual sectors. The Research Council, Innovation Norway and SIVA must work together to ensure that existing funding instruments are well coordinated and that they are adapted to the various sectors.

Existing industry and knowledge clusters must be expanded, and efforts must be made to promote the establishment of new clusters or innovation networks. Clusters and networks are based on the idea that technology areas are best developed in cooperation between a variety of players from e.g. academia, industry, and the investment sphere. Clusters and networks help innovation processes to advance by paving the way for cooperation across organisations and the interdisciplinary exchange of expertise. At the same time, clusters and networks provide a basis for targeting biotechnology towards the identified needs of society and markets. The Oslo Cancer Cluster, a cluster in the medical field, is considered to be among the most important clusters globally in the area of cancer treatment.

Several Norwegian medical research communities have interesting industrial potential. However, the requirements for the trial and approval of pharmaceuticals are very strict in order to document their effects and avoid side

effects. Therefore, the process of developing biomedicines for market release is long and costly. Access to capital is limited, especially in the early phases of projects before they have attracted private investors. This is a challenge for the public research and innovation agencies as well, both with regard to coordinating instruments in those parts of the value chain where public bodies can play a part and when it comes to providing adequate funding, given the capital intensity of pharmaceutical development.

Research institutions and industry need to cooperate on infrastructure and pilot installations. The Industrial Ph.D. scheme involving cooperation between companies and higher education institutions on doctoral-level education provides great opportunities to strengthen the recruitment of researchers to the Norwegian biotechnological industry.

It is important for commercialisation and industrial development to secure and take a deliberate approach to the safeguarding of intellectual property rights, especially in a knowledge economy. Intellectual property rights are also an important element when it comes to licensing and cooperation between various players – particularly in the case of capital intensive and long-term processes in which intellectual property rights play a crucial role for investors and buyers. Efforts must be made to ensure that industry, R&D players and the public research and innovation agencies have sufficient knowledge and awareness of the ownership of the existing intellectual property rights. This applies to the intellectual property being created within the biotechnology field as well. It is important to implement appropriate, specially designed regulations, schemes, and services in this field. This will help to enhance insight into the ramifications for research and commercialisation of various forms of regulation and ways of dealing with intellectual property, including how patent rules and ownership related to biological material can obstruct or advance innovation and commercialisation. The Government has begun work on a white paper on intellectual property rights, headed by the Ministry of Trade and Industry. The white paper is expected to be completed in 2012.

Guidelines and security measures should be developed in parallel with the technology, so that society is prepared for possible risks, and industry is provided with clear and predictable frameworks for its activities.

4.4 Competence and infrastructure

Knowledge environments at universities and university colleges, health trusts, independent research institutes and in trade and industry are responsible for contributing knowledge from their own research, acquiring knowledge from abroad, and establishing, developing, and offering up-to-date infrastructure. The higher education sector is also responsible for educating highly skilled graduates.

Many of the Norwegian knowledge environments are at the international forefront, both academically and with respect to equipment and infrastructure. The technology they offer and the professionals they educate contribute to value creation in industry and the health sector.

Biotechnology is based on a broad foundation of basic disciplines in the biosciences and associated disciplines within the natural sciences, mathematics, technology, and medicine.

Public instruments

The Research Council of Norway

The Research Council of Norway provides funding for research and development activity in trade and industry, independent research institutes, universities and university colleges. Research programmes of relevance to the field of biotechnology are:

- The FRIPRO funding scheme for independent projects, the Centres of Excellence (SFF) scheme, the National Financing Initiative for Research Infrastructure (INFRASTRUKTUR), the Programme on Functional Genomics (FUGE);
- The Centres for Research-based Innovation (SFI) scheme, the Food Programme (MATPROGRAMMET), the Programme on Aquaculture – An Industry in Growth (HAVBRUK), the Programme on Clean Energy for the Future (RENERGI), the Programme on Nature-Based Industrial Development (NATUROGNAERING);
- The Programme on User-driven Research-based Innovation (BIA), the Programme on Commercialisation of R&D Results (FORNY), the SkatteFUNN tax deduction scheme, the Industrial Ph.D. scheme, and the EUROSTARS Programme.

A new strategic programme in biotechnology (Programme on Biotechnology for Innovation – BIOTEK2021) is planned for the period 2012–2021. This programme will succeed the FUGE programme and have a profile that is more relevant to industry.

Innovation Norway

Innovation Norway provides funding services to trade and industry. These include:

- start-up grants, research and development contracts for the private and public sectors (IFU/OFU) and innovation loans;
- advisory services connected to international market opportunities and branding: International Growth and Navigator;
- a wide array of instruments for knowledge transfer related to intellectual property rights, design, regulatory activities and market orientation;
- funding for clusters and innovation communities in cooperation with the Research Council of Norway and SIVA: the Arena programme and the Norwegian Centres of Expertise (NCE) scheme.

SIVA – The Industrial Development Corporation of Norway

- invests in properties that support biotechnology, such as industrial and innovation parks;
- provides important infrastructure for research, development, production, laboratories, testing, pilot projects and upscaling;
- brings expertise, tools and networks to innovation communities. SIVA has several programmes that stimulate the commercialisation of biotechnology, such as R&D incubators, food and nature incubators, industrial incubators, and the cluster programmes (the NCE scheme and the Arena programme);
- mobilises private actors, investors and research communities;
- part owner of 11 seed funds and venture capital firms, of which five invest in biotechnology.

Subjects within the humanities, social sciences and law also provide essential perspectives on biotechnology.

Biotechnology is evolving rapidly. New fields and technologies are emerging that require an increasing amount of analysis-enabling equipment or very costly computing power. In coming years, a considerable proportion of the resources within biotechnology must be devoted to improving the knowledge base and maintaining a modern equipment park.

Activities in the area of competence and infrastructure are to be targeted towards:

- disciplines in the biosciences and associated disciplines within the natural sciences, mathematics, technology and medicine, as well as the social sciences and humanities;
- national and international cooperation and task distribution relating to specialist expertise and equipment;
- building an innovation culture and cooperation between universities and university colleges, independent research institutes, health trusts, and industry;
- international cooperation on biotechnological research, development, and education.

Research groups, collaborative partnerships and networks of people with various areas of expertise from a broad range of academic fields are necessary for renewal, restructuring and scientific breakthroughs in biotechnology. New opportunities are also emerging from the knowledge, methods, and tools developed in basic natural science and technology disciplines. Therefore, biotechnology-related activities must emphasise breadth and interdisciplinarity. Mobility of researchers between sectors is a means of enhancing interdisciplinarity.

Public research and innovation agencies and major players in the research system must work together to identify research fields that need to be given particular attention in the coming years. The process leading up to the establishment of the Research Council of Norway's programme on Biotechnology for Innovation (the BIOTEK2012 process) has laid the foundation for this. International trends indicate that bioinformatics and synthetic biology are already emerging as important fields at the forefront of research. Other, more nationally oriented needs for knowledge and expertise have been specified in the chapters relating to the thematic areas.

A cornerstone in higher education policy is the aim to strengthen cooperation, the division of labour, and academic consolidation (CDLC). For example, the University of Oslo, the Norwegian University of Life Sciences, and the Norwegian School of Veterinary Science work together on task sharing in education and research in the life sciences in the Oslo and Akershus region. The National Collaboration Group for Health Research (NSG) develops priority areas and promotes distribution of tasks across the health and higher education sectors. Initiatives that promote national coordination will become even more important in the years to come.

A key instrument under the FUGE programme was the establishment of national technology platforms that were available to all academic and commercial groups in Norway. The concept involving national cooperation on infrastructure will be continued. This must take place within the framework of outstanding research in thematically defined fields, in which accessibility of new technology for research communities nationwide, including in industry, will play an integral part. In this way, new technologies will over time become common property.

Technological development occurs rapidly, and the needs underlying it are in a constant state of flux. When existing infrastructure is phased out, it is important to assess whether there are technological aspects that must still

be addressed nationally when new technology is developed.

Buildings that facilitate interdisciplinary cooperation between the many core disciplines are a central aspect of the infrastructure for biotechnology. The planned facility in Ås that will bring together the Norwegian School of Veterinary Science, the Norwegian University of Life Sciences, and the Norwegian Veterinary Institute in a single location is a good example of this. The needs for infrastructure for the life sciences at the University of Oslo are also under consideration. Alternative concepts have been drawn up, and will now be sent out for external quality assurance.

Considerable R&D resources have been allocated to research in biotechnology. To ensure effective use of these resources and to achieve a balance between quality and diversity of knowledge, some of the resources must be distributed in open, competitive arenas for researcher-initiated projects. Experience from the past 10 years of biotechnology activities indicates that national and international cooperation, division of labour, and adequately-sized projects that are based in the institutional strategies are important criteria for success. Open competitive arenas for research in biotechnology and related subjects must have room for consideration of such factors in addition to the purely quality-based assessments. They must also allow latitude for developing research activities across the generic technology fields of biotechnology, ICT, and nanotechnology.

Education provides an important foundation for research, innovation, and industrial development in biotechnology. While biotechnology is included in many study programmes in the biosciences and other subjects, some universities and university colleges also offer specialised study programmes focusing on biotechnology as a technology subject. These programmes can help to generate understanding and enthusiasm among young people about the significance of the field and future career opportunities in biobased industries.

The education and research sector, in cooperation with industry, have drawn up the strategy *Realfag for framtida – Strategi for styrking av realfag og teknologi 2010-2014* ("Science for the Future – Strategy for Strengthening Mathematics, Science and Technology (MST) 2010–2014"). The main objective is to increase young people's interest in mathematics, natural science and technology; boost recruitment and completion at all levels; build stronger maths, science and technology skills among Norwegian students; and enhance the recruitment of women to mathematics, physics, chemistry, and the technology subjects. Implementation of the strategy is important for the future recruitment to biotechnology research and development.

The educational system is the most important element in the development of a culture for innovation and entrepreneurship, and is charged with enabling today's youth to become innovative employees, both in the private and public sector. The Government's action plan *Entreprenørskap i utdanningen – fra grunnskole til høyere utdanning 2009–2014* ("Entrepreneurship in Education and Training – From Basic Education to Higher Education 2009–2014") expands and reinforces the initiative on entrepreneurship in education. The aim of the action plan is to make entrepreneurship a clear educational goal and learning strategy. Cooperation between the higher education institutions, working life and industry will enhance quality and relevance.

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