# Breakthroughs
# A Swedish biotechnology policy

**Summary and proposals**

# Biotechnology for the 21st century

The primary applications of biotechnology are in the health service, agriculture and forestry, food production and in the environmental sector. These are areas of key importance for people's health and their quality of life. There are an increasing number of biotechnology companies and products, and biotechnology is becoming increasingly important for economic development. The number of applications, and the amount of commerce involving biotechnology products and services, are expected to increase even more rapidly in the future. Biotechnology can, in the future, impact the living situation and development for all inhabitants of the Earth. Biotechnology and information technology are expected to be the most important areas of development in the next century.

Biotechnology has made its biggest impact in medicine and healthcare. Expectations regarding this technology are very high. The future will probably bring a revolution in this sector, with improved opportunities to diagnose, cure and prevent many illnesses.

Modern biotechnology has developed from a number of breakthroughs in basic research in the natural sciences. In many cases, this has meant breakthroughs in many fields. What was previously thought to be impossible is now not only fully possible, but has even become routine in some cases. Genes can be transplanted from animals to humans. The cloning[1] of the sheep known as Dolly overthrew scientific dogma that claimed that plants, but not animals, could be cloned using specialised tissues.

Technical opportunities, however, not only result in optimism and confidence in the future, but also attract scepticism and anxiety.  The rapid rate of biological development can make it difficult to understand what is happening. The individual has insufficient opportunities for access, participation and influence. This is definite problem of democracy. There must be room for discussion and participation when the subject is a technology that affects each individual to such a high degree, and indeed one that literally touches the basic constituents of life itself. Dialogue is

[1] In 1997, researchers in Scotland succeeded in creating a genetic copy of a sheep, by transferring the nucleus of a cell from an udder to an unfertilised egg (reproductive cloning).

called for, between researchers and other specialists, public officials and other citizens.

The use of biotechnology often requires taking a stand on ethical issues, which the public clearly regards as important. Present generations have a great responsibility to take advantage of the opportunities afforded by the technology, and to use them in a responsible manner in harmony with basic values in society. If biotechnology is to meet our high expectations, its applications must be ethically acceptable but, at the same time, they must not prevent a social, economic and ecologically sustainable development.

Public regulation of biotechnology is not unified. The responsibility for its component fields is the province of several different departments and authorities. There is no unified regulatory scheme. Sweden lacks a cohesive and long-term policy for biotechnology.

"Biotechnology for the 21st Century" is the Biotechnology Committee's proposal for guidelines for a biotechnology policy for Sweden, and at the same time constitutes a summary of the final report (SOU 2000:103).

## Biotechnology – a cutting edge technology

Biotechnology is a collective term for the use of microbiological, cellular biological and molecular biological methods for technological purposes. It is a base technology with many areas of application. The most well known uses are in the production of drugs, production of foods, and in the cleaning of wastewater. Biotechnology is often associated with modern high technology. Biotechnology processes, however, have been used for thousands of years. The qualities of cells and genes were used long before their existence was known.

Examples of traditional biotechnology products are beer, wine, cheese and soured milk. Just over a hundred years ago, it was discovered that living organisms, bacteria and fungi, made the milk turn sour and the beer ferment. Biotechnology thereby gained a scientific base, and rapid development ensued. Biotechnology products began to be produced on a large scale, and what were originally handicrafts developed into an industry.

Modern biotechnology grew in the second half of the 20th century, as a result of advances in basic research in the natural sciences. Genetic technology has been a particularly significant area of growth. Genetic technology is a collective term for several different methods used to isolate, multiply, modify and map genetic material, or to transfer it between organisms. Genetic technology has made it possible to study normal life processes and the background to diseases on a molecular level. Traditional biotechnology uses either organisms as they exist in the natural world, or organisms that have been altered through selection, crossbreeding or mutations. Genetic technology has revolutionised the development of drugs, and provided new, efficient tools for plant breeding. Genetic technology also makes possible the customisation of organisms or biological molecules for industrial or other practical purposes, such as the use of enzymes in washing powder.

The mapping of the genes of humans, baking yeast, and the fruit fly has propelled biotechnology and genetic research into a new and fascinating phase. Biotechnology has become a cutting edge technology, and many people believe that the 21st century will be the century of biotechnology.

## Biotechnology today and tomorrow. Opportunities and risks

Biotechnology is based on both traditional methods and modern state-of-the-art technology. In the last decades, research has resulted in products and processes that would have been looked upon as utopian not so long ago. There are great expectations of further advances.

### Opportunities

*Research*

Biotechnology-related basic research made great advances in the 20th century. The structure of the double helix of DNA and its genetic code were discovered. Genetic technology was developed and the structural biochemical research methods became increasingly refined with regard to research into the relation between the structure and the function of biomolecules. This laid the foundation for strong development in the fields of cell and molecular biology. Life processes, and the course of diseases, could now be studied with a precision that has never been possible previously.

One of the most important areas of research for the future, is function genomics, the study of the functions of different genes in humans and other living organisms. A new cross-disciplinary area of research, bioinformatics, has been developed in recent years for the storage and processing of the enormous quantities of data generated by genetic research.

The practical consequences of research into genes and their functions are expected to be significant. Knowledge of the exact structure of the genes, and their importance for the characteristics of plants, animals and microorganisms, can mean that new efficient methods may develop in the production of foods, the manufacture of drugs, and the reduction of environmental impact.

Knowledge about the brain and the nervous system will probably increase dramatically. The physiological bases of memory, forgetfulness, sorrow and joy will be made clear. Efficient measures to combat diseases such as Alzheimer's disease, senile dementia, schizophrenia and depression can be developed. Memory can be improved.

Researchers active in the field of nanotechnology work with structures as small as millionths of a millimetre. Co-operation between biologists, chemists, and physicians can produce new sensors for medical purposes, and artificial enzymes. It can lead to the replacement of silicon technology by a technology in which biomolecules allow computers to be even smaller and faster.

Biotechnology research will have significant consequences for society, and for man's view of himself as a biological organism. Natural scientists, humanists and social scientists will co-operate in studying the ethical, social and legal consequences of biotechnology. The number of uses, and the amount of commerce involving biotechnology products and services, will probably increase in the future.

### *Commerce and Industry*

Biotechnology, like information technology, is widely usable in a number of industrial sectors, and is used in such varied contexts as producing drugs, bleaching paper pulp, and extracting minerals.

Products and technology are often developed in collaboration between large companies, small research companies and university researchers. As in other sectors, mergers of large companies are a sign of increasing concentration. At the same time, new and innovative smaller companies are formed as spin-offs from university research and large industrial groups.

The biotechnology sector is highly internationalised. The United States is far in advance of Europe regarding industrial development. Sweden has relatively many biotechnology companies, mostly specialising in health care. However, the use of biotechnology in Sweden is also likely to grow in other industries, such as the food sector, and the pulp and paper industry.

### *Medicine and healthcare*

Biotechnology has had most of its successful applications in the fields of medicine and healthcare. Drugs and vaccines produced through genetic technology have been on the market for nearly 20 years. Diagnoses based on antibodies and genetics have become increasingly important tools in medicine. Genetic technology has become an invaluable instrument in drug research.

The continued development will mean a revolution in the health sector. Increasingly detailed knowledge about the three-dimensional structure of biomolecules increase the opportunities of putting together more effective drugs with fewer side effects. Bacteria or other organisms will be used to produce an increasing number of medically important bodily substances.

The mapping of human genetic material increases the opportunity of reducing side effects and improving treatment results. Drug treatment can be made more efficient by being customised according to each patient's capability to absorb and metabolise drug substances. New drugs to combat cancer can be developed with improved knowledge about how cancer cells appear. Knowledge of the genetic makeup of infectious agents can allow the development of new vaccines and antibiotics to prevent, and cure, diseases such as AIDS, malaria, tuberculosis and cholera.

Diagnoses will become both more certain and more precise, and their uses will be more versatile. Simple genetic testing will become routine, and will improve the diagnosis of diseases. Testing will also markedly increase the possibilities of avoiding illnesses in the future and adjusting one's life style to one's genetic makeup.

New organs and tissues can be produced with the help of stem cells from the body, thereby reducing or eliminating the risk of rejection. Treatment of diabetes and Parkinson's disease, for example, will be radically changed. These advances can decrease the need for transplantable organs from humans and animals.

A number of serious hereditary diseases can be cured with the help of gene therapy.

### *Agriculture and forestry, etc*

Biotechnology is used in areas such as mapping the genetic material of plants and animals. The results can be used for typing, planning traditional plant and animal breeding, and serving as a basis for genetic modification. Genetic modification is primarily performed on agricultural plants. So far, it has been used very little in forestry and animal breeding, but there is scope for it to increase. Genetic modification can have great importance for the agricultural and forestry sectors, as well as for industry and the consumers. The results can include increased harvests, crops adapted to industry, and better nutritional values.

In the United States, genetic modifications have meant fewer harvest losses, as well as the reduced use of chemical biocides and fuel. This has raised agricultural profitability. In Europe, however, the commercial cultivation of genetically modified crops is almost negligible.

Genetic technology has so far mostly been used to modify traits that are of interest to the producers and industry. In the future, products may be developed that are more specifically aimed at the needs of the consumer, such as crops that are more nutritious, durable, and high yielding and are suitable for cultivation in both the industrialised world and in developing countries. One example of a crop with improved nutritional value is golden rice, which, in contrast to other rice, contains beta-carotene, the precursor of vitamin A. Lack of vitamin A is a serious health problem in many countries that have rice as a staple.

New types of forest trees, adapted to the needs of industry, can also be developed. The pressure on the remaining natural forests can thereby be reduced and the biological diversity preserved.

Characteristics in animals that can be especially valuable in the production of drugs, or in agriculture, risk being lost in offspring during natural reproduction. Cloning, in which the offspring is a genetic copy of the parent, produces offspring with these desirable characteristics intact.

*Food and animal fodder*

At present, enough food is produced to meet the needs of the world's population. Many people regard famine as an issue of how the food resources are distributed rather than an actual food shortage. This can change in the future. The population of the world is increasing, while there is less potential new arable land. Large areas of the existing agricultural land are losing fertility as a result of erosion, drought and over-exploitation. The seas are threatened by overfishing. In order to maintain the present level of fish consumption, the production of cultivated fish must increase significantly. In both plant cultivation and animal breeding, genetic technology can be a valuable complement to other methods to provide future generations with foods.

Traditional biotechnology is primarily applied to ”natural” microorganisms and enzymes in the food industry. Genetic technology and other modern biotechnology, however, could also provide many opportunities for the food companies. Opportunities include using enzymes that have been optimised for industrial use through genetic technology, and bioanalytical methods, such as DNA diagnosis, for product and process inspection. Another possibility is to use genetically modified microorganisms to improve the quality of foods, to produce additives (aroma, thickening agents, preservatives, etc.), and to develop methods of testing to find allergens. Industry could then use raw materials that have higher nutritional value and contain a lower level of natural toxins, thereby reducing the risk of allergy to the consumer. Possible examples are rice with increased iron content, gluten-free wheat flour, and solanin-free potatoes. Genetic technology will probably also be important in the development of "functional foods," which are designed to improve health or cure diseases.

### *Biotechnology for a better environment*

Biotechnology processes do not use up much energy and they conserve resources, but these processes are often slow and uneconomical compared to petrochemical or other chemical technologies. Development potential is immense, though, and will probably rise even further if environment friendly technology is made financially beneficial, for example through environmental taxes.

Biotechnology is used to clean air, wastewater and polluted soil. It is also used to produce bioenergy in the form of ethanol and biogas, and to replace chemicals harmful to the environment with biologically degradable alternatives based on renewable resources.

Using bioenergy can slow the greenhouse effect. Plant and forest tree breeding can encourage the chemical industry to replace petroleum with renewable raw materials. This can allow a conversion to environment friendly fuel, such as biodiesel and hydrogen gas. These can be produced through biotechnology, and would help to cut the release of carbon dioxide.

Environmental biotechnology is primarily based on the methods of traditional biotechnology. If genetic technology is used, it could offer even greater potential to attain a better environment.

## Assessment of the risks

Biotechnology, like other technologies, can involve risks. Certain risks are unacceptable, others can probably be overcome, and still more are negligible.

### *Research*

The first discussion of risks took place in 1973, when genetic technology was new. It concerned whether genetically modified bacteria or viruses could lead to the spread of epidemics. In both the United States and Europe, it was decided that all work on genetic technology should take place in special secure laboratories.

However, these fears soon proved to be exaggerated. Today, research in genetic technology, as a rule, is carried out without raised safety requirements. Secure laboratories are only used when organisms themselves constitute a risk, such as in work with HIV or typhus bacteria. Genetic technology has been used in a large number of experiments in laboratories all over the world, without any documented serious injury to people, animals or the environment.

*Industry*

Industrial processes with biotechnology, as with other technology, can involve risks for those working with them. There is a risk of allergy through handling enzymes. There are also examples of staff in sewage facilities who have suffered discomfort caused by bacteria in the surrounding air.

Drugs produced through genetic technology have been manufactured on a commercial scale since 1983, when human insulin was produced through the use of bacteria. Since then, many other substances have been produced using genetic technology. No industrial injuries have been reported as a result of these techniques. On the contrary, genetic technology processes are often safer for the staff than processes that are based on blood plasma or other biological material, since these can include infectious forms of viruses. The products are also safer for patients and health care staff for the same reason.

*Medicine and health care*

All drugs involve the risk of side effects. In order to minimise these risks, all drugs must be approved before they are released on the market. The effects on patients must be studied in scientifically based clinical trials, before approval is granted.

In the 1970s and 1980s, it was feared that patients could incur increased risk of suffering fever attacks and illnesses, because drugs produced by genetic technology could contain constituents of the organic cells used in production. The disinfection methods of the pharmaceutical industry, however, have proven to be very efficient, and inspections are scrupulous.

Treatment with stem cells can involve the risks of forming tumours. This is because stem cells, especially embryonic stem cells, are undifferentiated. Thus, in principle, they can develop into any kind of tissue or organ. Consequently, treatment with stem cells requires monitoring to ensure that they develop as planned and do not give rise to cancer cells.

Gene therapy as a medicinal method of treatment is still at the research stage. Deaths have occurred. This was caused, in at least one case, by an allergic reaction to the genetically modified virus that was used to place a new gene into the body. Viruses as carriers of genes should probably undergo clinical trials in roughly the same way as drugs do, before they are adopted for use.

When organs or tissues are transplanted to humans from other animal species, the transferred material can include viruses (retroviruses), that are virus forms ”concealed” in the genetic material of the foreign species. There are fears that viruses such as these could be activated in the human body, spread to third parties, and start a new epidemic, similar to AIDS. There is no definite evidence that this type of activation occurs, but more research is required into the risks.

Genetic testing will provide more information about the genes of individuals, and thus his or her characteristics and risk of developing diseases in the future. This type of confidential information can cause problems, both for individuals and their relatives. It also puts great demands on healthcare personnel, who must interpret and explain the information. Test results could also be used by employers and insurance companies, which could lead to unacceptable discrimination based on genetic makeup.

Diagnosis of diseases in embryos, before they are placed in the uterus in connection with test-tube fertilisation, or in the foetus, makes it possible to reject those that have diseases or are damaged. This could lead to a society that attempts to create the ”perfect” human being. This, in turn, can lead to discrimination against sick people and a contempt for weakness. Foetal diagnosis, and abortion of a damaged foetus, could be perceived as something compulsory.

*Agriculture and forestry, etc*

A number of genetically modified crops have been developed by large companies, which also manufacture and sell biocides. In certain cases, the crops developed have a tolerance to the companies' own chemicals. One fear is that this can lead to the company gaining a monopoly, and to increasing dependence on chemical preparations in agriculture. However, increased use of certain chemicals has been balanced by reduced use of other chemicals. Some people, however, claim that the cultivation of genetically modified crops that are resistant to herbicides is dangerous. This type of cultivation could encourage the permanent use of chemicals, and make it more difficult to move towards a type of agriculture that does not use chemical biocides. Others argue that chemical-free agriculture is hardly a realistic objective, if the efficiency of agriculture is to be retained and improved in the long term. This is a prerequisite if the entire population of the world is to be fed.

Another fear is that genetically modified organisms would spread to the natural environment and cause major problems. This risk varies from case to case. Most cultivated animals and plants completely lack the qualities necessary to survive in the wild without human attention. Many cultivated animals and plants used in Sweden lack relatives in the wild to whom they could transfer genes. Forest trees, hay-field plants and fish, however, are not domesticated to any appreciable extent, and often have relatives in the wild. The new genes would have to raise the competitive capability and survival characteristics of the recipient, for this problem to occur.

The impact of man on the natural environment, irrespective of whether we are referring to agriculture, forestry, the creation of golf courses, or the regulation of water, affects biodiversity. In the 20$^{th}$ century, greater demands for profitability have increased the efficiency and scale of agriculture. Methods such as chemical biocides, drainage and the use of purer bred seeds have caused a reduction in the biological diversity in agricultural landscapes. There are fears that genetic technology will aggravate this trend.

Another fear is that genes for antibiotic resistance will be transferred from genetically modified crops to bacteria in the stomach flora of humans or animals, or to bacteria in the soil. This would make it more difficult to overcome diseases with antibiotics.

There are a number of barriers that make this risk unlikely. It has not been possible to transfer genes from plant material to bacteria, even under laboratory conditions. In addition, antibiotic-resistant bacteria are common in the natural world. According to most specialists, the transfer of antibiotic-resistance[2] from plant material to bacteria hardly constitutes a risk to the health of either humans or animals. In any case, it is unnecessary to use genes to make the plant antibiotic-resistant, since there are alternatives.

Insects can be resistant, both to biocides that are implanted into plants using genetic technology, and to chemical biocides. In the long term, this can involve a risk that biocides will become less efficient. Monitoring the crops can decrease this risk, so that any signs of resistance can be discovered at an early stage. Resistance can also be limited by rotating crops and biocides.

Another suspicion was that using genetic modifications to produce viral resistance would cause new types of viral attack. The viral genes that are transferred to a plant, and which normally only protect against certain viruses, could combine with other forms of viruses that could infect the plant. The practical significance of the risk is still unknown.

*Food and animal fodder*

Many substances in foods can cause allergic reactions in people who are sensitive to them. Certain substances are known to be especially allergenic. If these substances are formed in plants or animals that are modified through genetic technology or some other form of technology, the foods produced from them could cause allergy problems.

When a gene is placed into an organism, is placement is generally done randomly. The new gene can damage, or impact in some other way, its new surroundings. One fear is that impact such as this could cause the formation of a damaging substance. A food, in this way, could be made unsuitable for consumption by humans. However, genetic modification by man is similar to a natural, if uncommon, course of events. "Jumping genes" can transpose in humans, plants and animals. As far as we know at present, jumping genes in agricultural crops have not caused any risk to people’s health.

[2] The problems of resistance to antibiotics in health care are caused by their overuse.

## Ethics of biotechnology

It is evident that many applications in biotechnology require making ethically based – and often difficult – decisions. These decisions must be based upon the fundamental ethical principles that form the basis of Swedish legislation, international conventions, declarations and other agreements to which Sweden is a party. Where human beings are concerned, principles of human value, self-determination and justice apply. In the case of animals, a fundamental principle is that they are to be well treated, and protected from unnecessary suffering or disease. For plants, the fundamental principles refer to long-term sustainability, ecological consideration, and biological diversity.

One characteristic of biotechnology is that research and technical development are several steps ahead of reflection over ethical issues. This means that ethics can be forced a role of justifying the use of an already developed technology, and thereby legitimise its moral content. The speed of development in biotechnology often means that by the time the ethical problems concerning one established application of biotechnology are discussed and highlighted in retrospect, new applications appear with their own ethical considerations. Ethical assessment lags behind the applications. Values rather than opportunities should naturally form the basis of legal regulations and other norms. The fundamental values regarding the application of biotechnology to humans and their relationship to the natural world and the manner of handling conflicting values must be identified. There are no easy answers to be expected in the form of simple and unambiguous guidelines. The dilemma has been described as the existence of a greater or lesser element of tragedy in all choices that are made – to fulfil one value requires a sacrifice of another value. It is therefore important to emphasise the values that are part of the ethical conflicts that characterise different biotechnology applications, and the conflicts of values that occur.

Of course, fundamental ethical values can be different for different people, but there is a broad consensus of views regarding applications that directly affect humans. The principles on biomedical clinical research, for example, adopted by the World Medical Association, embrace principles of self-determination, kindness, non-injury and fairness, can be accepted as fundamental values by most people. It is harder to find corresponding, generally applicable, values regarding nature, for example. People's views of nature can differ markedly. Most people will back the principle of caution, even if they apply different content to it. Many people would probably also support the idea that nature is to be used and not abused or exploited.

Some have called special ethics suited for biotechnology. This could be because biotechnology is often an activity that crosses limits, with the fundamental constituents of life as both the means and objective. Here, though, the conclusion is the opposite. The ethical values that should form the basis of decisions on biotechnology applications, the conflicts of values that can crop up in connection with these standpoints, and the ethical analysis that should precede these, are no different from those applying in other situations. This does not prevent ethics from occupying an extremely prominent position in biotechnology, since very important values are often involved. Another important aspect in the case of biotechnology is the aspect of time. The ethical discussion must be a natural part of the procedure, beginning at the research and development stage. Another important aspect is democracy. Applications of biotechnology often impact on many people as well as future generations. It is therefore necessary to involve as many people as possible in the ethical discussion. Bioethics must be an issue for everyone.

## Education and educational requirements

Basic knowledge in the natural sciences, as well as an ability to evaluate and adopt a position on different applications of biotechnology, is taught in school. According to the national curriculum and local syllabi, students should be able to discuss different aspects of genetic technology when they leave secondary school. Science subjects in the compulsory and upper secondary schools include issues pertaining to biotechnology, such as the structure of cells and genetic material. Social and ethical aspects of biotechnology can be covered in the social studies subjects and in religion.

Adults are greatly exposed to biotechnology via the media. Scientific journalists, general journalists and information officers review and disseminate news from research institutions and companies. The training and continuing professional development of these groups is of great importance for public awareness of biotechnology.

Developments in biotechnology also make demands on training and further education of different professions in, for example, the industrial and care sectors. A basic prerequisite for creating a sufficiently large pool of people with scientific or technical skills at higher education level is that students choose these specialisations at upper secondary school. A number of initiatives have been taken to stimulate interest. For teachers, several continuing professional development programmes have been arranged to stimulate more attractive teaching of these subjects. One example is the national resource centres that are linked to universities, and specialise in chemistry, physics, mathematics or technology. One of their functions is to participate in continuing professional development for teachers.

In industries that use biotechnology, more people with higher education qualifications in the natural sciences or technology are needed. There will also be a need for people with cross-scientific expertise. In order to bring biology and technology closer together, a number of educational programmes have been established, specialising in biotechnology or technical biology. These are primarily Master of Science courses. The demand for postgraduates in this area will probably continue to be strong, as well as the demand for chemists with different areas of specialisation. A link between IT and biology or chemistry will probably also be in great demand.

With increasing knowledge about the human genome, and new opportunities for diagnosing and treating diseases, healthcare personnel will increasingly need to know about hereditary diseases, and be able to communicate new information to patients. This will lead to changes in the basic education of different groups of healthcare personnel. Great demands will also be made on further education.

## An international perspective

Biotechnology is regarded internationally as a sector of the future with enormous potential. In all developed countries – and in a number of developing countries – a lot of resources have been put into research and development in the biotechnology sector. It is primarily the mapping of the genetic material (genes) of humans and other organisms, genome research, and research into the function of the genes (functional genomics), that attract most interest. The mapping of the genetic material in humans, and in many plants, animals and bacteria, involves a scientific breakthrough. New and better drugs, vaccines and seeds will be developed in the future.

Genetic technology was developed in the United States at the start of the 1970s. The United States is the leading country in genetic technology research, and there are more, and bigger, biotechnology companies, and more biotechnology products, in the United States than anywhere else in the world. In addition, Canada, Japan and China are making huge investments in biotechnology research and development. Leading research is also conducted in Europe. The European companies, however, put fewer resources into research and development than those of the United States. In Germany, France and the United Kingdom, powerful steps are being taken to strengthen biotechnology research, and stimulate the development of new companies using the results of the research. Sweden has a strong biotechnology research base, even by international standards, and is in fourth place in Europe with regard to the number of small, innovative biotechnology companies.

Biotechnology is a sophisticated technology. It requires major inputs of resources, in the form of skills and capital. The richer countries, and the major chemical and drug companies, have dominated the biotechnology sector up to now. In developing countries, there are fears that the new technology will widen further the gap between rich and poor countries. In international negotiations, the developing countries are therefore demanding technical assistance to enable them to develop their own skills in the biotechnology sector. They, too, wish to take advantage of the opportunities afforded by biotechnology, and develop new drugs, vaccines and types of plants. A large number of programmes are being conducted to transfer knowledge and practical experience from the richer countries to the poorer ones. In spite of this, the gap between them is tending to grow rather than shrink. The Rio Declaration on Environment and Development (1992), and other international agreements, make clear that the richer and more technically advanced countries have a great responsibility to help the poorer countries gain access to the opportunities afforded by modern biotechnology.

In recent years, opposition in Europe to genetically modified crops and foods produced from those crops has increased. There are thought to be unknown risks. The result is that the market for genetically modified foods is virtually non-existent. Since 1998, there has practically been a moratorium on the commercial cultivation of genetically modified crops in the EU. Government authorities and organisations in the United States claim that the European opposition is not based on facts, since it is not based on scientifically sustainable arguments. Instead, they take the view that the real objective is to shut out the products of efficient American agriculture from the European markets. The EU and its member countries prefer caution, as a matter of principle, and take the view that the slightest suspicion of a risk is sufficient reason to justify opposition to the use, or import, of genetically modified products. These differences of opinion can lead to a trade conflict of the same type that occurred as a result of the EU embargo on the import of meat from hormone treated animals.

But opposition to genetically modified crops and foods is also starting to grow in the United States. Australia and Japan have introduced requirements for the labelling of genetically modified products.

At the same time, interest is growing in many developing countries for the opportunities afforded by genetic technology. An example of this interest is that China and several other developing countries see an opportunity to improve the quality of foods by producing the golden rice discussed above through genetic technology. In Germany, France and the United Kingdom, large and objective-oriented measures have been taken to stimulate the development of innovations and biotechnology companies. More must be done in Sweden if this country is to retain its position and competitiveness, internationally. Resources must be put into high quality research and development, and into finding industrial applications for academic research findings. Improved funding of development projects should be available at an earlier stage in the projects.

## Laws and other regulations

Biotechnology is mostly regulated in Sweden through general provisions, not specifically applicable to biotechnology. Existing laws on confidentiality, crime, procurement, damages, databases, etc, apply, irrespective of the technology used in individual cases. Even laws pertaining to the health service usually apply, irrespective of the technology used. In many cases, there is indirect monitoring of the use of biotechnology: one example is that applications for funding from research councils require a review of the ethical issues involved.

There are special regulations concerning the use of genetically modified plants, animals and microorganisms, and their release onto the market. These regulations, part of the Environmental Code, are largely based on EU laws. The Environmental Code also includes regulations about the preliminary examination of biological herbicides and pesticides.

Regarding healthcare, there are special laws on the use of genetic technology in general health surveys, and on measures in research into, and treatment using, fertilised eggs from humans. The provisions limit the possibilities of using DNA analyses in connection with general health surveys, and prevent experiments for developing methods to develop inheritable genetic effects. The police data law also includes regulations on the use of DNA analyses.

In addition to the regulations mentioned, there are more laws that pertain to biotechnology. Some examples of these are the Medicinal Products Act, the Swedish Transplants Act, the Animal Feeds Act and the Food Act, as well as legislation regarding patents. The purpose of patent law is to promote technical development by guaranteeing a reasonable investment protection for inventions. The inventor is awarded exclusive rights to the commercialisation of the invention for a limited period in return for it being made public. However, patent law does not apply to types of plants and breeds of animals. Plants variety rights provide protection to plant varieties similar to that given by a patent. Patent law does not apply to ”essentially biological procedures,” with the exception of microbiological procedures.

There are EU directives on the contained use, and deliberate release of, genetically modified microorganisms. There are also regulations that prevent genetically modified organisms in the ecological production of agricultural products, and on the risk assessment and labelling of new foods and food ingredients. Special directives and regulations include provisions concerning the sale and supervision of drugs, safety and quality of medical technological products, and protection of biotechnology inventions.

Applicable EU directives and regulations are under revision, with new ones being developed One example is a revision of the directive concerning the release of genetically modified organisms. Regulations are also being prepared regarding non-conventional foodstuffs, with others to require labelling and traceability through the entire chain of production of for products that include, or consist of, genetically modified organisms. On the other hand, there is no directive about the use of human biological material and living tissue from animals.

## The opportunities for the individual to access, participate and influence

Modern biotechnology makes it possible to manage and modify the fundamental constituents of life. The technology is used in areas of crucial importance for people’s health and well-being, and it impacts on everyone.

In the debate on biotechnology and especially genetic technology, specialists and the public often take differing viewpoints. Put very simply, the specialists emphasise the opportunities, and the public focuses on the risks. The circumstances are a little different in reality. Specialists can be uncertain about some uses, and large parts of the public are positive primarily to applications in healthcare and the environmental sector. It is often assumed that the general opposition to certain biotechnology applications is based on a lack of knowledge. Opposition could, therefore, be reduced if there was improved information about, and awareness of, biotechnology. However, it has proved to be lack of access, participation and influence, as well as ethical considerations, rather than lack of knowledge, that influence people’s attitudes to various biotechnology applications.

Technology is progressing at incredible speed. The rate can be too fast, for both specialists and the public. Many issues need to be thoroughly discussed so that the opportunities and risks are made clear. There must be room for discussion of ethical questions.

The regulation by public authorities is divided among a number of specialist authorities that are responsible for licensing and supervision. Consequently, there is no unified and co-ordinated supervision. It is hard to see the big picture of how biotechnology is developing.

If there is to be popular confidence in biotechnology, a unified supervisory system for this technology and its uses is required - a Biotechnology Inspectorate. Individuals must also be given concrete opportunities for knowledge, participation and influence. A Technology Council could offer opportunities like these, and would also act as a bridge between researchers and other specialists, politicians and voters.

## A Swedish biotechnology policy in 21 points

The proposal for a Swedish biotechnology policy aims to strengthen Sweden's capability to take advantage of the opportunities offered by biotechnology, for the benefit of the individual, industry and the environment. This biotechnology policy aims to promote the accumulation of knowledge in the sector, to facilitate the conversion of the results of research projects to practical applications, under ethically acceptable conditions and with the risks overcome. The practical opportunities of the individual for knowledge, participation and influence in the biotechnology sector must be strengthened considerably.

1. The present organisation of the authorities that deal with genetic technology and other biotechnology matters is impractical. Greater co-ordination is desirable in view of the opportunities and risks involved in biotechnology. The Swedish Genetic Technology Advisory Board therefore, should be restructured into a Biotechnology Inspectorate, which would complement other authorities in the sector. The primary function of the Biotechnology Inspectorate would be to monitor fundamentally important and new applications, and conduct supervision. The Biotechnology Inspectorate should have a special responsibility to ensure that ethical assessments in connection with biotechnology issues are made

in a manner shown in the final report, *”Att spränga gränser, bioteknikens möjligheter och risker” (SOU 2000:103).*

2. Biotechnology is developing at a very rapid rate. It is not easy to keep up to date with the opportunities and risks involved in the technology. There is a great need for technological evaluation and a broad national debate. There are also corresponding needs in other areas of technology, which would require the establishment of a Technology Council. The Technology Council could promote the accumulation of knowledge, disseminate information, and create an active dialogue between researchers and other specialists, politicians and other citizens.

3. There is no significant legal regulation of biotechnology applications regarding humans. A law should be introduced concerning the conditions for gene therapy, cloning and pre-implantation genetics. An outline for legislation has been proposed in the final report, *”Att spränga gränser, bioteknikens möjligheter och risker” (SOU 2000:103)*.

4. In Sweden, research using patients and other volunteers is preceded by the ethical assessment of a research ethics committee. Neither this research nor these committees and their activities are regulated by law. Legislation on this should be introduced. An outline for legislation has been proposed in the final report, *”Att spränga gränser, bioteknikens möjligheter och risker” (SOU 2000:103)*.

5. The demands of consumers for a free and informed choice regarding foods must be fulfilled. Compulsory labelling is to be required, for all products resulting from genetic technology, at all stages of the production process, from raw material to final product.

6. There is no EU directive about products that contain, or consist of, human biological material or living animal tissue. This can result in the EU countries developing their own, and divergent, regulatory systems. Sweden should press for an EU directive on the management of human biological material and living animal tissue.

7. Sweden should work to ensure that the risk assessment of products that include, or consist of, genetically modified organisms, is developed into a technology-neutral risk and benefit assessment. This assessment should apply to all products, irrespective of the method of production. The assessment should be based upon the qualities of the products, and consider any risks to people's health to the environment, with regard to both the development and production of the product, and its use. All risk and benefit analysis should include an ethical assessment.

8. Internationally, a great deal of resources are being put into research related to biotechnology. The pace of development is rapid and is expected to lead to important applications in the future. Biotechnology research must be a prioritised area. Central funding for research projects and postgraduate programmes in this sector should be greatly increased. The measures should primarily focus on this sector, where Sweden is either at the cutting edge, internationally, or has the potential to make an impact on the international market. When choosing priorities between different areas of research within biotechnology, research that focuses on the function of the genes, and their importance for normal life processes and diseases in humans and other organisms, should be given special attention, as well as access to specialist teachers at university level. To this end, positions should be set up at universities and other institutions of higher education, and the opportunities for co-operation between universities and colleges and industry should be examined.

9. Developing countries have a great need to access the opportunities afforded by biotechnology. Shortage of both technical and legal expertise, and economic resources, limit their opportunities to benefit from biotechnology. Increased funding should be provided to relevant organisations and research projects to enhance the opportunities to benefit from biotechnology. Co-operation in research projects, and transfer of skills and expertise should be stimulated to enhance the technical and legal expertise of developing countries, and to increase their possibilities of using and monitoring this technology.

10. A restructuring is taking place in the biotechnology sector, as in other sectors. The large companies are tending to become even larger through acquisitions and mergers. This has created large groups with interests in drugs, chemicals and foods. This can create problems by forming monopoly situations and reducing competition. The risk of the companies abusing their market dominance must be monitored carefully.

11. Research into the risks to the environment caused by biotechnology, and its other consequences for the public, should be supported. Special resources should be allocated to directed programmes.

12. Before genetically modified organisms are released onto the market, it is vital that there be better background material for risk assessments from experimental release. Experimental release of genetically modified organisms into the environment should therefore be implemented and evaluated in a scientifically approved manner, in order to compile as much information as possible.

13. Deliberate release into the environment of genetically modified organisms with antibiotic resistant genes should cease. Other and better technology should be developed.

14. Advances in the biotechnology sector have increased the opportunities of replacing experiments on animals with experiments on cell and tissue cultures. At the same time, increasing knowledge about human and animal genes has meant that experimental animals can be used for new purposes. This can increase the use of experimental animals. Research into the replacement of experimental animals with other methods should be stimulated through the allocation of resources to special programmes.

15. Inventors conducting research can require help with the commercialisation of their results. In addition, they often have difficulty in finding financial backing for the earliest stages of development. The conversion of research findings into product ideas should be facilitated. Cost-free advice about commercial development should be provided. Society and

industry should together facilitate the contacts between researchers and companies to increase access to seed money at an early stage of development.

16. The establishment of new business ventures and the development of new products in the biotechnology sector often occur at the front line of research. Co-operative links between research and industry must be stimulated. This can be attained by putting more resources into industrial postgraduate programmes, by making efforts to combine research institutions and companies in innovation centres, by encouraging exchanges of personnel between the academic world and industry, and by making co-operation with industry, patents, and product development worthwhile for researchers.

17. Industrial and other applications of the findings of research projects should be facilitated. Publicly accessible research applications have been shown to be a hindrance to future patents and commercialisation of the results. Making applications for research funding temporarily confidential should therefore be considered.

18. Further biotechnology expertise is needed to satisfy the demands of the labour market. Schools play a fundamental role here. To increase interest at academic level, teaching in biotechnology needs to be strengthened, both in compulsory schools and upper secondary schools, and also in basic teacher training and continuing professional development of teachers.

19. A special national resource centre should be set up, with responsibility for pedagogic development and the development of skills of teachers in biotechnology. Like already extant centres for other natural scientific subjects, this resource centre should be placed at a university or another institution of higher education.

20. Special courses in the natural sciences, technology and ethics at academic level should be offered to people who, in their professional activities, come into contact with biotechnology issues and their ethical implications. The aim of this would be

to stimulate the dissemination of knowledge, and promote a broad society-wide debate on biotechnology and its applications.

21. The increased use of genetic testing in medicine and healthcare requires enhanced expertise in order to use, interpret and explain the test results. Training of doctors, nurses, and other health care groups involved should include increased study of genetics, molecular genetics, and ethics. An educational programme for genetic counsellors should be set up, to meet the increasing demand for qualified genetic counselling.