Gene Technology Policy

Adopted by the SSNC board
on 5th February 1999

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Glossary

Antagonistic effects – effects that oppose and counteract each other.

Biotechnology and gene technology – "Biotechnology means use of organisms – that is, biological units that can multiply or transfer genetic material – or parts of organisms to produce or enhance goods or services. Biotechnology is defined as a synthesis of biochemistry, microbiology and process technology with the objective of technically utilising the attributes of microorganisms, cell and tissue cultures and cell constituents.

Gene technology is an area within biotechnology that uses intentionally altered genes, for example by transferring single genes that introduce certain traits. A genetically modified organism is an organism in which the genetic material has been altered in way that does not occur naturally by mating or natural recombination of genes." (Source: Miljöbalksutbildningens kompendium, p. 240)

"Green Revolution" – The introduction of new high-yield varieties of wheat and rice in India and other Asian countries in the 1960s. It was expected that the new varieties would solve the food crisis. But, whereas food production increased in some areas, the number of small farmers was reduced, as they could not afford the fertilisers and pesticides that the new, sensitive varieties required. Poverty and, as a result, malnutrition are still present in rural areas. Only a few of he Green Revolution's varieties began to be grown over large areas, and the genetic resource base was reduced as locally adapted and hardy varieties were crowded out. In some areas, the increased use of pesticides in combination with incorrect irrigation has led to environmental problems and reduced harvests.

"Life industries" – A collective term for the large multinational companies that own and carry out research and development in large areas of the production chain for food and medicine. For example, Novartis not only develops and produces seed and pesticides but also veterinary and human medicines.

North – The industrial countries in the Northern Hemisphere and Australia.

Prospectors – Companies that search for resources (minerals, oil, genes, etc.) or business ideas.

Qualitative quantum leap – Something entirely new has occurred within science. It is not only a question of more of the same, that is to say a quantitative difference, but of something essentially different, that is to say, a qualitative difference. "Qualitative" should not necessarily be regarded as something positive.

Socio-economic – The effects of changes that influence both social and economical conditions. A technology that renders the work force superfluous in a certain area changes the economy both for individuals who lose their jobs and for those from whom they buy their goods and services. This affects the social networks and the social conditions in the area; for example, people can be forced to move elsewhere; differences between rich and poor can increase or decrease.

Family structures are changed. An example of a change that has had socio-economic effects worldwide was the introduction of the tractor in farming.

South – Countries in Asia, Africa and Latin America

Synergetic effects – Different effects enforce each other. Two plus two makes more than four.

SSNC GENE TECHNOLOGY POLICY

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GENE TECHNOLOGY POLICY OF THE SWEDISH SOCIETY FOR NATURE CONSERVATION

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1. Introduction

Issues relating to gene technology concern a growing number of people today. The transfer of genes between organisms, the patenting of genetic material and the effects of gene technology on food production all have a bearing on issues which have long concerned the Swedish Society for Nature Conservation, SSNC. Gene technology is now used in applied as well as basic research. Among other things, it is used to make medicines, to develop foods, and it is used in farming, environmental care and the chemical industry. It is likely to find an increasing number of applications.

This policy chiefly concerns the food and farming sectors and the national and global effects of gene technology on biodiversity and social values. The policy does not cover the introduction of non-modified species, varieties or races that are alien to the ecosystems to which they are spread.

Gene technology, which is very important for both basic medical research and clinical medicine, raises difficult ethical questions. In our opinion, however, this is a matter that falls outside the field of interest and traditions of SSNC. Nevertheless, some of our general comments may be applicable within other areas than those covered by the policy.

Gene technology highlights the basic values that apply to our relationship to life in general. Consideration of these ethical aspects is of the greatest importance. It is a part of the SSNC's defence of all things living to underline these values.

2. Gene technology – a quantum leap

Biotechnology is at least as old as agriculture itself. Man has long made use of cells and parts of cells for plant breeding, animal breeding, baking and brewing. Today's crops are largely the result of thousands of years of experimentation and accidental discoveries when crossbreeding various plants. Until quite recently, modern plant breeding has largely consisted of systematising this technology.

The latest developments within biochemistry and other sciences have, however, drastically changed biotechnology. One of its most advanced areas is gene technology, a collective term for methods that permit the isolation, multiplication and implanting of genetic material into living cells.

It is sometimes claimed that gene technology does not in principle differ from traditional biotechnology. SSNC does not share this view, as gene technology makes possible changes that previously were quite impossible in nature itself. In our view, genetic engineering represents a scientific "quantum leap" in development. Using gene technology, genes can cross over natural biological barriers, and parts of the germ

plasma can be tailored to meet highly specific purposes. Gene technology is fundamentally different from traditional biotechnology and can influence the environment and health in ways that cannot be predicted today. The technology can also bring about a change in people's attitude to nature.

Gene technology is also developing very quickly. Obtaining a clear overview of the subject is therefore difficult, and opportunities for afterthought and dialogue are limited.

The political, social, economic and environmental consequences of gene technology have yet to be analysed. Nor have they been discussed within the democratic fora of the global community. This hampers opportunities for a detailed ethical assessment of the technology and its various applications.

In SSNC's estimation gene technology is not a logical extension of biotechnological tradition, but represents a qualitative scientific change. It is a methodology that is being developed with great rapidity and is of a type that differs from traditional biotechnology. All in all, it leads to political, socio-economic and environmental effects of new kinds, having wholly new ethical dimensions.

3. Ethical guidelines

When a community needs to evaluate a new technology, the consequences of which are difficult to forecast, a set of fundamental ethical guidelines becomes an important asset. Fundamental ethical values that are based on very long human experience can serve as an alarm signal, even if the effects of the new technology are partly unknown.

An important requirement for a new technology to be regarded as beneficial is that it supports, or least does not contradict, sustainable development. The Swedish Society for Nature Conservation regards sustainable development as a necessary – but not a sufficient – condition for the well-being of human beings and other organisms.

Gene technology permits extended control of sophisticated processes in nature. By targeted manipulation of events that could not previously be influenced, gene technology can create great potential profits within certain sectors, not least in medicine. However, the changes made are often so radical that unexpected and extensive damage to nature and the community cannot be excluded. It is very difficult to forecast with reasonable certainty how great these effects will be. At the same time it is already possible to identify some negative effects, chiefly in the socio-economic sector. *(See 6. "Global food production").*

Gene technology brings with it a number of recognised problems and also serious risks that are difficult to assess. But it also brings opportunities of doing good. How should this ethical duality be handled in a decision-making situation? One way, working on a scientific, social and political basis, is to select a course of action which, above all others, may be expected to achieve the greatest health and happiness for all people and all species in the whole of the foreseeable future. This requires that the interests of individuals and species are balanced against each other, and that it will be possible to predict future consequences.

Intuitively, such a starting-point seems reasonable. But where gene technology is concerned it is not enough. Important moral interdictions of certain types of actions may be set aside, besides which it is extremely difficult to see the long-term results of different alternatives, which makes it almost impossible to estimate the benefits.

The well-being of animals and people is therefore not a sufficient ethical object. As a complement, moral "signposts" in the form of norms and restraints against certain types of actions must be established. Such norms might be formulated as follows: "Do unto others as you would have others do unto you". That is to say: "Subject no living thing to meaningless suffering!", "Respect the integrity of all living beings!". Together, norms like these form an ethical framework that specifies limits that must not be exceeded. Within the

bounds of that framework, however, the interests of all those affected must be taken into account and balanced against each other.

SSNC believes that all relevant consequences for the well-being of human beings and other living things should form the basis of an ethical evaluation of gene technology research and application. Certain ethical "Stop-signs" or prohibitions are necessary in order to prevent such actions that can infringe fundamental values, even when calculated benefits suggest forging on. Non-human life also has an inherent value and legitimate interests that should be respected. An evaluation of effects must be carried out from a strictly interpreted precautionary principle. Where no conclusive proof of harmlessness exists risks must be assumed likely.

In the discussion concerning the use of gene technology, especially from a global perspective, it is also important to take into account the uneven power balance between countries and peoples. This means that large groups of people may find their interests ignored in a cost/benefit appraisal.

The interests of the powerless are always likely to come last and should therefore be given special attention when evaluating gene technology. The precautionary principle should be interpreted very strictly.

4. Gene technology under democratic control

Gene technology research and its applications have many objectives. Scientists find it exciting to work with a new technology and they try to create something that they believe to be beneficial. Gene technology can be used to identify illnesses and to improve their treatment. Politicians foresee more employment opportunities and companies hope for new markets. There is nothing basically wrong with this. But even the best of intentions can lead to unexpected and negative results. Where such a powerful tool as gene technology is involved, there is indeed cause for moderation and reflection.

Against the background of the ethical problem presented by gene technology, it is also important that the subject be widely and thoroughly discussed. If a slow-down of the pace of development is necessary to allow such a broad discussion to take place, then some braking action is in order. Unfortunately, the subject is currently debated chiefly among microbiologists and other scientists, with the consequent risk that the ethical base on which the whole project should rest will be quite narrow. It would be a most unfortunate situation if public organisations, mass media, decision-makers and interested members of the general public were to be largely excluded from discussions on gene technology.

SSNC believes that both the research and application of gene technology should be placed under full democratic transparency and control. It is of the greatest importance that these issues are raised for general public discussion. The growth of gene technology calls the Swedish community and the Swedish popular organisations to take part in the debate and to become involved. SSNC believes that an understanding of the new technologies is of great importance, but that the concern and scepticism expressed about gene technology – regardless of the level of comprehension of the technology by the individuals concerned – is an important ethical signal to put on the brakes.

5. Deliberate release

5.1 Deliberate release of genetically modified organisms

The risks associated with the release of genetically modified plants and animals into the environment are difficult to predict. The problem consists partly of the direct effect of the modified genes on the environment as well as possible synergetic or antagonistic effects.

Uncertainty is great, especially when small-scale trials are transferred to applications on a large scale. Genetic changes that give advantages in survival can lead to uncontrolled distribution and serious changes in the ecosystem. Alien genes may be transferred between closely related species, which can, for example, cause weeds to become resistant to herbicides or to permit them to spread easier. A changed balance of organisms may create toxic effects in the ecosystem, cause allergies or spread antibiotic resistance. Genetically modified plants with herbicide resistance may, when crossed, spread this resistance to weeds. This in turn can lead to increased use of chemicals to control weeds.

Today, permission to release genetically modified organisms is granted on the basis of limited risk evaluation. Benefits to the community are hardly evaluated. No real assessment is made of the benefit of the trait being tested, weighted against possible subsequent damage to the environment. Ethical trials are also very poorly developed. As a consequence, current practice may lead to unethical decisions, causing extensive damage to the environment in exchange for very little gain for society.

SSNC believes that the release of genetically modified organisms should not be permitted at present. Legislation and practice do not give sufficient guarantees that ethical aspects and the risk of negative effects will be fully evaluated and compared with any possible benefits to society.

SSNC urges, furthermore, that all decisions concerning any future deliberate release be based on thorough, case-by-case assessments in which benefits to the community, long- and short-term risks to the environment, and ethical issues are weighted and evaluated. The precautionary principle should apply without exception.

All supposed benefits must be put through exhaustive tests. Evaluation should specify any benefits to society, which groups would gain from it, whether there are any alternative methods available to achieve the community-related target, and what would happen if the application did not take place.

SSNC might accept deliberate release in the form of field trials in the future. Such acceptance presumes, however, satisfactory preparatory studies, well-developed trial procedures confirming that benefits predominate, and that the trial be acceptable from an ethical viewpoint. If painstakingly performed field tests do not reveal any further risks, SSNC can accept that deliberate release is carried out.

SSNC makes some exceptions, however: Organisms that have been given an antibiotic resistant gene should not be released into the environment. Similarly, herbicide-resistant crops should not be developed or released into the environment.

The long-term results of gene technology are difficult to predict and there is a great need for long-term control. It is therefore important that the community, in the first instance the Swedish Environmental Protection Agency, carefully registers and follows the deliberate release of genetically modified organisms. The use of naturally occurring marker genes could be a way of facilitating tracking. Where there is any suspicion of negative effects, the community should be able to withdraw licenses immediately without being liable to pay compensation.

SSNC believes that all future deliberate release of genetically modified organisms into the environment should be registered and followed up at both European and national levels. If and when negative effects are suspected, licenses should immediately be withdrawn without compensation.

A system for tracing accidental spread should be established on both a global and a European level.

5.2 Liability and compensation

The deliberate release and introduction onto the market of genetically modified organisms is allied with risk-taking, and there is a tangible likelihood of unpredicted negative effects. Those who wish to make use of gene technology should be held liable for whatever damages is incurred. This responsibility should be regarded as a complement to the granting of official licenses.

The principle that should apply for deliberate release and introduction is that the full environmental costs should be reflected in the market price. The immense lack of knowledge, the rapid development, the difficult ethical issues and the long-term perspective mean, however, that economic controls can only be a complement to other regulations.

SSNC believes that strict liability should apply to those who wish to release or introduce genetically modified organisms, in limited trials or on the open market.

In order to make compensation function in practice; it should be combined with obligatory liability insurance. This should make risk-related costs clear to businesses and their customers. The signals sent by prices will improve the self-control of companies; high-risk projects of dubious worth will be very expensive.

Taking into account the fact that possible effects on the ecosystem can appear a long time after an introduction, the insurance requirements should be supplemented with a fee-based fund that assumes responsibility for companies that have gone into liquidation or have otherwise stopped trading.

SSNC urges the introduction of obligatory liability insurance for the deliberate release and market introduction of genetically modified organisms. To finance future compensation claims, a fee-based fund should be set up.

6. Global food supply

6.1 **Gene technology does not solve problems of hunger.**

Some people believe that gene technology may offer the solution to hunger and malnutrition. But the key to solving the world food supply crisis is peace and that the poor of the world gain access to resources and opportunities for sustainable development on their own terms. That is why proponents' faith in gene technology appears exaggerated – as was the belief in the "Green Revolution". Instead, genetic engineering means that the poor in rural areas of the South may well become more dependent on the multinational "Life industries", so called, in the North.

It is a structure of this type that creates uncertainty within the world's food supply. Reliance on gene technology can result in false priorities in the field of research, as well as in the international development collaboration on global food security.

A better alternative to large-scale development of gene technology would be plant breeding based on the diversity of traditional crops, combined with the development of sustainable, locally adapted technology together with farmers, in such a way that their skills and requirements are fully utilised. A condition for success is that the role of the civil society is strengthened.

SSNC is not convinced that the belief in the ability of gene technology to achieve global food security has a basis in reality. Such a belief distorts the perspective and leads to wrong priorities. The development of sustainable agricultural methods and a strengthening of the civil society's position are of much greater importance for food security.

6.2 Breeding and food production

Plant breeding and domestic animal breeding have long been important tools for increasing food security. The basis for successful development is access to broad genetic variation. It is not possible today to decide which traits may prove valuable in the future. Until now, high yields, Involving a few plant species and animal races, have had the highest priority in breeding work. This has meant that the genetic resource base in cultivation and animal production has become narrower. Inbred vulnerability in combina-

tion with yield requirements has led to the use of pesticides, medicines and other technological measures. Today there are no obvious signs that the use of gene technology will change this pattern.

SSNC believes that the genetic resource base must be safeguarded when breeding domestic animals. Use of genetically modified domestic animals must not be allowed to threaten the genetic resource base or cause an increase in vulnerability in breeding. Nor should gene technology be permitted to cause suffering to animals. Plant breeding must not threaten the genetic resource base. Use of genetically modified plants must not be allowed to lead to increased vulnerability within plant breeding.

7. The right to diversity

7.1 The right to diversity should be universal

The raw material of gene technology is the biodiversity that has developed in nature over a very long period of time. Man has gradually learnt to make use of this diversity and has systematically selected attributes like yield, nutritional content, hardiness, fertility and resistance to weeds. In traditional communities, knowledge of genetic resources is often a collective asset.

Over ninety per cent of world genetic resources are connected to biotopes in the South. Many communities in the South still manage and use traditional collective knowledge concerning biodiversity in their daily lives. It is also in the South that prospectors seek commercially viable genetic resources for farming, the pharmaceutical industry, and the rest of the biotechnology industry. Several companies in the North have patented genetic material as well as the processes required to make use of the material extracted from them. In doing so, the companies involved have in practice laid claim to the assets of other countries or cultures. This usually goes by the name of "biopiracy" or biological theft. The situation raises the question of who has the right to genetic resources.

SSNC believes that the preservation and control of biological and genetic diversity should be a common concern for all mankind. The local communities that have developed and traditionally managed genetic diversity are of great importance to its survival and should be ensured of the right to the control of their own genetic resources.

7.2 No to patents on life!

That it might be possible to patent and own life, ranging from species and varieties to individual genes and gene sequences in animals, plants and people, was totally untaught of at the start of the twentieth century. The rights to a patent were reserved to inventors, giving them the possibility to exploit their inventions with a certain amount of protection from competitors. Patents usually give the inventor a period of 20 years in which he or she can exact a royalty from those who wish to make use of the invention. In this way, the patent works as an indirect compensation for the often costly development of new technology.

Living organisms, genetically modified organisms and gene sequences are not, however, inventions. To regard living organisms, even if improved by breeding, as patentable constructions is unrealistic and contradicts all intuitive ethical norms.

It may be justifiable to patent the industrial application of a gene, but not the genetic material itself. Any other uses of the gene would still be available for further use and research. This presumes, however, that the rights of other cultures to processes deriving from traditional knowledge are respected.

SSNC believes that the patenting of living organisms or parts of living organisms and their genes should not be permitted, whether or not the genetic material is genetically modified. Such patenting is ethically indefensible. Mankind's claim on other species cannot be allowed to be so great, and there is something -

intuitively unrealistic in regarding living organisms as inventions. Neither should descriptions of the functions of a gene sequence be patentable.

7.3 Plant breeder's rights and gene banks.

In addition to patent rights, there are traditional plant breeder's rights that apply to new, uniform, stable and pure plant varieties. In its earlier form, the plant breeders' rights gave the farmer the right to save seeds from the current harvest for sowing the following year without cost. Other plant breeders were also free to use the protected variety for further breeding. Within the EU, the Council Regulation on Community Plant Variety Rights gives farmers with smaller areas of land the right to use their own seed for sowing without cost. The existence of patents on plant varieties, genes or gene sequences from plants leads, however, to a situation where farmers are denied the right to save seeds from their harvest for subsequent sowing. Thus, traditional users can be required to pay for genetic material that they themselves have developed, when they pay royalties to use a variety with traits they themselves have selected.

In SSNC's judgement, taking out patents on plant varieties and genetic plant material should not be permitted; farmers right to use seeds for sowing should be guaranteed. SSNC believes that the traditional plant breeders rights give adequate protection to plant breeders.

As new, high yielding, varieties have taken over from the earlier traditional varieties, gene banks have been created to preserve genetic material for use in future plant breeding. Gene banks can never replace conservation in active cultivation, but are important in the current situation, where the genetic resource base is being eroded. Genetic plant material from gene banks, or varieties developed from this type of material, must not under any condition be patented.

SSNC believes that farmers and gene banks should have the rights to the resources that they manage. We believe that conservation in gene banks can never replace conservation by cultivation, and that the best guarantee for conservation is that genetically diverse varieties are cultivated and developed by traditional farmers in the areas from which they come.

7.4 Global agreements

The United Nations and the World Trade Organisation have each drawn up their own internationally binding agreement, the Convention on Biological Diversity and the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), respectively. Among other things, these documents regulate the use of the world's genetic resources. The agreements give different signals, however, to global society as to how genetic resources should be managed.

The Convention on Biological Diversity focuses on the rights of local communities to the resources they have developed and manage, and stresses that local control is necessary for sustainable use and conservation. Nations are accorded sovereign rights to their genetic resources. According to the convention, the inequitable transfer of genetic resources between North and South should be redressed. The parties agree to ensure that legislation on Intellectual Property Rights does not run counter to the objectives of the convention and ensures a fair and equitable sharing of benefits from the products that are developed from the rich diversity of genetic resources.

The TRIPS agreement, on the other hand, requires all member states of the WTO to introduce legislation that grants companies the right to monopolise the development and commercialisation of plant varieties. The risk is therefore apparent that TRIPS will force states with limited resources in the South to adopt standardised patent legislation that makes local, traditional, collective management of genetic resources impossible.

SSNC believes that the intentions of the Convention on Biological Diversity should be reflected in all international and national laws and agreements that relate to genetic resources. International trade agreements especially should be changed in that direction.

8. Labelling

The application of gene technology affects many people. Many are sceptical and concerned about the new technology and oppose its use. A basic requirement for all use of gene technology should therefore be a well-defined and democratically drawn up system for labelling of gene technology products. Labelling should provide consumers with the opportunity to avoid inadvertently supporting the growing of genetically modified organisms. As a first step, labelling should make clear which products consist of, contain, or have been made with the help of genetically modified organisms. Labelling should be enforced as far as it is possible to trace the modified organisms.

SSNC believes that labelling of products that consist of, contain traces of, or have been made from GMOs should always be compulsory. Also, as far as it is possible, products that have been made with the help of genetically modified organisms should be labelled. Labelling should be designed for the consumer's benefit and be clear and uniform.