

**Working Group Memorandum 2003:18
Ministry of Agriculture and Forestry, Finland**

**Gene Technology Strategy and Action Plan
of the Ministry of Agriculture and Forestry
2003-2007**

Helsinki 2003

To the Ministry of Agriculture and Forestry

The Gene Technology Strategy of the Ministry of Agriculture and Forestry is based on the Strategy for Biotechnology and Genetic Engineering in Agriculture completed at the Department of Agriculture in December 2000. A working group of the Ministry was set up to draft a new strategy by complementing the gene technology strategy for agriculture with issues involving gene technology dealt with in the other departments of the Ministry and by harmonising the main principles, approaches and proposed measures of the different departments.

The working group was appointed on 24 August 2001. It was chaired by Agricultural Counsellor Mirja Suurnäkki from the Department of Agriculture and the secretaries were Senior Research Officer Leena Hömmö (1 January-30 June 2002 Senior Research Officer Elina Nikkola) from the Department of Agriculture and Senior Research Officer Jussi Tammissola from the Department of Food and Health. The members were Senior Officer Hannu Kukkonen (from 1 April 2002 Senior Officer Mikko Peltonen) from the Department of Forestry, Environmental Director Veikko Marttila from the Department of Rural Areas and Natural Resources, Agricultural Counsellor Päivi Mannerkorpi from the Department of Food and Health, Veterinary Officer Kai Pelkonen from the Department of Food and Health and Fishery Counsellor Pentti Munne from the Department of Fisheries and Game. From 22 August 2002 Senior Officer Raija Aaltonen attended the meetings as a specialist.

The working group founded its work on the Strategy for Biotechnology and Genetic Engineering in Agriculture (Working Group Memorandum, Ministry of Agriculture and Forestry 2001:12, completed on 15 December 2000) and complemented this by special studies on the forest, fishery and game sectors. Special studies were commissioned on the following topics (only available in Finnish): "Population genetics of transgenic forest trees" (Helmi Kuittinen, University of Oulu), "Biotechnology and gene technology research on forest trees" (Tuija Aronen, Finnish Forest Research Institute METLA), "Opportunities offered by biotechnology and gene technology in forest tree breeding as well as production and forestry use of bred material" (Jouni Mikola, Finnish Forest Research Institute METLA) and "Biotechnology in aquaculture - a review of research in Finland" (Hannu Mölsä, University of Kuopio). The studies will be published in scientific journals and publication series and on the Internet pages of the Ministry of Agriculture and Forestry. The studies concerning forestry have been published in the scientific journal *Metsätieteen aikakauskirja* 2/2002 (in Finnish). The special studies made in connection with this strategy or the biotechnology strategy for agriculture are listed in Annex 1.

Based on discussions at the Ministry, the Working Group decided to limit the strategy to concern only gene technology instead of the whole wide field of biotechnology, because the former involves a great deal of preparation of international norms and Community legislation and there is wide public discussion on this. The Working Group also decided to incorporate an action programme to the strategy.

As part of the preparation process a seminar was held on 17 May 2002, with participants from different ministries, research institutes, interest groups and NGOs. Discussions on the strategy were carried out with the administrative bodies governed by the Ministry of Agriculture and Forestry on 12 September. The strategy was circulated widely for comments between 17 January and 31 March 2003. Statements were requested from

altogether 107 organisations, of which 62 replied. Statements were also requested from the departments and special units of the Ministry. The comments were taken into account in the preparation of the strategy as far as possible.

The gene technology strategy of the Ministry of Agriculture and Forestry consists of a summary, which presents the main principles, objectives and priorities of the strategy, and the special studies mentioned above.

The Working Group respectfully submits the Gene Technology Strategy and Action Plan to the Minister of Agriculture and Forestry.

Helsinki, 3 September 2003

Chairperson: Mirja Suurnäkki

Secretaries: Leena Hömmö Jussi Tammisola

Members: Raija Aaltonen Päivi Mannerkorpi

Veikko Marttila Pentti Munne

Elina Nikkola Kai Pelkonen

Mikko Peltonen

TABLE OF CONTENTS

Summary

STRATEGY

Main principles

Background

General approach of the strategy

Regulation and control of gene technology

Research in gene technology

Preparation of gene technology issues at the Ministry of Agriculture and Forestry and other ministries

ACTION PROGRAMME

General administrative measures

Detailed measures for different sectors

Agriculture

Plant production

Livestock production

Animal nutrition

Animal breeding

Forestry

Fishery

Game husbandry

Food safety and quality

Consumer aspects

Environmental impacts

Annex 1. Background and special studies drawn up in connection with the strategy process

Annex 2. Legislation and international agreements concerning gene technology

Summary

The Ministry of Agriculture and Forestry appointed a Working Group to draw up a gene technology strategy for its administrative sector on 24 August 2001. The strategy was to be based on the Strategy for Biotechnology and Genetic Engineering in Agriculture completed on 15 December 2000. The Gene Technology Strategy and Action Plan of the Ministry of Agriculture and Forestry for 2003-2007 presents the main principles, objectives and proposed measures for the use of gene technology in sectors governed by the Ministry.

Today biosciences are one of the most active fields of science, which constantly produces considerable amounts of new information. The mapping of the genomes of living organisms and understanding of the fundamental principles of heredity have expanded the possibilities for the utilisation of gene technology to almost all fields of science and a great number of the sectors of the society. In agriculture, forestry and fishery gene technology is hoped to increase the productivity of plants and animals and their resistance to various kinds of diseases and environmental stress as well as to introduce new possibilities for the development of the quality characteristics. A great deal of attention has also been directed at managing the risks that gene technology may involve.

The cultivation area of genetically modified crops in the world has grown by about 10 per cent a year. In 2002 it was 58.7 million hectares, most of this in the USA. At present the area under genetically modified crops is growing the most rapidly in the developing countries. In Europe the cultivation of genetically modified crops is as yet relatively uncommon and in Finland no genetically modified varieties have so far been approved for cultivation.

Research and use of gene technology and the preparation of new legislation and international standards for this have increased in the sectors governed by the Ministry of Agriculture and Forestry. The European Community has recently adopted new legislation concerning genetically modified products and the unofficial ban on the use of genetically modified products, i.e. moratorium, followed since 1989 is being dissolved. We may well expect that the tasks relating to the preparation of provisions and standards, approval of products and control as well as development of control methods are going to increase in the administrative sector. To support these activities and develop the industries there is also a need for up-to-date research information on the possibilities to utilise gene technology and the framework conditions for its utilisation.

The report describes the regulation, control, research and use of gene technology. An action programme for 2003-2007 was also incorporated in the strategy, which was supplemented by special studies for the part of forestry and fishery. In addition to the special seminars, the relevant organisations and associations were heard widely on the topics relating to gene technology.

The main principles that the Working Group decided to include in the strategy were the following: Gene technology methods offer opportunities to promote and create new operating conditions for industries. The applications must be developed in a customer- and environmentally oriented way, aimed at even higher quality and more diversified products, taking account of the special characteristics of Finnish agriculture and nature. Research supports the maintenance and development of multidisciplinary scientific expertise. Gene

technology methods are applied in a controlled manner, founded on the viability of different types of agriculture, sustainable use of natural resources, safety and high quality of the products, open and transparent operations and efficient control. Use and marketing of genetically modified products call for the prior approval procedure, where the safety of the products to humans, animals and the environment is assessed. Decision-making on approval is based on scientific risk assessment and precaution, including the ethical aspects. Genetically modified products and products manufactured from these are appropriately labelled. Production chains must be open and traceable. Uncontrolled release of genetically modified organisms to the nature and the possible ecological damages caused by this are prevented. Control must be efficient, sufficient and equitable. Control systems and methods must be developed. Preparation and decision-making is open and transparent and communication is efficient.

The Working Group proposes several administrative actions to improve the coordination of the gene technology issues in the administrative sector of the Ministry of Agriculture and Forestry and the cooperation with authorities outside the sector. The Working Group directed special attention at the needs for education and research arising from the development and introduction of gene technology methods. The action programme specifies the main objectives and measures for plant and animal production, forestry, fishery, game husbandry, food production, consumer aspects and control of environmental impacts.

The background studies listed in Annex 1 are available only in Finnish. Annex 2 to the Finnish version of the strategy document gives a list of gene technology terms and their definitions. A similar list was not included in this English version. Annex 3 to the Finnish document presents a number of Community and national statutes as well as international agreements relating to gene technology. These are only listed in Annex 2 to this English version.

STRATEGY

Main principles

The development and use of gene technology methods offer opportunities to promote and create new operating conditions in agriculture, food economy, game husbandry, fishery and forestry.

Gene technology methods are developed and used on the condition that they are applied in a controlled manner, founded on the viability of different types of agriculture, sustainable use of natural resources, safety and high quality of the products, open and transparent operations and efficient control. The special characteristics of Finnish agriculture and nature are taken into account in the application of gene technology.

The use of gene technology in agriculture, forestry, fishery and food production is developed in a customer- and environmentally oriented way, aimed at even higher quality and more diversified products.

Use and marketing of genetically modified (GM) products must be based on the prior approval procedure, where no permission is granted before the use of a GM organism in a product has been proven safe to humans, animals and the environment.

Decision-making on prior approval is based on high expertise, scientific risk assessment and precaution, including the ethical aspects. The environmental impacts of genetically modified organisms are assessed. Uncontrolled release of genetically modified organisms to the nature and the possible ecological damages caused by this are prevented.

The control of the use of genetically modified organisms, marketing of products containing these and the production chains is efficient, sufficient and equitable. Control systems and methods as well as distribution of labour and cooperation between the authorities are developed.

Research supports the maintenance and development of multidisciplinary scientific expertise required for the application of gene technology in agriculture and food sector, forestry and fishery.

To ensure sufficient customer information and choice, genetically modified products and products manufactured from these are appropriately labelled. Production chains must be open and traceable to be able to show the origin, production method, composition and quality of the products.

Preparation and decision-making relating to gene technology is open and transparent and communication is efficient.

Background

Gene technology applications in sectors governed by the Ministry of Agriculture and Forestry

Biotechnology, especially gene technology, will very likely be one of the key technologies in the near future. New information on the genomes of living organisms and fundamental principles of heredity has made it possible to modify the genetic constitution of organisms more rapidly and accurately than before, even crossing the borders between species. This is the new technology we call gene technology.

Research and development in medicine and diagnostics are important users of gene technology. The method is used especially in the development and production of new medicines and vaccines. The EU has approved eight live and five inactivated genetically modified animal vaccines. Such vaccines are already being used for predators and production animals, and they can also be developed for fish. Gene technology has made it possible to establish many serious diseases with significance for public health as being caused by certain genetic mutations, which has contributed to the development of new treatments and medicines.

In agriculture, forestry, game husbandry and fishery gene technology has been hoped to increase the productivity of plants and animals and their resistance to various kinds of diseases and environmental stress and improve the opportunities to develop the quality characteristics. Gene technology may increase the yields of crops and improve the quality, promote the growth and quality characteristics of forest trees, improve the efficiency of the production processes of feedingstuffs and improve their nutritional quality. Genetically modified plants and animals could be used for the production of medicines and vaccines and various kinds of spare tissue and organs.

Today it is possible to influence the characteristics of all types of production animals by means of gene technology. In a few years the first genetically modified lines of animals may well gain access to commercial production.

Because of the climatic conditions Finnish agriculture cannot compete on the international market by means of production volumes, while quality and special products may constitute significant competition factors. According to a study made at the Agricultural Economics Research Institute, genetically modified, so-called first wave products (e.g. resistance to pesticides, pests and diseases) lower the production costs and increase the yields. This benefits mainly farmers who are the first to introduce the new technologies. The use of gene technology applications in forestry and fishery in Finland is still far in the future.

In 2002 transgenic crops were cultivated on 58.7 million hectares in the world. The area has been growing by about 10 per cent per year. 66 per cent of the area under GM crops is in the USA, 23 per cent in Argentina, 6 per cent in Canada and 4 per cent in China. The EU has approved three GM varieties of maize for cultivation, but the share of Europe in the area under GM crops is still very small (0.02 per cent). No GM varieties have been approved for cultivation in Finland.

By virtue of Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (the so-called open uses directive), by 1999 the EU had

approved for the market four genetically modified maize varieties and one soya, three varieties of rapeseed, one chicory, one tobacco, three carnations and a testing equipment for antibiotic residues in milk based on the use of a genetically modified bacterium. Two live GM vaccines intended for open use (field distribution) were approved by Directive 90/220. Of the approved plant products one variety of both soya and maize have also been approved for use as food. Since then no new GM organisms of agriculture have been authorised for the market, even if they would have been proven safe, but these have been left to wait for the completion of the extensive legislative package on genetic modification.

Within the Community products processed from GM plants, such as starch products and vegetable oils, have been introduced into food use by means of the notification procedure laid down in the Regulation on novel foods. Two such notifications have been made for cotton products, seven for rape products and four for maize products. In addition to these, a notification has been made for riboflavin (vitamin B2), which is produced by the genetically modified *Bacillus* microbe. In Finland these products may be used as raw material of food and feeds. However, Finnish food, feed and forest industry have had considerable reservations concerning the use of GM raw material in their production, and Finnish farmers have also been fairly cautious. The main reason for this has been the fear that the consumer reaction might be negative. Safety issues and ethical considerations have also caused some doubts relating to the new technology.

If the GM raw material has been purified to the extent that no identifiable or measurable traces of the modification can be found in the product, the legislation has not required any labelling of these products. However, under the recently completed Community legislation the foods and feedingstuffs of GM origin must be labelled independent of whether they contain modified genetic material or not. Less processed products contain the modified genetic material, and for these products the current legislation requires labels which tell about genetic modification. In Finland GM organisms have also been approved for research and field test purposes.

In order to secure its economic interests Finland must direct special attention at the education and research needs which arise from the development and introduction of gene technology methods in the sectors governed by the Ministry of Agriculture and Forestry. The protection of gene technology inventions and the related publication may not only prevent the transfer of know-how across the Finnish borders but also promote the development of the GM research and applications, provided that the extent of the patent rights is specified accurately.

Conditions for the utilisation of gene technology

The advantages and disadvantages of genetically modified microbes were discussed widely in the scientific community already in the 1970s. The GM plant species reached the commercialisation stage towards the end of the 1990s, which led to wide discussion on the use of gene technology in the food chain especially in the media and international forums. The topics discussed also in Finland include genetically modified plant species and their cultivation and trade, possibilities to improve the traits of production animals, and ethical questions relating to gene technology. The arguments presented in this discussion have caused doubts and uncertainty among the consumers and led to negative attitudes towards gene technology, which has made the food and feed industry less willing to use genetically modified raw material. In connection with the application of gene technology in

other sectors there has been discussion especially on the safety and environmental issues they may involve. The use of gene technology in, for example, forestry is a question which calls for careful environmental impact assessment due to the long generation interval of the trees and economic significance of forests. Depending on the trait concerned, the changes in the life processes of trees may have various kinds of unforeseeable impacts on the forest ecosystems. Environmental impacts and impacts on animal welfare must also be assessed carefully before any decisions on the import and farming of GM fish can be made.

The critical discussion on gene technology has been particularly strong in many EU countries, and by developing the legislation the Community has tried to find solutions to the problems relating to the use of new technologies. According to the Community legislation on gene technology, genetically modified organisms must pass a detailed approval procedure, where their health and environmental impacts are also assessed case by case. The purpose of the legislation is to ensure by means of risk assessment and management and in accordance with the precautionary principle that the production chains of genetically modified products are safe for humans, animals and the environment. In Finland, too, prior approval and control are absolute conditions for introducing products containing GM organisms to the market.

International trade in genetically modified organisms is one of the main topics discussed in the WTO at present. By a decision made on 13 May 2003 the United States notified that they intend to launch a WTO process for dissolving the moratorium concerning the access of GM products to the EU markets, which had been in force since 1998. A number of other countries joined the USA in this effort (Australia, Chile, Columbia, El Salvador, Honduras, Mexico, New Zealand, Peru and Uruguay). Canada has left a separate notification of its own concerning WTO consultation.

The trade in GM organisms on the international markets is also regulated by the Cartagena Protocol on Biosafety of the Convention on Biological Diversity (78/1994), which the European Community and its Member States signed in May 2000 and which is currently under the ratification process.

The objective of the Protocol on Biosafety is to contribute to ensuring that living organisms produced by means of modern biotechnology are transferred, handled and used in a way which does not cause any damage to biodiversity and its sustainable use, also taking into account the risks to human health.

The Protocol requires the permission of the recipient country before living GM organisms can be released to the environment within its territory. However, the Protocol on Biosafety concerns only such living organisms which may have adverse impacts on the conservation and sustainable use of biological diversity.

Because of the rapid development of gene technology during the past decade, the administrative sector of the Ministry of Agriculture and Forestry is also faced with new challenges. When carrying out their duties at the Ministry and administrative bodies under it, the civil servants must take a stand on gene technology issues in the planning of activities, preparation of legislation and inspection, control and research tasks. The gene technology strategy for the sectors governed by the Ministry of Agriculture and Forestry

has been prepared to support the decision making concerning the policies and legislation which relate to the research and utilisation of this new technology.

General approach of the strategy

Definitions

In this strategy:

- *customer* means a consumer, producer or other customer
- *gene technology* means molecular biology directed to genes
- *quality* means hygienic, nutritional, sensory, technical and ethical quality as well as environmental and service quality
- *product* means foodstuffs and their raw materials, as well as production inputs of agriculture, forestry, fishery and game husbandry (e.g. seed, plant propagating material, feedingstuffs, fertilisers and pesticides)

Mission statement of the Ministry of Agriculture and Forestry

The administrative sector of the Ministry of Agriculture and Forestry comprises agriculture and horticulture, rural development, forestry, veterinary service, safety and control of foodstuffs, fishery, game and reindeer husbandry, use and management of water resources, and land survey. According to its mission, the Ministry of Agriculture and Forestry lays the foundation for sustainable and diversified use of renewable natural resources and development of economic and leisure-time activities in rural areas as well as ensures the high quality of foodstuffs and health of animals and plants.

Strategy for Biotechnology and Genetic Engineering in Agriculture

The Strategy for Biotechnology and Genetic Engineering in Agriculture completed in 2000 is available on the Internet pages of the Ministry of Agriculture and Forestry. The strategy presents the objectives and measures to be taken into account for ensuring the safety and quality of agricultural inputs and foodstuffs, consumers' confidence in the food production chain, controlling environmental impacts, and sustainable plant and animal breeding. The strategy work included a thorough consideration of the ethical questions, environmental impacts and research relating to the utilisation of gene technology in agriculture. This, together with the approach to the strategy for the whole administrative sector, is founded on the mission statement of the Ministry given above. The other strategies and action programmes of the Ministry, such as the revised Strategy for the Sustainable Use of Renewable Natural Resources, Quality Strategy for the Finnish Food Sector and Finland's National Forest Programme 2010, have also been used in drafting this strategy.

Strategy for the Sustainable Use of Renewable Natural Resources

The natural resources strategy revised in 2002 lays down the outlines of the actions by the Ministry and the sectors governed by it concerning the compliance with the principle of sustainable development in the use, management and conservation of renewable natural resources and preparing for the future development. The strategy also takes account of the objectives of nature and environmental protection and animal welfare, including the ethical treatment of production animals.

As one vision of agriculture and food production the natural resources strategy refers to the use of genetically modified organisms on the basis of a scientific approval procedure for the production of more robust and productive plant varieties, high-quality and diversified foodstuffs and medicines in a customer- and environmentally oriented way.

The Strategy for the Sustainable Use of Renewable Natural Resources is available on the Internet pages of the Ministry of Agriculture and Forestry.

Finland's National Plant and Animal Genetic Resources Programme

The objective of the Convention on Biological Diversity CBD is to protect the biological diversity of world's ecosystems, plant and animal species (organisms) and the genes contained in these, promote the sustainable use of natural resources and ensure a fair and equal distribution of the benefits derived from the use of biological natural resources. In addition to the wild living organisms, the concept of biodiversity comprises the cultivated crops and domestic animal populations. By approving the CBD Finland has given a commitment to promoting the protection and sustainable use of biological diversity in all activities of the society.

As part of the work on the national biodiversity action programme drawn up to implement the CBD and its objectives, the Ministry of Agriculture and Forestry drafted a National Plant Genetic Resources Programme in 2001. This presents the main principles, objectives and proposals for measures relating to the protection and sustainable use of the genetic resources of agriculture, horticulture and forestry. The preparation of a similar programme for animal genetic resources was also started. Both programmes direct special attention at the conservation of local crops and landrace breeds and their use for production purposes.

Strategy for Finnish agriculture

The final report of the strategy project on Finnish agriculture (Working Group memorandum 2001:16b) discusses the possibilities to utilise gene technology in agriculture as well. The strategy states that greatest changes that will be reflected on the markets can be expected to occur in the development of gene technology and information technology applications for agriculture.

According to the strategic priorities presented in the report, "The use of biotechnology and marketing of the GM products must be based on the prior approval procedure, where licences are not granted before the use of the new method or organism in the product is proven safe for humans, animals and the environment."

The final report of the strategy project on Finnish agriculture is available on the Internet pages of the Ministry of Agriculture and Forestry.

National Quality Strategy for the Finnish Food Sector

All the parties to the food chain in Finland are committed to the Quality Strategy for the Food Sector. The strategy aims to develop the quality of the products and activities, ensure that the quality stays high on a permanent basis and improve the competitiveness

and profitability of the companies through joint measures of the administration, research, training and advisory services, and the food chain. It is vital that the quality, purity, origin and production method of the products can be proven in a reliable way and the production is founded on the principle of sustainable development and ethically acceptable.

The strategy is based on quality and chain thinking. To ensure the quality of the final product, the production chain and its control must be efficient and traceable and the quality assurance and responsibility for the quality must be the key in all stages of the chain from primary production to the consumer.

One important principle in the strategy is customer orientation. Taking the needs and expectations of the consumers into account is a key factor in terms of the success of the whole food sector, which means that the products and quality of the actions must meet the demands. The public sector must ensure, among other things, that different consumer groups, such as people with allergies or different philosophies of life, have the opportunity to select a diet which meets their particular needs.

Finland's National Forest Programme 2010

The National Forest Programme, which extends until 2010, continues the tradition of the earlier forest programmes implemented in Finland. The programme aims to ensure work and livelihoods based on forests, biodiversity and viability of forests and recreation provided by forests to all citizens. The content of the present programme is wider than in the earlier ones as it takes account of the economic, ecological, social and cultural sustainability of the use of forests. In addition to the national needs, it responds to the new needs which have arisen in the context of the international forest policy. The forest programme has been prepared in open and broad cooperation with the interest groups and citizens.

The programme is based on the view that a competitive forest cluster and forests as a renewable natural resource offer a solid foundation for sustainable development. The State, together with the companies and entrepreneurs, takes care of the operating environment, including competitive energy prices and good road network, as well as the technology and development programmes needed for the development of wood industry and wood energy. The ecological sustainability of forests is safeguarded by continuing the efforts relating to the environmental management of commercial forests in the context of the environmental programme for forestry (1994) and its follow-up processes.

Forest know-how and innovation in the forest sector is improved by developing research, application of research results in practice and education and training. Finnish interests and sustainable forestry are promoted through active international forest policy, international forest research and training cooperation and communication on forests and environmental issues.

The multiple use of forests comprises hunting, reindeer herding, collection of nature's products, as well as landscape and cultural values, outdoor recreation and tourism. These are taken into account and promoted in connection with the use and protection of forests.

Structural Programme for the Fisheries Industry in Finland 2000-2006

The objective of the Structural Programme for the Fisheries Industry is that at the end of the programme period Finland would have a competitive and profitable fishing industry, capable of offering a diversified selection of high-quality fish produced in a responsible manner in accordance with the market demand. Inputs in quality and product development are a necessary condition for maintaining and increasing the sales of fish products. The role of aquaculture is highly significant, and increasing the range of fish species used in farming is important. The development of the whole sector calls for new research information and its application to improve the profitability of the enterprises and the quality of the products and production processes. The structural programme and its supplement are available on the Internet pages of the Ministry of Agriculture and Forestry.

Even if the structural programme does not present any clear positions on the use of gene technology in developing the fishery sector, the principles and objectives of the programme must be taken into account when making the decisions on the utilisation of gene technology in the sector. The most important field in this respect is aquaculture, and efforts are being made to develop the research concerning breeding and new species to be used and breeding. In terms of fish consumption it is to be expected that gene technology will be utilised for improving the quality and the efficiency of the production, especially for the part of imported fish. The development must be founded on the safety of the products and approval by the consumers.

Development strategy for recreational fishing of the Ministry of Agriculture and Forestry

Leisure-time fishing is a form of outdoor recreation which is well in line with the principle of sustainable development, utilises renewable natural resources in diversified ways and enjoys wide interest among the citizens. The preconditions for this activity are in good shape in Finland. The objective is that recreational fishing utilises primarily the naturally propagating fish populations in a diversified and sustainable way and the management of fish populations is carefully planned and the results are being monitored. Efforts are also made to maintain the role of fishing as recreation in the increasingly urban society so that opportunities are created to business activities as well. The programme is available on the Internet pages of the Ministry of Agriculture and Forestry.

The strategy is connected to gene technology mainly for the part of the management of fishing waters and fish farming for stocking. According to the strategy, naturally propagating species are the ones to be used in the management of fish populations and the populations of the natural populations and their diversity is ensured. This means that the stocking of genetically modified species is not in line with the objectives of the strategy. Special attention is directed at the quality of the fish used for stocking.

Strategies and action programmes for specific products

The Ministry of Agriculture and Forestry has also started the drafting of strategies and action programmes for certain products and special products which are particularly important for the competitiveness of agriculture and the food sector. These include the National Grain Strategy and strategy plan for potato, organic production strategy

completed in 2001, and action programme for the seed sector. Genetically modified products can also be considered as special products through which the profitability of agriculture can be improved, which is why the adoption of a common strategy for these is highly important for the development of the sector.

Life sciences and biotechnology - a strategy for Europe

In September 2001 the European Commission launched an extensive public round of hearing on current biotechnology topics. As a result of this the Commission published a proposal for the EU Strategy for Life Sciences and Biotechnology on 23 January 2002 (http://europe.eu.int/comm/biotechnology/introduction_fi.html).

The Commission proposed a strategy which would make it possible to respond to the challenges through a policy based on both scientific fact and interests and concerns of the people, taking account of the ethical considerations. The strategy should allow the EU to benefit from the great potential of biosciences and biotechnology, guarantee appropriate administrative practices and act in accordance with its international obligations. The Commission proposes an integrated strategy where the different elements are interdependent and support each other.

The implementation of the strategy calls for the development of consistent and credible actions through an open and continuous process founded on mutual cooperation. In addition to the strategy the Commission proposes an action plan which contains 30 concrete measures to be implemented by the Commission and the European Community, as well as recommendations for other public and private actors. The implementation period of the measures is 2002-2010.

Finland has considered the implementation of the biotechnology strategy and action programme highly important. Finland has stressed that on the Community level priority should be given to measures with strong Community competence, such as drafting the legislation concerning the utilisation of the new technologies. Research and education are extremely important as the foundation for competitiveness, and there should be wide and open public discussion on, for example, the ethical questions relating to the utilisation of gene technology. Such discussion should, however, mainly be carried out nationally. Finland has taken an active part in the preparation of the roadmap for the implementation of the strategy.

The Council Conclusions included in the strategy document were approved in the Competitiveness Council on 26 November 2002. The Conclusions are based on the objective set in Lisbon in 2000, according to which the EU should develop into world's most competitive and dynamic skills-based economy.

The task of the contact network managed by the DG Enterprises is to take care of the implementation and coordination of the action programme included in the EU's biotechnology strategy. The Commission has published the first progress report of the strategy (5.3.2003 COM(2003) 96 final). The main issue in the first stage of the implementation of the action programme is to create a benchmarking programme for the biotechnology sector and improve the financing possibilities of the SMEs operating in the sector. The measures were to be discussed in the Council during 2003, and their implementation is going to require the effort of various parties for a number of years.

Regulation and control of gene technology

The utilisation of gene technology in the economic sectors governed by the Ministry of Agriculture and Forestry is one of the most strictly regulated fields of activities. The benefits and possible disadvantages of the new technologies for the environment and human and animal health are discussed in various forums and legislation and international agreements regulating the field are being drafted constantly. Together with the Community and national legislation these agreements naturally constitute the framework within which the measures proposed in the strategy must stay. On the other hand, the strategy must also create the starting points and basic principles for the legislation needed in the administrative sector so that the opportunities offered by gene technology can be utilised sensibly, economically and safely in agriculture, forestry, fishery, game husbandry and food production.

In Finland provisions on the approval and use of genetically modified organisms are laid down in the Gene Technology Act, Animal Welfare Act, Seed Trade Act, Pesticides Act, Act on Trade in Forest Reproductive Material, Feedingstuff Act, and decrees concerning organic production. The Gene Technology Act is currently being revised, and it is going to impose further obligations to the Ministry of Agriculture and Forestry and the administrative bodies under it. The Ministry of Social Affairs and Health is the supreme authority responsible for the steering and control of the compliance with the Gene Technology Act and provisions issued under it in general, and especially for the part of issues relating to human health. The act will clarify the role of the different ministries in the control. The Ministry of the Environment is responsible for the steering and control of the compliance with the act and provisions issued under it relating to the combating and prevention of environmental damages caused by the use of genetically modified organisms. In agriculture, forestry, fishery and game management the Ministry of Agriculture and Forestry supervises the steering and control relating to the act. The Ministry of Trade and Industry steers the control of foodstuffs, GM foods included, under the Food Act. The Board for Gene Technology with representatives from the above-mentioned ministries plans and coordinates the control of the compliance with the Gene Technology Act. Control and inspection tasks under the Gene Technology Act are managed by the National Product Control Agency for Welfare and Health, Finnish Environment Institute SYKE and Plant Production Inspection Centre KTTK. In addition to these, the State authorities and research institutes are obligated to give statements to the Board for Gene Technology and to act as expert authorities and institutes in the gene technology sector.

The European Community has a number of directives and regulations concerning the use of genetically modified organisms. The most important ones for the administrative sector of the Ministry of Agriculture and Forestry are the directives on the contained use of GMOs and their release into the environment, Regulation on genetically modified food and feed and Regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, Regulation on novel foods, directives on seeds for sowing, Directive on forest reproductive material, Directive on additives in feedingstuffs and Council Regulation on organic production of agricultural products and food. Community legislation on gene technology is being developed further with the aim of compiling an extensive legislative package which covers the whole chain of gene technology application. The long-term objective of the Commission is that provisions on genetic modification are primarily laid down in the

legislation concerning specific sectors. The focus in the development of the legislation is in ensuring the safety of the genetically modified products to the environment and human and animal health. Efforts are made to achieve this by developing the approval procedure for GM products and their labelling as well as traceability and control in the whole production chain. The approval of genetically modified products must be based on scientific risk assessment and prior approval procedure based on precautionary principle as well as risk management by means of control which covers the whole production chain.

The principle in food production is that genetically modified foods and feeds are appropriately labelled. This principle has been adopted in all national and Community legislation concerning GMOs. Labelling is needed to ensure sufficient consumer information to allow them to make the choices. The package labels must show, for example, if the product has impacts on the health of special groups (e.g. allergies) or if it may cause ethical doubts (e.g. animal genes in plants). The possible GM ingredients are clearly shown in the list of ingredients using the expression "modified by gene technology" or, in the future very likely, "genetically modified", e.g. "contains genetically modified soya".

The labelling applies, for example, to all packed GM foods. According to the current legislation on novel foods, highly processed raw materials which contain no traces of the modification form an exception to this (e.g. pure vegetable oil). The provisions also account for the so-called unintended or minute presence of GMOs. The threshold has been set at one per cent for each ingredient. There is also a specific statute on additives, which entered into force in April 2000.

Control of GM products

The utilisation of gene technology imposes new requirements especially for the development of the control systems. This calls for well coordinated cooperation between the authorities and commitment of the whole food chain. Thus, for example, the assessment of the environmental and health impacts of GMOs utilised in agriculture must be done in cooperation between the agriculture and forestry, environmental and health administration on both national and the EU level. According to the legislation on gene technology, the Ministry of Agriculture and Forestry is responsible for the general steering of the compliance with the inspection and control operations in its own administrative sector. Genetically modified seeds for sowing, planting material, forest reproductive material, pesticides and feedingstuffs are controlled by the Plant Production Inspection Centre KTTK, assisted by the Finnish Customs. The local control authorities are the Employment and Economic Development Centres under the steering of the Plant Production Inspection Centre KTTK. The KTTK is subject to the performance guidance of the Ministry of Agriculture and Forestry and it draws up annual control plans for different fields. The control of GM foods is steered by the National Food Agency. Food control is carried out in practice by the authorities responsible for food control in the municipalities and provinces and the Finnish Customs. Genetically modified game animals and fish are subject to direct control of the Ministry. Locally the control is carried out by the Employment and Economic Development Centres.

The responsibility for the control of medicines manufactured by means of gene technology, such as proteins produced by means of recombination DNA technology, gene therapy, GM vaccines and medicines for humans or animals produced in genetically modified animals or plants, is divided between several authorities. The National Agency for Medicines is

responsible for inspections, scientific advice and clinical research on medicines, the Board for Gene Technology manages the issues relating to the contained use of GMOs and their release to the environment and the impacts of this, and the European Medicines Agency EMEA is responsible for the licences to sell GM products.

Safety assessment in product approval

An operator who applies for a licence for marketing a GM product within the Community in accordance with Directive 2001/18/EC is obliged to draw up a risk assessment of the environmental impacts involved. The notification, together with the risk assessment, is first inspected by the competent authority in the Member State to whom the notification was submitted. After this the notification is sent to the competent authorities of the other Member States who verify, for example, the validity of the risk assessment. In Finland the competent authority referred to in the directive is the Board for Gene Technology, which requests statements from the expert authority or institute defined in the legislation and selected case by case. The Commission requests a statement on the risks relating to the product from the relevant Scientific Committees.

According to Community Regulation on novel foods (258/97/EC), a safety assessment must be drawn up on novel foods concerning the use of the products as food, including GM products introduced to food use. The first safety assessment is prepared by the competent authority of the Member State where the application was submitted. After this the report of the first assessment is sent for inspection to the competent authorities of the other Member States who may present their objections. In Finland the first assessment is made by the Novel Food Board, which consists of the scientific experts in the field. If any objections are presented the Commission requests a statement on the safety of the product on the basis of these from its own Scientific Committee.

According to the Regulation on genetically modified food and feed adopted in the Community in 2003 (EC No 1829/2003), in the future the Community approval for a GM food or feed is granted through an open and centralised procedure on the basis of scientific risk assessment carried out by the European Food Safety Authority (EFSA), provided that the criteria for approval are fulfilled. The EFSA will set up a network of experts consisting of the national risk assessment authorities. The approval is granted for 10 years and the approval may be renewed for further 10-year periods. The approved products are entered to the register of GM foods and feeds, together with information on the product, studies made to show the safety of the product and analysis methods. To increase the openness of the decision-making procedure a summary of the application documents and the statement of the European Food Safety Authority is made available to the public, who may present comments to the Commission within 30 days from the publication of the statement.

Coexistence of production types

The Community has issued guidelines to enable the coexistence of different production types (GM, conventional and organic production). Special attention is directed, for example, at the reproductive biology and relative fitness in the prevailing ecosystem, because these are significant in defining the necessary isolation distances and crop rotations. An extensive research report ordered by the Commission was published in spring 2002 and on 24 April the Commission invited a large number of NGOs to a round

table on the possibilities for the coexistence of GM and non-GM crops. The Commission is also preparing a directive on the control of GM seeds.

Compensation for damage

One important objective in the control of the use of genetically modified organisms is to prevent in advance the adverse impacts of the use of gene technology on the environment and health and property of the people. In addition to the prevention, rules are needed on the compensation of the possible damages.

Provisions applicable to (environmental) damages caused by the use of gene technology have been laid down at least in the Gene Technology Act (377/1995), Act on Compensation for Environmental Damage (737/1994), Product Liability Act (694/1990) and Tort Liability Act (412/1974). The Gene Technology Act and Act on Compensation for Environmental Damages apply mainly to the compensation for damage caused by contained use of genetically modified organisms and research and development experiments as well as release of GM products to the market.

Instead, the product Liability Act would apply to the compensation for damages caused by products containing GMOs to their users. Product liability does not concern the actual environmental damages, but the Act on Compensation for Environmental Damage may be applied for the part of these. In most cases the Tort Liability Act would apply to compensating for the "purity accidents" of independent users, such as farmers.

According to the Gene Technology Act, Act on Compensation for Environmental Damage and Product Liability Act, compensation for damage caused by the use of gene technology is founded on the principle of strong liability. We are concerned with strong liability when the liability for damage arises independent of the negligence of the originator. Instead, liability for damage under the Tort Liability Act is based of negligence. In the law of damages the liability covers damages caused by both deliberate act and reprehensible negligence.

The Community has prepared a proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage. The directive also covers possible environmental damages caused by the release of GMOs to the environment, to which the so-called severe liability applies. The Cartagena Protocol on Biosafety also contains an article according to which the parties to an agreement must decide in their first meeting how to draw up the international rules and procedures concerning the liability for damages caused by the movement of live genetically modified organisms across state borders and the compensation for these.

Ethical questions

Ethical values are highly important in the context of developing modern biotechnology and especially the applications where gene technology is used. In the fields of agriculture and food economy, environmental protection and healthcare in particular the biotechnology applications often involve new phenomena and ethical considerations, whose social impacts must be assessed in open discussions. The prevailing values may vary a great

deal in different cultures, and these need to be taken into account in the approval of the applications.

For the majority of the citizens biosciences and biotechnology are very difficult and abstract issues. Open discussion calls for balanced and objective information on the opportunities of the field, as well as the risks involved. The fifth Eurobarometer published in March 2003 which was concerned with the opinions and attitudes of the citizens of Europe relating to biotechnology and biosciences showed that 25 per cent of those who responded could not say whether biotechnology will improve the quality of life in the future. 44 per cent of the respondents had a positive view of the opportunities offered by biotechnology while 17 per cent had a negative position. There is a great deal of variation in the citizens' opinions concerning the different biotechnology applications. The utilisation of biotechnology in healthcare was considered acceptable, while the attitudes to the applications in agriculture and food production were quite reserved. However, in general the positions of Finnish consumers concerning the utilisation of both genetically modified crops and GM foods were quite positive.

To improve the consumer information and awareness, the Ministry of Education is preparing measures to improve the communication on scientific research and the information this produces to the citizens. The Neo Bio programme launched by the National Technology Agency of Finland includes Internet pages (in Finnish) where the public may present questions on biotechnology to the experts.

Expert bodies dealing with ethical questions are:

- National Advisory Board for Biotechnology
- Board for Gene Technology
- National Advisory Board on Health Care Ethics, which deals with the ethical questions relating to healthcare and the positions of patients
- National Advisory Board on Research Ethics, which deals with ethical questions relating to scientific research and promotes research ethics
- Cooperation Group for Laboratory Animal Sciences, which coordinates research using laboratory animals and training and other activities in the field as well as promotes the welfare of the laboratory animals and ethical principles in animal testing

Research in gene technology

Modern biotechnology research, including research in gene technology, is one of the key areas in scientific research in all industrialised countries and, for example, in the OECD it is very high on the list of priorities. A number of international and national research and financing programmes and research centres have been set up to promote research in biotechnology and molecular biology.

In the life sciences and biotechnology strategy proposed by the Commission creating sufficient conditions for research in life sciences and biotechnology and, through this, for the development of the sector and innovation is considered a central element in laying the foundation for Europe's competitiveness. Gene research has received considerable emphasis in the EU's framework programmes for research and in developing the European Research Area.

Research in life sciences is one of the seven thematic areas of the Sixth Framework Programme for Research (2003-2006), and 2.3 billion euros of the total budget of 17.5 billion of the programme is allocated for research in this sector. The objective is to improve the basic knowledge on the genomes of different organisms and utilise the results in the biotechnology of the health sector and in preventing and treatment of certain significant illnesses. Another objective is to promote the prevention of cancer and infectious diseases connected to poverty (aids, malaria, tuberculosis) through research.

The ethical questions relating to the study of human stem cells received considerable emphasis in the preparation of the Sixth Framework Programme for Research. No final agreement could be reached on the conditions and principles of financing stem cell research from Community funds and a Council statement according to which detailed rules for the approval procedure of research projects involving the use of stem cells were to be drafted by the end of 2003 was attached to the decision on the adoption of the special programme for biotechnology research. The report on stem cell research published by the Commission on 14 April 2003 presents an extensive assessment of the scientific, ethical, legal, social and economic aspects involved in the research in this field. The report laid the foundation for the discussion and decision making on these matters.

In Finland there is a solid basis for research and training in biotechnology. The Academy of Finland, National Technology Agency TEKES and Finnish National Fund for Research and Development SITRA laid the foundation for today's high-level biotechnology and gene technology expertise in the 1980s by investing strongly in the research in these. Strong inputs in these sectors continued throughout the 1990s and now every tenth of the EU's biotechnology enterprises are located in Finland.

There are five significant concentrations of biotechnology research and enterprises in Finland (Helsinki region, Turku, Kuopio, Oulu and Tampere). An international evaluation of Finland's whole biotechnology innovation network was carried out in 2002. The evaluation commended especially the good cooperation between the Academy of Finland and National Technology Agency in the financing of biotechnology research. The Ministry of Agriculture and Forestry was encouraged to increase research funding directed to biotechnology in its own sector, because this sector is very likely to benefit greatly from new research results in the next few years. The funding of gene technology research by the Ministry calls for careful consideration where the wishes and needs of all stakeholders are taken into account. According to the recommendations of the evaluation panel, the Ministry should aim for close cooperation with the other financiers. When directing agriculture to special production of, for example, medicines the cooperation with the medicine and process industries should be developed. The evaluation directed special attention at the transfer of the technology in the innovation chain from basic research all the way to the companies utilising the information. In the utilisation of the research results it must also be ensured that the legislation concerning the ownership of innovations supports their creation and utilisation. The Finnish legislation on patents has implemented the Directive of the European Parliament and of the Council 98/44/EC on the legal protection of biotechnological innovations.

In the near future the new gene research, especially gene mapping and genomics, will produce new information on the impacts of genes on the appearance of many important production and quality traits and the location of the genes regulating these in the genome.

This information can also be used in various ways in the conventional plant and animal breeding as well as e.g. in developing diagnostics for determining plant and animal diseases, pests, food or soil microbes or possible unintended occurrence of GM material. It is important to take the most recent achievements and trends of genetic research into account in the research strategies drawn up in the administrative sector of the Ministry of Agriculture and Forestry and to ensure that we are capable of utilising the scientific results without unnecessary delays in our own production also in this rapidly developing field.

One of the topics subject to perhaps the most intensive research efforts and wide ethical debate at the moment is animal cloning. In Finland, like in all EU countries, the cloning of humans is prohibited, but animal cloning is subject to the normal legislation concerning animal testing. In Finland there is research on the cloning of animals, but using this for breeding production animals is not a current matter.

Information obtained from gene research lays the foundation for responsible utilisation of gene technology in agriculture, food economy, game husbandry, fishery and forestry so that the technologies and products they yield cause no harm to the environment or human or animal health. The Ministry of Agriculture and Forestry participates in the research programme concerning the social, health and environmental impacts of gene technology initiated by the Academy of Finland in spring 2003 (ESGEMO). The information obtained from this is expected to benefit especially the assessment of the environmental risks of GMOs in the northern conditions. The research programme started in 2004 and it extends until 2007.

Research is also needed when developing new control and analysis methods for tracing GMOs. The proposal for Commission Regulation on GM foods and feeds contained a proposal for setting up a Community Reference Laboratory, whose tasks would include the testing and validation of analysis and identification methods. In autumn 2002 the Joint Research Centre of the Community (JRC) together with national reference laboratories for control set up the European network of GMO laboratories with the aim of evaluating and developing the sampling and analysis methods needed in the control of GM products. The Finnish organisations in this network are the Plant Production Inspection Centre KTTK, Customs Laboratory and the National Veterinary and Food Research Institute (EELA). The Plant Production Inspection Centre has put together a background group for preparing the network operations. This background group is open to all research and control institutions.

Gene technology research in the administrative sector is described in more detail in the Strategy for Biotechnology and Genetic Engineering of the Department of Agriculture completed in 2001, which is available on the Internet pages of the Ministry of Agriculture and Forestry. For the work on the Ministry's strategy special studies were made on gene technology research for the part of forestry and fishery.

Preparation of gene technology issues at the Ministry of Agriculture and Forestry and other ministries

The Gene Technology Act defines the official cooperation bodies where matters concerning GMOs are dealt with. According to the act, the competent authority making the decisions on the use of gene technology is the Board for Gene Technology, with representatives from the Ministry of Social Affairs and Health, Ministry of Trade and

Industry, Ministry of Agriculture and Forestry and Ministry of the Environment. There is also expertise on the ethical considerations in the board. According to the Gene Technology Decree, the Government appoints, on the submission of the Ministry of Social Affairs and Health, a National Advisory Board for Biotechnology for three years at a time. The tasks of the Advisory Board are to:

- 1) promote cooperation between the authorities, research and operators in dealing with gene technology issues;
- 2) follow and promote international cooperation in biotechnology;
- 3) follow the development concerning biotechnology and biotechnology research as well as health and environmental impacts of biotechnology;
- 4) develop and promote research, communication and training relating to biotechnology;
- 5) promote the consideration of ethical aspects of biotechnology; and
- 6) take care of other tasks concerning biotechnology as commissioned by the ministries.

Biotechnology and gene technology issues touch upon the administrative sectors of almost all ministries. The official preparation of the matters takes place in working groups subject to the ministry which is responsible for the matter, and the normal preparation procedure is followed in EU matters. Because the preparation of biotechnology issues is scattered to different ministries, the Government issued a resolution on the organisation of the coordination of biotechnology issues in the State administration on 4 October 2001. By the resolution a network of contact persons was set up, consisting of civil servants responsible for biotechnology issues from all ministries and the Prime Minister's Office. The network is coordinated by the Ministry of Trade and Industry, and the experts participate in the work of the network according to the need. The purpose of the network is to ensure the exchange of information and contacts between the administrative sectors in the preparation of biotechnology issues. The network does not make any decisions or substitute for the official preparation bodies.

In addition to the network, an unofficial ministerial working group was set up to deal with national and international issues which call for political decision making.

At the Ministry of Agriculture and Forestry the Department of Agriculture has the main responsibility for the overall coordination of biotechnology issues. The other departments are responsible for the gene technology legislation, control, research and issues relating to these in their own specific sectors.

At the Ministry there is an unofficial, cross-sectoral GM control working group steered by the Department of Food and Health, with representatives from the key civil servants and authorities dealing with issues relating to GM control from the administrative sector, the Board for Gene Technology and environmental administration. The task of the group is to follow the development of GM control and exchange information on measures that have been taken or incidents which call for action in the national GM control. The group also harmonises the control programmes applied in different sectors.

The objective of the Gene Technology Strategy of the Ministry of Agriculture and Forestry is to allow the utilisation of the new gene technology methods in the administrative sector of the Ministry in a safe and ethical manner. This must be based on sustainable use of natural resources, safety and high quality of the products, ethics, openness, efficient control, development and maintenance of research and expertise and possibilities to use the new methods. Extensive utilisation of gene technology in agriculture, forestry, fishery

and food production depends on the consumer approval. What is needed is relevant, open and balanced consumer information on the benefits and possible disadvantages relating to these technologies.

In carrying out its tasks the Ministry of Agriculture and Forestry and the whole administrative sector take positions on gene technology and its use as well as approval and control of products manufactured by means of this technology in agriculture and the food sector in various contexts, including the planning of policies, preparation of legislation (international, EU and national), inspection and control operations and research. Important fields in this respect are plant and animal breeding, quality of agricultural inputs and foodstuffs and its verification by means of control, organic production and steering of research. In certain other sectors governed by the Ministry, such as forestry and fishery, the role of gene technology issues will be increasingly important in the future.

The Gene Technology Strategy of the Ministry of Agriculture and Forestry constitutes the common guideline of the Ministry in dealing with gene technology issues. The positions in the different tasks carried out in the administrative sector must follow the same basic guidelines and principles and the grounds and arguments used must also be uniform. The development of gene technology is extremely rapid, which is why the strategy covers only the next few years 2003-2007. After this the strategy will be revised as considered appropriate.

ACTION PROGRAMME

General administrative measures

Gene technology is one of the life sciences, and it is one of the most strictly controlled and regulated technologies. However, the control in Europe is highly complex and the decision making is somewhat unclear, which slows down and may even prevent the utilisation of the research results. In Finland the horizontal legislation on gene technology, the Gene Technology Act and Gene Technology Decree, are the competence of the Ministry of Social Affairs and Health. Further provisions on gene technology are laid down in different sectors, and these are the responsibility of the relevant ministries.

Clear, transparent and predictable regulation and related control constitute an essential condition for competitiveness. The working group considers it important that in the preparation of Community legislation on the gene technology sector a proper balance is found between the safety requirements and approval for the market. Product approval must primarily be based on independent scientific risk assessment, while the precautionary principle must be taken into account in risk management. The safety of GM products produced in agriculture, food industry, game husbandry, fishery and forestry to humans, animals and the environment must be ensured through close cooperation in the preparation and implementation of gene technology legislation and control between different authorities. Consumers' right of choice must be taken care of through proper labelling of the products. It must also be ensured that the legislation does not prevent the market access of new products produced by means of gene technologies or create unnecessary administrative burden or obstacles to the enterprises.

The Community legislation regulating the utilisation of gene technology places great additional demands for control. However, the Community legislation should support the control work of the authorities so that the limited resources are directed to the control of relevant matters.

The working group also stressed that research and product development in the sector must be ensured by means of sufficient funding. The results of the evaluation of international biotechnology innovation networks completed in December 2002 and the strategies of the research institutes representing different sectors must be taken into account in directing the gene technology research in the administrative sector. International cooperation and cooperation with the Academy of Finland and National Technology Agency should be stressed in research funding.

Environmental impacts

The environmental impacts of genetically modified organisms have been studied for quite a long time. For example, the Commission of the European Community has funded the study of the safety of GMOs for over 15 years. The report published on this presents a summary of 81 projects carried out by over 400 research groups by means of EU funding totalling almost 70 million euros. The report is available on the Internet at <http://europa.eu.int/comm/research/quality-of-life/gmo/index.html>. The special studies attached to the Gene Technology Strategy of the Ministry of Agriculture and Forestry also deal with the possible environmental impacts of GMOs.

The environmental impacts of GMOs should always be thoroughly studied before authorisation is granted for their use. Appropriate special measures and farming practices must be applied to ensure that, for example, medicinal or technical products intended for non-food use do not end up in the food chain at any stage. The potential risks of GMOs must be assessed case by case and the development of GM products must take place step-by-step and in accordance with the precautionary principle. This is also the foundation adopted in the main principles, objectives and measures of the Gene Technology Strategy of the Ministry of Agriculture and Forestry.

When assessing the environmental impacts of gene technology it must be borne in mind that gene technology can also be utilised in the sectors governed by the Ministry of Agriculture and Forestry to develop more eco-efficient and environmentally friendly production practices, inputs and processes. There are already indications of such positive environmental impacts. In the United States the use of genetically modified soya has doubled the area cultivated without ploughing, which has been observed to reduce erosion and increase the biodiversity of arable land. The use of Bt cotton in China has reduced the pesticide sprayings to a fraction of the earlier levels and made it possible to no longer use toxic organophosphates and organochlorins. A pig bred in Canada is capable of receiving the phosphorus it needs from the phytase in plants, which means that there is no need to add phosphorus to feedingstuffs and the raising of pigs does not contaminate waters through phosphorus emissions. Gene technology is also utilised to convert processing technology into more environmentally friendly direction. Gene technology is important in improving the properties and production of enzymes to make them applicable to industrial use. Over 3,000 enzymes are being used in industrial processes in, for example, foodstuffs, washing agents, bleaching of paper, textiles, feedingstuffs and waste treatment. Applications are used in forest industry, for example, in bleaching of pulp. Environmental advantages can also be derived by improving the properties of the wood raw material (e.g. reducing the amount of lignin in pulpwood).

Proposals

The working group proposes that

- 1) A working group is set up for the coordination of gene technology issues within the Ministry of Agriculture and Forestry, with representatives from the different sectors governed by the Ministry. The task of the working group is to draw up a special communication strategy in cooperation with the Press and Information Unit on how correct and sufficient information on the utilisation of gene technology and its advantages and disadvantages is communicated to the citizens and how the Ministry takes an active part in the public discussion on the matter, for example, together with the National Advisory Board for Biotechnology. The working group follows the international and national trends in gene technology and takes positions and initiatives in matters concerning the administrative sector. This coordination group would also follow the realisation of the proposals presented below. If necessary, the working group will hear the representatives of relevant organisations, including NGOs, and ad-hoc working groups may be set up on a case-by-case basis. The work of the group can be followed on the Internet pages of the Ministry.
- 2) The Ministry prepares a proposal concerning the organisation of the control of the whole production chain of GM production animals by the end of 2004.

- 3) The activity of the GM control group for the food chain steered by the Department of Food and Health becomes an established and regular practice.
- 4) The need for research, legislation and instructions is examined to provide for the coexistence of different types of production (conventional agriculture, organic production, GM production). The objectives of the National Plant Genetic Resources Programme and the corresponding programme for animal genetic resources are taken into account in the coexistence provision to ensure the on-farm protection and sustainable use of indigenous plants and animal breeds.
- 5) To clarify the gene technology issues and the related needs, the Agrifood Research Finland MTT draws up a proposal for a gene technology research strategy of the Centre to the Ministry of Agriculture and Forestry during 2004. When preparing the strategy the Agrifood Research Finland hears the other relevant research institutes and universities.
- 6) To find out the most important research needs relating to forestry the Finnish Forest Research Institute METLA draws up a proposal for a gene technology research strategy for forestry during 2004.
- 7) The resourcing of the biotechnology research is studied as set down in the results of the international evaluation of Finland's biotechnology innovation network. The research in the priority areas raised in the gene technology research strategies of the Agrifood Research Finland and Finnish Forest Research Institute is reinforced through both performance guidance and uncommitted research funding. The need for increasing the resources available for gene technology research is also examined in this context.
- 8) The Plant Production Inspection Centre KTTK draws up a control programme concerning genetically modified seeds and feedingstuffs during 2003. During the same year the Plant Production Inspection Centre, National Food Agency EVI and National Veterinary and Food Research Institute EELA together with the Ministry of Agriculture and Forestry draw up a programme concerning the control of genetically modified products in the administrative sector (seeds, feedingstuffs, foodstuffs, microorganisms). In the unofficial GM control working group steered by the Ministry of Agriculture and Forestry it was agreed that a survey of how the GM products are being controlled in Finland is drawn up together with the other control authorities (Finnish Environment Institute SYKE, National Product Control Agency for Welfare and Health) on the basis of surveys made in different administrative sectors. The Plant Production Inspection Centre coordinates the national background group preparing the activity of the European Network of GMO Laboratories ENGL. All interested parties are welcome to participate in the work of the background group.

Detailed measures for different sectors

Agriculture

Plant production

Background

Because of the northern climate conditions prevailing in Finland the productivity of agriculture cannot reach the same level as in the competing countries. The quantity and quality of the crops can be improved, for example, by increasing their tolerance to cold and resistance to diseases and pests. Improving the resistance of plants to diseases and pests makes it possible to reduce the use of pesticides, which has positive impacts on the environment and the quality of the final products. The breeding of new quality characteristics and development of value-added products may benefit the farmers, small and medium-sized enterprises and consumers in international competition.

Objectives

In Finland the conditions have been created for economically and environmentally sustainable cultivation of crops and horticultural production which produce safe and high-quality raw material (including non-food) for the industry. In this work the applications offered by the new technologies have been taken into account in developing fertilisers and pesticides, improving the diagnostics of pests, soil remediation, and manufacturing medicines and therapeutic proteins by means of plants. Raw material produced in Finland is internationally competitive and we have certain special products, some of which may have been produced by means of gene technology, based on high expertise which can be exported successfully. Control and cultivation techniques ensure the operating conditions of different types of production (GM crop production, conventional production and organic production). The possible environmental impacts of GM production are always assessed in a comprehensive way and in the long term, i.e. economic profit in the short term may not compromise the environment or the domestic production of safe, high-quality foodstuffs. The advantage/disadvantage analysis also takes account of the impacts of the cultivation of GM varieties on the quantities of plant protection substances and socio-economic impacts, such as the possible growing dependence of farmers on the seed producers. Efficient labelling and traceability systems, utilising e.g. the geographic information system, ensure the safety of the products and consumer choice at all stages of the production chain. Genetic information obtained from basic research is rapidly taken advantage of in applied research and plant breeding to serve all types of production. The research-extension-farmer chain brings the information on new cultivation opportunities, including the cultivation of GM varieties, rapidly to the farmers as well as supports and steers the production.

Measures and their implementation timetable

- implementation of provisions and agreements concerning GMOs and use and marketing of products manufactured from these, participation in their development in relevant bodies *continuous*

- ensuring the safety of GM products intended for food, feed and plant production to humans, animals and the environment through participation in the work of the Board for Gene Technology and European Food Safety Authority (EFSA) *continuous*
- development of the control of GM products, taking into account especially the upcoming legislation and development of analysis methods, as well as through closer cooperation between control organisations *continuous*
- selection of key areas with special strengths to which the plant breeding investments should be directed (e.g. certain GM cereal crops or processes) and supporting research relating to these, taking account of the expectations of farmers, consumers and companies *2004*
- supporting research based on gene technology which aims to develop more rapid, accurate and efficient methods to identify plant pests (fungi, bacterial and viral diseases, pest insects) *continuous*
- extension organisations are steered to active follow-up of development work and research results relating to gene technology and to communicating new information rapidly to the farmers in order to achieve the possible competitive advantage. *continuous*

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Plant Production Inspection Centre KTTK, Agrifood Research Finland MTT.

Other cooperation partners

Finnish Environment Institute SYKE, Board for Gene Technology, Ministry of Social Affairs and Health, Ministry of the Environment, Ministry of Trade and Industry, Novel Foods Board, agricultural advisory organisations, Central Union of Agricultural Producers and Forest Owners, universities, National Agency for Medicines.

Livestock production

Animal nutrition

Background

In the EU feed materials and feed additives produced by means of special production technologies are authorised for marketing through the prior approval procedure. This procedure, together with the safety and quality requirements as well as control, ensures the safety of products used in animal nutrition to humans, animals and the environment.

In feed additives used in animal nutrition gene technology has been applied for quite a long time to improve the microbes which produce enzymes, antibiotics and amino acids. Certain GM crops used for animal nutrition have also been authorised to the EU market (soya, maize, rape), but these are not yet available in Finland.

Objectives

To ensure the quality of animal production and foodstuffs derived from animals, the feed products available on the market used for animal nutrition are safe, competitive and of high quality. The whole feed production chain is open and traceable and the control is sufficient, efficient and equitable. Feedingstuffs are manufactured according to the needs of the

different types of production (GM, conventional and organic production). In feed production special attention is directed at preventing the unintended occurrence of GM material. Gene technology is utilised in the development of the control methods and to improve the nutritional properties and quality of feedingstuffs and foodstuffs of animal origin (e.g. amino acid composition, fatty acid composition).

As the markets of GM feed products develop, Finland will be capable of utilising gene technology to produce feedingstuffs with even higher nutritional quality, which are appropriately labelled to ensure the availability of information and allow the producers to make their choices. Genetic information obtained from basic research is rapidly utilised in applied research and production of feed products.

Measures and their implementation timetable

- ensuring the safety of GM feeds to humans, animals and the environment and implementation of provisions and agreements concerning the use and marketing of GM feeds and their raw materials, participation in their development in relevant bodies
continuous
- development of the existing bodies and expert networks to function as support to the safety analyses by the EFSA in the assessment of novel feeds and feed additives
2004
- development of the control of GM products, taking into account especially the upcoming legislation and development of analysis methods, as well as through closer cooperation between control organisations
continuous
- supporting gene technology research which aims to develop new, more rapid, accurate and economical methods to ensure the safety and quality of feedingstuffs and for the control needs
continuous
- increased cooperation with enterprises in allocating the existing resources in gene technology research to the development of the quality and nutritional properties of feedingstuffs and through this to the improvement of foodstuffs of animal origin.
continuous

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Plant Production Inspection Centre KTTK, Agrifood Research Finland MTT, National Veterinary and Food Research Institute.

Other cooperation partners

Finnish Environment Institute SYKE, Customs Laboratory, Board for Gene Technology, Ministry of Social Affairs and Health, Ministry of the Environment, agricultural advisory organisations, Central Union of Agricultural Producers and Forest Owners, universities, National Agency for Medicines.

Animal breeding

Background

The first genetically modified production animals, fast-growing salmonids, will probably enter commercial production in the world in a few years. In the near future no other GM production animals are likely to be introduced to food production. However, genetically modified rabbits, goats, pigs and sheep have already been developed for medicinal

purposes to produce treatment proteins for humans which cannot be produced by means of genetically modified microbes, as well as medicinal substances, cell therapy and possibly transplantation products. Production animals may also be bred to utilise the nutrients in feed more efficiently, which reduces the negative environmental impacts of livestock production. When planning the development of genetically modified production animals or their use for production, special attention should be directed at the ethical obligations, challenges and limitations involved. Provisions on the ethical treatment of GM production animals are laid down in the Gene Technology Act and Animal Welfare Act. At present no GM animals are used for production purposes in Finland.

Objectives

The objective is economically profitable and environmentally sustainable livestock production which also promotes the welfare of animals. Livestock production is founded on long-term animal breeding efforts to achieve healthy and internationally competitive animal material. New special products are being introduced, such as functional foods and foodstuffs intended for special consumer groups. The health, welfare, productivity, fertility and resistance of production animals improve and the environmental burden of livestock production decreases. Breeding populations are genetically diverse. Genetic information obtained from basic research is rapidly utilised in applied research and animal breeding.

Measures and their implementation timetable

- so-called Nordic breeding profile where attention is directed to the health and structural properties as well as the production properties continues to be taken into account in the breeding objectives by means of performance guidance *continuous*
- international cooperation in the gene mapping of properties relating to the yield and health of production animals is continued *continuous*
- supporting ethical and environmentally sustainable gene technology research aimed at healthier and more productive production animals which cause less burden to the environment on the basis of the strategy of the Agrifood Research Finland MTT *continuous*
- study of the advantages and disadvantages relating to the medicinal or food production of genetically modified production animals
- extension organisations are steered to active follow-up of development work and research results relating to gene technology and to communicating new information rapidly to the farmers in order to achieve the possible competitive advantage. *continuous*

Implementers in the administrative sector

Ministry of Agriculture and Forestry, provincial veterinary officers, municipal veterinarians, Agrifood Research Finland MTT.

Other cooperation partners

Customs Laboratory, Board for Gene Technology, Ministry of the Environment, animal breeding and advisory organisations, universities, National Agency for Medicines.

Forestry

Background

Compared to agriculture and food production, Finnish forestry has so far been lagging behind in gene technology applications. The most realistic first-stage gene technology applications relate to the development of traditional forest breeding based on selection. The most significant special feature in forest breeding, as well as greatest problem compared to other plant or animal breeding, is the longevity of the organism to be bred. The long generation interval and testing periods to observe the economically significant properties of trees restrict the progress of breeding and transfer of the results to practice. Modern gene technology offers great promises to speeding up forest breeding and increased precision. Among the domestic species the biotechnology and gene technology applications concerning aspen and birch are the most advanced. Of the coniferous trees spruce has proven an easier species in terms of new technologies than pine. The safety system constructed around gene technology restricts the research of applications to forest trees, because all testing must be carried out in the short term, in practice with young, non-flowering trees. This is why the research of, for example, the activity and impacts of genes transferred to trees is very difficult.

Objectives

Finnish gene technology research and expertise relating to forest trees stays on a high international level and the potential for gene technology applications in forestry develops. In the first stage the opportunities offered by the new technology are utilised for speeding up forest breeding and improving its efficiency. In the research and use of genetically modified materials it is ensured that no uncontrolled release of GMOs to the environment takes place. The environmental impacts of genetically modified forest reproductive material are assessed and only applications which have been proven safe are introduced to use. On the other hand, no unnecessary obstacles to the research and use of new technologies are raised. Research, control and steering ensure that the gene technology applications are in harmony with the principles of ecological, economic and social sustainability of forestry.

Measures and their implementation timetable

- promoting the utilisation of the opportunities offered by the new technologies in forestry by supporting other technologies needed for the utilisation of gene technology, especially research and development of biotechnological vegetative reproduction and clone forestry
continuous
- supporting the gene mapping of organisms important for forestry, development of marker gene and gene transfer technologies and technologies to prevent flowering and research of the resistance and quality properties of trees
continuous
- study of whether the permit and control procedures for field experiments in forest tree research can be developed so that the work of the authorities and researchers would be easier and clearer than at present
2004
- preparing instructions for research and utilisation of genetically modified forest trees to reduce the ecological risks
2005

- participation in the research programme of the Academy of Finland (ESGEMO) concerning the study of the environmental impacts of genetically modified organisms
2004-2007
- ensuring sufficient research services, expertise and operative resources for efficient implementation of official control by means of performance guidance, *continuous*

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Finnish Forest Research Institute METLA, Plant Production Inspection Centre KTTK, Metsähallitus.

Other cooperation partners

Finnish Environment Institute SYKE, Customs Laboratory, Board for Gene Technology, Ministry of Social Affairs and Health, Ministry of the Environment, Central Union of Agricultural Producers and Forest Owners, universities, Finnish Forest Industries Federation.

Fishery

Background

The growing need for fish raw material and too efficient fishing relative to the fish resources have led to a decline in the catches of commercial fish from the sea. The decline in wild fish populations causes increased pressures to aquaculture, whose role as a producer of high-quality, safe and wholesome foodstuffs will be growing. Globally aquaculture is one of the most rapidly growing food production sectors. In Finland there are also opportunities for increasing the production of fish farming and diversifying the range of species used in this. To reach the growth objectives set for aquaculture, research and development efforts need to be directed at the efficiency of the production, new species for farming and environmental technologies so that the growth of the sectors rests on an ecologically, economically and socially sustainable foundation.

The methods of gene technology and molecular biology offer new opportunities to develop the farming of fish and crayfish through basic and applied research: these can be applied, for example, to the study of the development of fish embryos, muscle growth, growth rate, metabolism and immunology. New methods may also support the selection breeding of fish for farming purposes. Health considerations, such as the resistance of fish to pathogens and stress caused by environmental factors, should also be taken into account in the genetic breeding of fish species. Further topics for which gene technology may have new methods to offer are feed research and development of feedingstuffs, genetic breeding of fish and disease diagnostics and development of vaccines, as well as controlling the environmental impacts of aquaculture.

The first time we will be dealing with genetically modified species and products manufactured from these is in connection with the import of feedingstuffs intended for fish farming and aquaculture.

Objectives

The use of gene technology in fish and crayfish husbandry is promoted, taking into account the issues relating to environmental protection and controlling the potential environmental risks as well as the attitudes and wishes of the consumers. The objective is that we possess sufficient preparedness in terms of both information and operations for the follow-up of the development in the field, development and utilisation of the technologies and assessment of their impacts.

Measures and their implementation timetable

- survey and prioritisation of the most important future research needs in cooperation with the researchers in the field 2003
- launching the assessment of the positive and negative environmental impacts and ecological risks of gene technology applications in aquaculture 2004
- development of safe production methods, especially to prevent negative environmental impacts continuous
- launching an assessment concerning selection breeding and transgenic fish breeding 2005
- launching the collection of a gene bank of the most important fish species for aquaculture (rainbow trout, whitefish, crayfish) and certain other fish species (e.g. trout, arctic charr). 2004

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Finnish Game and Fisheries Research Institute RKTL, Agrifood Research Finland MTT, National Veterinary and Food Research Institute EELA.

Other cooperation partners

Finnish Environment Institute SYKE, Board for Gene Technology, Ministry of Social Affairs and Health, Ministry of the Environment, Institute of Applied Biotechnology, universities, National Agency for Medicines.

Game husbandry

Background

In Europe sylvatic (forest) rabies in wild predators has been prevented by means of rabies vaccine baits spread in forests. On the EU market there is one live genetically modified bait rabies vaccine, which has been tested with foxes and was approved for open use in the Community under Directive 90/220/EEC in 1993. Finland has prevented rabies by means of vaccine baits since 1988, but the vaccine used is not genetically modified but it is a substance based on weakened rabies virus. There is sufficient evidence for its efficacy also in raccoon dogs, which are important in the Finnish conditions.

Objectives

In game husbandry gene technology applications may be needed in Finland mainly for the prevention of zoonoses and other serious animal diseases and in the study of game resources.

Measures and their implementation timetable

- follow-up of the development of gene technology applications and possible impacts on game husbandry *continuous*
- development of the application of gene technology methods in the study of game populations. *continuous*

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Finnish Game and Fisheries Research Institute RKTL, National Veterinary and Food Research Institute EELA.

Other cooperation partners

Finnish Environment Institute SYKE, Board for Gene Technology, Ministry of the Environment, universities, National Agency for Medicines.

Food safety and quality

Background

The supply and quality of foodstuffs are on a very high level in Finland, thanks to the development of the production methods of agriculture and food economy and plant and animal breeding. The safety and other quality aspects of agricultural production inputs used in the production of foodstuffs and their raw materials as well as the production environment have also been ensured for a long time through legislation and control (prior approval procedure, quality and safety requirements, quality assurance).

The development of genetic information and gene technology in the last quarter of the 20th century led to more efficient and accurate breeding of especially microbes and plants, and since 1996, for example, soya, maize, rape and cotton varieties bred by means of gene technology have been introduced to extensive cultivation in several countries. In horticulture genetically modified new varieties have been developed from e.g. tomato, melon and cucumber. In Finland no genetically modified plant varieties are yet being used for production purposes.

Objectives

The foodstuffs available on the market are safe and their quality is high independent of the production technology and location of the production. The domestic food economy is internationally competitive. The production chains of foodstuffs are transparent and traceable and the origin, type of production, composition and quality of the products can be shown in a reliable way. GM foods are appropriately labelled. The control of foodstuffs and their production chains is efficient, sufficient and equitable. As the markets for genetically

modified foodstuffs develop, Finland has the preparedness to apply gene technology to produce modified foodstuffs of even higher quality which are clearly labelled.

Measures and their implementation timetable

- implementation of the Community legislation on GM products and amending the national legislation in accordance with the adopted Community legislation *continuous*
- steering the development of safe and appropriate GM products by improving the efficiency of the differentiation of the approval procedure based on risk assessment according to the type of application in the Community legislation and in the activity of the European Food Safety Authority (EFSA) *2005*
- development of the existing bodies and networks of experts to support the safety analyses of EFSA in the assessment of GM foods *2004*
- development of the control of GM products with special emphasis on the future legislation and development of analysis methods and through closer cooperation between control organisations *continuous*
- supporting gene technology research within the available resources and through performance guidance in order to develop new, more rapid, precise and economical methods for ensuring the hygienic quality of foodstuffs (various kinds of diagnostic methods to detect bacterial or viral contaminations) *continuous*
- concentrating resources to the development of the quality and health impacts of the products on the basis of the gene technology research strategy of the Agrifood Research Finland MTT (special products, functional foods, probiotics, etc.). *2004 -*

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Plant Production Inspection Centre KTTK, Agrifood Research Finland MTT, National Veterinary and Food Research Institute EELA, Finnish Game and Fisheries Research Institute RKTL.

Other cooperation partners

National Food Agency EVI, Board for Gene Technology, Ministry of Social Affairs and Health, Ministry of the Environment, Ministry of Trade and Industry, European Food Safety Authority EFSA, universities.

Consumer aspects

Background

Different consumer groups have very different kinds of attitudes to food and GM products. Consumer choices are influenced by the price, production method and origin of food, ethical considerations and environmental impacts. Some consumers have special requirements concerning the wholesomeness of food, while some are against the use of gene technology in food production. The consumer organisations stress the significance of these consumer views called "the other justifiable factors" and demand that the role of consumers should be extended from objects under the protection of the authorities into active and influential actors of the food chain. Food production must serve all consumer groups.

Objectives

New kinds of foodstuffs and other products of better properties and price-quality ratio are developed for the consumers. The consumer may rely that the foodstuffs available on the market and their raw materials are safe and of high quality. Consumers have the possibility to select the products their wish to buy. Different consumer groups, such as persons with allergies or following a special diet due to health, ethical or religious reasons, are taken into account in the food production chain. Consumers are confident that the public sector takes care of the control of the production, processing, marketing and labelling of GM, conventional and organic products. Consumers take an active part in the discussion on the utilisation of GMOs in the administrative sector of the Ministry of Agriculture and Forestry and follow the research and approval of the products for marketing, for example, through the notifications concerning deliberate release on the WWW pages of the Board for Gene Technology. Consumers must also be active in taking advantage of the opportunity to be heard when GMOs are being approved for deliberate release.

Measures and their implementation timetable

- consumer expectations and demands concerning safe and ethical production practices and high quality are taken into account in issues relating to the development and use of GMOs in the administrative sector of the Ministry *continuous*
- legislation, control and cooperation through the whole food chain ensure that the products, including GM products, are safe and of high quality as well as appropriately labelled to provide sufficient information to the consumers and producers to allow them to make their choices *continuous*
- active participation in the discussion on the utilisation of gene technology and development of communication on GM products and activities of the administration and food chain relating to these *continuous*
- encouraging researchers to participate in public discussion on genetic modification and to present the real, scientifically proven advantages and disadvantages which genetic modification may have to agriculture and food economy, consumers and the environment *continuous*
- scientific consumer study is taken advantage of to find out the consumer opinions concerning GM foods and to improve consumer information. *2004 -*

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Plant Production Inspection Centre KTTK, Agrifood Research Finland MTT, National Veterinary and Food Research Institute EELA.

Other cooperation partners

Board for Gene Technology, National Advisory Board for Biotechnology, Ministry of Social Affairs and Health, Ministry of Trade and Industry, consumer organisations, universities, research institutes.

Environmental impacts

Background

The positive and negative impacts of the use of production organisms (plant, animal, microbe) on the environment depend on the properties and species of the organism, methods of use and the environment where the use takes place. This means that the benefits and disadvantages of the use of GMOs on the environment must be assessed scientifically and case by case, also taking account of the methods for plant and animal production and processing which are currently being used. For the part of GM products it must be ensured that the objectives of the national programmes concerning the plant and animal genetic resources are realised. In forestry the fact that most of the trees are wind-pollinated and production mainly takes place in forest areas calls for special attention. Similarly, thorough environmental impact assessment is needed for the use of gene technology in fish breeding and aquaculture. The assessment of the environmental risks due to deliberate release of GMOs in field tests takes place nationally, while market access is subject to an assessment on the EU level. Information on any field tests must also be communicated to the other Member States. Through this all kinds of release of GMOs to the environment is subject to critical examination of several different research institutes, which ensures that the authorisations are granted on the basis of all possible scientific information available. Lack of information and uncertainty which may restrict the environmental impact assessment are taken into account in risk management in accordance with the precautionary principle.

Objectives

Thanks to risk assessments founded on scientific information the environmental impacts of GMOs and processes used in agriculture and food sector and their impacts on forest and water ecosystems are known. Uncontrolled release of GMOs to the environment has been prevented. GM applications which improve the state of the environment are developed.

Measures and their implementation timetable

- ensuring that in the research and use (contained use and deliberate release) of GMOs the authorisation is based on scientific risk assessment and management *continuous*
- assessing case by case the magnitude of the risk that GMOs or modified genes may spread to the environment in Finland and be introduced in cultivated or natural populations and whether GMOs or modified genes may have harmful impacts in these *continuous*
- supporting research relating to risk assessment and risk management needed particularly for the GM applications to be developed in Finland especially for the part of the special properties and ecological impacts of different groups of living organisms (microorganisms, different groups of plants and animals) *continuous*
- studying the possibilities to use different production GMOs to reducing negative environmental impacts of agriculture, such as fertiliser emissions and erosion *2004*
- studying the environmental impacts of the cultivation recommendations of herbicide/pesticide resistant genetically modified crops *2004*

- studying the total impacts of genetically modified foodstuffs and feedingstuffs on environmental balances on the basis of their life cycle analysis. 2004

Implementers in the administrative sector

Ministry of Agriculture and Forestry, Plant Production Inspection Centre KTTK, Agrifood Research Finland MTT, Finnish Forest Research Institute METLA, Finnish Game and Fisheries Research Institute RKTL.

Other cooperation partners

Finnish Environment Institute SYKE, Board for Gene Technology, Ministry of the Environment, universities, Technical Research Centre of Finland VTT.

Annex 1.

Background and special studies drawn up in connection with the strategy process

1. Special studies made for the Strategy for Biotechnology and Genetic Engineering in Agriculture (in Finnish):

- Bio- ja geeniteknologian eettiset kysymykset (Ethical questions in biotechnology and gene technology), Veikko Launis, University of Turku
- Geenitekniikan ja muuntogeenisen ruuan taloudelliset vaikutukset Suomen elintarvikeketjussa (Economic impacts of gene technology and genetically modified food in Finnish food chain), Meri Virolainen and Jyrki Niemi, Agrifood Research Finland MTT
- Siirtogeeniset tuotantoeläimet ja niiden mahdolliset ympäristövaikutukset Suomessa (Transgenic production animals and their potential environmental impacts in Finland), Johanna Vilkki, Tiina Pitkänen, Juha Kantanen and Kari Elo, Agrifood Research Finland MTT

2. Special studies made for the Gene Technology Strategy and Action Plan of the Ministry of Agriculture and Forestry for 2003-2007 (in Finnish):

- Siirtogeenisten metsäpuiden populaatiogenetiikka (Population genetics of transgenic forest trees), Helmi Kuittinen, University of Oulu
- Metsäpuilla tehtävä bio- ja geenitekniikan tutkimus (Biotechnology and gene technology research on forest trees) Tuija Aronen, Finnish Forest Research Institute METLA
- Bio- ja geenitekniikan mahdollisuudet metsäpuiden jalostuksessa sekä jalostetun aineiston tuotannossa ja metsätaloukskäytössä (Opportunities offered by biotechnology and gene technology in forest tree breeding as well as production and forestry use of bred material) Jouni Mikola, Finnish Forest Research Institute METLA
- Vesiviljelyn biotekniikka - katsaus tutkimuksen suuntaviivoihin Suomessa (Biotechnology in aquaculture - a review of research in Finland), Hannu Mölsä, University of Kuopio.

Annex 2.

Legislation and international agreements concerning gene technology

Community legislation

Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms

Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Council Directive 98/95/EC amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed and on the common catalogue of varieties of agricultural plant species

Council Directive 1999/105/EC on the marketing of forest reproductive material

Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs

Council Regulation (EC) No 1804/1999 supplementing Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production

Council Directive 82/471/EEC concerning certain products used in animal nutrition

Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients

Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms

Directive 2004/35/EC of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage

Finnish legislation

Gene Technology Act (377/1995, as amended 490/2000)

Gene Technology Decree (821/1995, as amended 491/2000)

Seed Trade Act (728/2000)

Act on Trade in Forest Reproductive Material (241/2000)

Decree on Forest Reproductive Material (1055/2002)

Pesticides Act (1969/327, last amended 402/2002)

Feedingstuffs Act (396/1998)

Decision of the Ministry of Agriculture and Forestry on feed additives (125/1998)

International agreements

Cartagena Protocol on Biosafety of the Convention on Biological Diversity (78/1994)

UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention 1998)