# Gene Technology Strategy and Action Programme of the Ministry of Agriculture and Forestry 2009-2013

Helsinki 2009

Working Group Memorandum 2009:6, Ministry of Agriculture and Forestry, Finland

# To the Minister of Agriculture and Forestry

The fast development of gene technology during the last decade has brought new challenges also for the Finnish agriculture and forestry administration. Government officials within the Ministry of Agriculture and Forestry and its subordinate administration are required to adopt an official position regarding questions related to gene technology when planning their activities, in the preparation of legislation, as well as in inspection, monitoring and research activities.

The gene technology strategy coming under the administrative sector of the Ministry of Agriculture and Forestry was drawn up to support decision making in creating policy and legislative solutions related to research and utilisation of gene technology.

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. In this context, gene technology comprises both gene transfer methods and methods of analysis for genetic material (genomics).

The revised Gene Technology Strategy and Action Programme of the Ministry of Agriculture and Forestry is based on the Gene Technology Strategy and Action Programme for 2003–2007 (Working Group Memorandum 2003:18) drawn up for the Ministry's administrative sector and completed at the Ministry in 2003.

The aim of the revised strategy is to respond to the considerable changes impending within the administrative sector's operational environment. The strategy was drawn up by the Ministry's internal Working Group responsible for coordinating gene technology issues (Biogen). The setting up of the Working Group is based on a measure proposed in the 2003 Gene Technology Strategy.

The Working Group was appointed on 23rd June 2004. It was chaired by Agricultural Counsellor Leena Vestala of the Department of Agriculture, with Agricultural Counsellor Päivi Mannerkorpi of the Department of Food and Health as deputy chair. Ministerial Adviser Tuula Pehu of the Department of General Affairs and Senior Research Officer Jussi Tammisola of the Department of Food and Health were appointed as the group secretaries. Tuula Pehu took up the chairmanship of the Working Group following the transfer of Leena Vestala to another organisation. Agricultural Counsellor Kirsi Heinonen of the Department of Food and Health took over as deputy chair following the departure of Päivi Mannerkorpi to another organisation. The other members appointed were Senior Veterinary Officer Seppo Kuosmanen of the Department of Food and Health, Fishery Counsellor Pentti Munne of the Department of Fisheries and Game, Ministerial Adviser Elina Nikkola of the Department of General Affairs (Senior Officer Johanna Niemivuo-Lahti of the Department of General Affairs as deputy), Research Director Mikko Peltonen of the Department of General Affairs, Senior Officer Markus Schulman of the International Affairs Unit and Communications Director Pekka Väisänen of the Press and Information Unit (Information Officer Mervi Ukkonen of the Press and Information Unit as deputy). In addition, participant experts in the Working Group's meetings have included Ministerial Adviser Marita Aalto of the Department of Food and Health, Senior Officer Sanna

Paanukoski of the Department of Forestry, Senior Officer Jouni Tammi of the Department of Fisheries and Game and Commercial Counsellor Leena Mannonen of the Department of Food and Health.

The Working Group respectfully submits the Gene Technology Strategy and Action Programme 2009–2013 to the Minister of Agriculture and Forestry.

Helsinki, 10 December 2008

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# TABLE OF CONTENTS

# Summary

The Gene Technology Strategy and Action Programme of the Ministry of Agriculture and Forestry for 2009-2013 presents the main principles, objectives and proposed measures for the use of gene technology in sectors governed by the Ministry. The strategy was drawn up by the internal Biogen Working Group of the Ministry of Agriculture and Forestry. The gene technology strategy coming under the administrative sector of the Ministry of Agriculture and Forestry was drawn up to support decision making in creating policy and legislative solutions related to research and utilisation of gene technology.

In the current, rapidly changing environment preserving the competitiveness of Finland's agricultural and food production is rooted in research and development based on new genetic know-how. Research in this field is rapidly advancing, and is a key focus area in most industrial countries. For Finland to remain at the forefront of development and to be able to meet the considerable challenges ahead will require adequate future investment in research based on new genetic know-how. This applies to agriculture as well. A significant future challenge from the viewpoint of agriculture and forestry, in particular, will be the adaptation to climate change.

In the Strategy and Action Programme, the Working Group proposes several administrative actions to improve the coordination of gene technology issues within the administrative sector of the Ministry of Agriculture and Forestry and cooperation with authorities outside the sector.

The Action Programme also 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 main objectives of the Action Programme are: i) adaptation to climate change, ii) improved efficiency of bioenergy use, iii) sustainable development and vi) development of functional foods and foodstuffs.

The implementation of the Action Programme is based on the following main principles:

Gene technology methods offer opportunities to promote and create new operating conditions for industries. Applications must, however, be developed in such a way that the viability of different production sectors is ensured.

Research must support the utilisation of gene technology in agriculture and forestry and the maintenance and development of multidisciplinary scientific expertise.

The use and marketing of genetically modified products call for a prior approval procedure which complies with European Community legislation and national legislation in which the safety of the products for humans, animals and the environment is assessed. Decision-making regarding approvals must be based on scientific risk assessment and precaution, including ethical aspects. The use of genetically modified products and the control of their marketing must be efficient, sufficient and equitable, and production chains must be transparent and traceable.

To ensure sufficient customer information and choice, genetically modified products and products manufactured from these must be appropriately labelled. Distribution of wide-ranging public information related to the use of gene technology is also imperative.

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

# STRATEGY

## Main principles

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

**Gene technology methods are applied in a controlled manner based on the viability of different types of agricultural production, sustainable use of natural resources, product safety and high quality, open and transparent operations, and efficient control. The special characteristics of Finland's agriculture, forestry and natural environment should be 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, and aimed at higher quality and more diversified products.**

**Use and marketing of genetically modified products are based on the prior approval procedure, whereby permission is granted only after these products have been proven to be safe to humans, animals and the environment.**

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

**Control of the use of genetically modified organisms, the 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.**

**The maintenance and development of multidisciplinary scientific expertise required for the application of gene technology in the agriculture and food, forestry and fishery sectors is supported by research. Research and development work emphasises the importance of international cooperation and innovative know-how.**

**To ensure sufficient customer information and choice, genetically modified products are appropriately labelled. Production chains must be transparent and traceable with respect to the origin, production method, composition and quality of products.**

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

# Background

In the current, rapidly changing environment preserving the competitiveness of Finland's agricultural and food production is rooted in research and development based on new genetic know-how. Research in this field is rapidly advancing, and is a key focus area in most industrial countries as well as in many transition economies, such as India, Brazil and China (WB 2008). Staying at the forefront of development requires, from Finland as well, sufficient future investment in research based on new genetic know-how. This also applies to agriculture.

A significant future challenge, in particular, will be the adaptation to climate change. Efforts to achieve a biosociety accordant with sustainable development are strengthening, and the impacts of these efforts can be observed in many fields, including agriculture and forestry. The usefulness of gene technology in research and product development is likely to be proven in future by the speed and accuracy of gene technology methods and the new knowledge that these methods can provide. There are many possible application areas based on gene technology in sustainable agriculture, forestry and food production.

To meet the challenges brought by the changing environment, considerable investment in the improvement of the efficiency and ecological tolerance of plant varieties is needed. Principal crop plants must be bred to tolerate dry, hot, saline and flood conditions as well as to withstand diseases and pests.

To reduce carbon emissions in energy production, more efforts are being directed towards replacing fossil fuels with energy derived from biomass. The demand for rapid increases in biofuel production has played a key role in stimulating the rise in global food prices. Plant productivity and eco-efficiency must thus be improved, particularly in the production of biofuels, to make it economically and ecologically sustainable in the future (EPSO 2007).The efficiency of the use of field and forest biomass for energy production can be improved both by plant breeding based on new genetic know-how as well as by boosting the efficiency of production processes. With the help of biotechnology and gene technology, the use of biomass in the production of materials can be promoted by developing new *non-food* applications for raw material production for industrial purposes.

Agricultural production, in accordance with the principle of sustainable development, requires efficient prevention of the negative environmental impacts of modern agricultural practices and land use, particularly those due to emissions of nutrient and plant protection products, erosion and habitat fragmentation. Genetically modified crop varieties have already shown their efficiency in the reduction of chemical loading and erosion of agricultural environments in countries in which the use of genetically modified crops is widespread. Crop yields can also be improved with the help of gene technology, which improves the efficiency of agricultural land use and thus fewer natural environments are cleared for agricultural use.

In future, health-related factors are likely to increasingly determine consumer choices in Finland, bringing an increase in demand for welfare associated products. This trend will be further strengthened by the growth in Finland’s ageing, high purchasing power population. Once the health effects of nutrition are better understood in the future, nutrients may become a significant

means of preventing health problems. In food production, Finland has already distinguished itself in the development of functional foods. These applications have been based mainly on the use of microbes in food production processes. The health impacts of foods can be improved, even in the primary production phase, by refining their quality characteristics through the application of genetic know-how, thus broadening the existing range of functional foods.

In spite of these opportunities, investment in the development of genetically modified agricultural products and foods has so far remained relatively insignificant, both in Europe and in Finland. In Europe, negative consumer attitudes towards foods produced using gene technology have become a notable barrier against the use of the technology. Despite widespread information, public opinion remains uncertain regarding the application of the technology in agriculture. One reason for this is the strong polarisation of the public debate, which is apparent in public comments from different quarters and also in media coverage related to gene technology. In such a discordant climate, it is difficult for ordinary people, i.e. the consumers, who may be unfamiliar with the topic to know which side to believe.

The gene technology debate can also appear somewhat irrelevant to the Finnish consumer as virtually no genetically modified products can be found on the shelves of Finnish shops. Consumers will be forced to take a stand on the issue only when genetically modified products actually become available to them. A foretaste of consumers' awakening interest was received when two Finnish meat processing companies announced their switch over to using genetically modified soy feed in pig farming. The ensuing animated public debate focussed on the demand to provide the consumer with the ability to choose between products derived from different types of agricultural production.

The international trade in genetically modified organisms has become a key issue of debate, particularly within the World Trade Organization (WTO). By a decision made in 2003, the United States notified that they intend to launch a WTO process for dissolving the moratorium concerning the access of genetically modified products to EU markets, which had been in force since 1998. A number of other countries joined the USA in this effort. In 2006, the WTO gave its decision on the matter: the EU moratorium was seen as illegal, and a demand to abandon it was issued. Regardless of the decision, not all EU countries have given up, *de facto*, their national import bans related to genetically modified products.

# General approach of the Strategy

### Definitions

In this Strategy:
– *customer* means a consumer, producer or other customer
– *gene technology* means a group of methods used to isolate, analyse and transfer genes on a molecular level[1] (gene technology includes, for example, gene transfer, determining the order of DNA bases, i.e. sequencing, the use of DNA markers in selection, production of genetically modified organisms and gene therapy)
– *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 and reindeer husbandry (e.g. seed, plant propagating material, feedstuffs, fertilisers and pesticides).[1] A definition by *Biologian sanakirja* (Tirri et al., 2001).

**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 science, 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. In addition, it ensures the high quality of foodstuffs and health of animals and plants. The Gene Technology Strategy of the Ministry of Agriculture and Forestry is based on this mission statement.

**Other strategies and action programmes drawn up in the administrative sector of the Ministry**

Gene Technology Strategy and Action Programme of the Ministry of Agriculture and Forestry 2003-2007 **http://www.mmm.fi/fi/index/etusivu/maatalous/maataloustuotanto/Bio-jageenitekniikka.html**
**http://wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2003/tr2003_18.pdf**

Natural Resources Strategy of the Ministry of Agriculture and Forestry
**http://www.mmm.fi/fi/index/etusivu/ymparisto/luonnonvarastrategia.html**

Finland's National Plant and Animal Genetic Resources Programmes
**http://www.mmm.fi/fi/index/etusivu/ymparisto/luonnonmonimuotoisuus/geenivarat_3.html**

Strategy for Finnish agriculture. Final Report of the Steering Group. Working Group Memorandum MMM 2001:16, Helsinki 2001**http://www.mmm.fi/fi/index/julkaisut/tyoryhmamuistiot/aikaisemmat_muistiot.html**

National Quality Strategy for the Finnish Food Sector
**http://www.mmm.fi/fi/index/etusivu/elintarvikkeet/laatujaturvallisuus/kansallinenelintarvikket aloudenlaatustrategia.html**

National Forest Programme 2010/2015
**http://www.mmm.fi/attachments/5fLUy9oi5/5ywg0T9jr/Files/CurrentFile/3_2008FI_netti.pdf**

Recreational Fishing Development Strategy of the Ministry of Agriculture and Forestry
**http://www.mmm.fi/fi/index/etusivu/kalastus_riista_porot/vapaa_ajankalastus/julkaisut.html**

Life Sciences and Biotechnology – a Strategy for Europe
**ec.europa.eu/biotechnology/index_fi.htm**

# Application of gene technology in agriculture and forestry

Research applying gene technology is being actively conducted around the world in all sectors of agriculture and forestry, although large-scale commercial production is dominated by genetically modified crops.

Demand for livestock products is predicted to grow seven per cent per year during the next decade. This growing demand cannot be met without the application of livestock biotechnology. Although genetically modified animals have been produced from all key livestock species, either for biomedical applications (production of therapeutic proteins and organ/tissue donations) or for increasing production efficiency (increased yield, resistance to diseases), there are no applications in commercial production. Ethical problems associated with the development of genetically modified animals and public opposition have slowed the commercial utilisation of genetically modified animals. It is thus likely that in the near future the development will focus on other genomics-based methods of molecular biology.

Genetically modified trees are being investigated in numerous field tests around the world, including the European Union. So far, the result has been two commercial applications: the virus resistant papaya in Hawaii and the insect resistant poplar in China. The aim of the gene technology based breeding is to increase the rate of growth and resistance to disease of the trees, to improve the physical and chemical quality of their wood and to improve bioenergy production. Gene mapping and other methods of molecular biology are, nevertheless, currently the foremost tree breeding methods used. A far-reaching debate on possible environmental risks to forest trees has slowed the use of genetically modified forest trees in forestry.

### The current situation of genetically modified crops

The area of cultivation of genetically modified plant varieties in the world has increased by about 10 per cent a year. In 2008, a total of 125 million hectares of genetically modified plants were grown in 25 countries (James, 2008).The production of genetically modified plants is the most widespread in the USA, Argentina, Brazil, India, Canada and China, the leading plant species being soybean, maize, cotton and oilseed rape. Genetically modified papaya and melon are grown to a lesser extent, and the production of genetically modified rice and alfalfa began in 2006. In the USA and Canada, the use of genetically modified sugar beet started in 2008. Since then, the share of GM sugar beet of the USA's total sugar beet cultivation area has reached 59 per cent.

The first genetically modified plant varieties came on the market in 1996. By 2007–2008, 615 approvals for use as food, feed or in cultivation – representing a total of 129 modifications of 23 different crop plants – had been granted in 55 countries. First-generation breeding properties such as herbicide tolerance or resistance to insect pests are in widespread use.

Genetically modified (corn borer resistant) maize is the only commercially cultivated genetically modified plant in the EU. The cultivation area for genetically modified maize in the EU was 107,000 hectares in 2008. Genetically modified maize has been grown mainly in Spain, where the corn borer is the principal cause of crop damage and formation of fungal toxins. The cultivation area for genetically modified maize in Spain was 79,000 hectares in 2008. Its cultivation area in the Czech Republic, Romania, Portugal, Germany, Poland and Slovakia totaled 28,000 hectares in 2008. In France, no genetically modified maize was grown in 2008, as the country placed a temporary ban on its cultivation under Directive 2001/18/EC. The Commission has requested a statement on the matter from the European Food Safety Authority (EFSA). The statement points out that the ban on cultivation cannot be approved on the basis of the directive. In the previous year, the cultivation area for genetically modified maize in France was 21,000 hectares. Germany placed a similar ban on the cultivation of Bt maize in spring 2009.

Approximately 500 field test applications are currently under consideration in the EU. Although the majority of these concern the first generation genetically modified crop applications mentioned above, some consist of second generation genetically modified crops, thus broadening the range of properties under development. In these applications, the crop quality characteristics have been modified: for example, potato with modified starch composition, oilseed rape with modified oil composition, and field pea with modified protein composition. In addition, the list includes plants, such as antibody-producing maize, that produce therapeutic proteins. The drought resistance of crops such as potato and maize has also been improved through gene technology.

Genetically modified soya is imported to most EU countries and, although cultivation of GM soya is still not permitted within the EU, an application for its cultivation is currently under consideration.

There are no genetically modified varieties in commercial cultivation in Finland. The varieties of maize so far approved for cultivation in the EU are either not suitable for Finnish growth conditions or the characteristics bred into them (corn borer resistance) are not beneficial in Finland.

Using current methods of gene technology breeding, it takes about ten years from the discovery of a gene to the release of a developed variety. Product approval of genetically modified plants, however, remains slow and expensive. For this reason, genetic modifications are applied in plant breeding only if the desired results cannot be achieved by other means.

**Trends in gene technology development**

As a result of extensive research programmes, knowledge of plant genomes has increased significantly in recent years, and new breeding characteristics are being introduced, for example, to improve the nutritional value of the most important food plants (OSU 2008).The genes in these new applications often originate from plants, and in certain cases the structure and function of the plants' own genes have been successfully fine-tuned.

RNA interference can be used to attenuate or turn off the function of a selected gene. The method was awarded the Nobel price in 2006.The method makes it possible, for example, to turn off plants' toxic genes or breed aromatic wheat by silencing the wheat's non-fragrance genes. In plant protection, a plant can be "vaccinated" genetically with RNA sequences that are exclusively effective against a single harmful organism, such as a specific virus, fungus, bacterium or insect pest species. The selective, high-precision control measure protects the plant against the target organism without harming other, non-targeted organisms (GTN 2008).

The function of a beneficial plant gene can often be enhanced by giving the plant an additional copy of the gene. For example, high-yield rice has been developed by enhancing the grain-filling gene function in this way (Wang et al., 2008).

By equipping the gene with a suitable control part it can be made to function only in a desired part of the plant or during a preferred time period. Edible cottonseed was developed by selectively turning off cotton's production of toxins only in the seeds (Sunilkumar et al., 2006). The activity of the grain-filling gene was enhanced only in the flower of rice – its enhancement elsewhere in the plant would have been detrimental. Salt-tolerant rice accumulates salt from the ground and transfers it to the vacuoles[2] of its leaf cells, where it causes no harm to the plant (Zhao and Zhang, 2006, 2007). Sugar cane is bred for cellulosic ethanol production by introducing into it the gene of an enzyme that breaks down cellulose. Interference of the enzyme with sugar cane growth is avoided as the production of the enzyme only begins in the plant a few days before harvesting (Dale, 2007).

The gene insert site in the plant can, in some cases, be selected beforehand. The modifying gene can also be programmed to shear away from the plant chromosome in certain cell tissues, thus preventing it from occurring in, for example, edible parts of the plant or its offspring.[2] A vacuole is a fluid filled cavity within the cell. It is surrounded by a membrane which separates the materials within the vacuole from other cell contents.

Artificial minichromosomes are being introduced for maize (Carlson et al., 2007).In a separate minichromosome, a stack formed of several genes can be bred into the plant in a controlled manner and without location effects, to be used, for example, in the production of valuable chemicals or medicines.

Using certain targeted mutagenesis methods, it has been found possible to substitute a sequence of one or more DNA bases with another desired DNA base sequence. The EU is considering whether some of these methods could be excluded from the scope of gene technology regulations.

**New challenges – climate, energy, food security**

Substantial changes in the global climate will require many important plant varieties to be re-bred in order to adapt to the new ecological conditions. In many current key agricultural production areas, the predicted changes would be detrimental to plant production. For example, in the Mediterranean countries higher temperatures and increased dryness may prove too harsh for many existing crop species.

In spite of the changes, we must be able to significantly increase food production in the coming decades. To keep in pace with continuing global population growth, crop production must increase 50 per cent and meat production by 85 per cent by the year 2030 (WB, 2008). The number of people living below the poverty line has started to increase, although, according to the UN Millennium Development Goals, the number should be halved by the year 2015.

Plant varieties need to be bred with the necessary tolerance against drought, salinity, flooding and cold. In northern Europe, crop plant resistance to new diseases and pests should also be improved.

The climate changes predicted for northern Europe would be predominantly beneficial from the viewpoint of agriculture. According to current predictions, climate warming would lengthen the growing season in this region, causing crop harvests even to double by the middle of the century. Taking advantage of this change requires the development of new plant varieties that are adapted not only to changing climatic conditions but also to other conditions specific to this region, such as long summer days (Peltonen-Sainio, 2008).

In efforts to mitigate climate change, attempts are being made to switch from fossil energy sources to renewable biomass. Current crop plants in Europe are still inefficient for the production of vehicle fuel when compared with, for example, tropical sugar cane or oil palm (IEA 2007).

With the help of gene modification, significant improvements can be bred into the energy efficiency of biofuel plant species (EPSO), thus enabling the same production area to yield more biofuel at a lower production input. The sugar content of sugar cane can already be doubled. In addition, cane varieties are being bred with tolerance to drought and salinity and with lower fertilisation demand. The efficiency of the use of reed canary grass could also be improved with similar breeding solutions.

The crop area of native oil plants in Finland cannot be increased to meet the demand for biodiesel as, due to diseases, oil plants can only be grown in the same field every five years. Cultivation of turnip rape will be replaced by oilseed rape as a result of climate warming. With the help of disease-resistant varieties, whose breeding has already succeeded in China, the crop area of oilseed rape could be increased manyfold in Finland.

# Public acceptance

The advantages and disadvantages of genetically modified microbes were discussed widely in the scientific community already in the 1970s. The genetically modified 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 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.

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.

The Eurobarometer issued by the EU Commission in March 2006, which measures EU public opinion relating to biotechnology and biosciences, showed that there is wide support in the EU countries for both medical and industrial biotechnology (e.g. bioplastics and bioproduction of pharmaceutical substances). According to the Eurobarometer, attitudes to biotechnology in agriculture are, by contrast, sceptical and will probably continue to be so if no benefits for the consumer are perceived in the new plant species and agricultural products. Of the respondents, 58% held a negative and 42% positive view of the utilisation of biotechnology in agricultural production.

Based on the results of the EU's latest Special Eurobarometer on the environment (EU 2008 a), EU citizens are not overly concerned about the use of genetically modified organisms in agricultural production, and the degree of concern is abating. Respondents rated the issue 11$^{th}$ (10$^{th}$ in the 2004 survey) in the list of key concerns, with one-fifth (one-fourth in 2004) of respondents expressing concern regarding the matter.

On the other hand, the results of opinion polls are not necessarily mirrored in EU consumer shopping behaviour. This is shown by an extensive European report published in 2008 (EU 2008 b), which compares polling responses given by consumers regarding genetically modified products with their actual shopping behaviour. The report shows that if genetically modified foodstuffs are available on the shop shelf, European consumers will buy them.

Judging by the contents of their shopping bags, the majority of the many respondents who stated that they would not buy genetically modified products did not, in practise, actively avoid foodstuffs labelled as genetically modified. On the other hand, of those who did purchase products labelled "GM-free", one in five stated that the label had been the reason for their purchase choice, whereas 80% stated that they had bought the product for some other reason.

The survey, conducted during 2006–2008, interviewed 40,000 respondents in ten EU countries (the Czech Republic, Estonia, Germany, Greece, the Netherlands, Poland, Slovenia, Spain, Sweden, and the United Kingdom). The study covered 68 foodstuffs labelled as genetically modified and other foodstuffs available in the different countries labelled as 'GM-free'.

## 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 EU, 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 (ERA).

The share of biotechnology in the EU's Seventh Framework Programme for 2007–2013 is 1,935 billion euros. The biotechnology theme consists of three activities:

1. Sustainable production and management of biological resources from land, forest, and aquatic environments
2. 'Fork to farm': Food (including food from aquatic environments), health and well being
3. The use of life sciences, biotechnology and biochemistry for sustainable non-food products and processes

Similar programmes are underway also elsewhere in the world. For instance, in 2008 a 3 billion euro programme was launched in China for the development of genetically modified plant varieties.

Finland also has a solid grounding in biotechnology research and training. The Academy of Finland, the Finnish Funding Agency for Technology and Innovation (Tekes) and the 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 research in these areas. Today, Finland has five significant concentrations of biotechnology research and enterprise located in different parts of the country (Helsinki region, Turku, Kuopio, Oulu and Tampere).

## Regulation and control of gene technology issues

The use of gene technology in the areas of industry and commerce administered by the Ministry of Agriculture and Forestry is currently one of the Ministry’s most strictly regulated activities. The potential advantages and disadvantages of the application of new gene technologies with respect to the environment and human and animal health are under debate, and the norms regulating this area are under constant development in numerous international forums, such as the joint Codex Alimentarius Commission of the United Nations' Food and Agriculture Organization (FAO) and the World Health Organization, and the OECD's working groups. The objective is to safely and economically make use of the opportunities offered by gene technology in agriculture, forestry, fishery, reindeer and game husbandry and food production.

**Key European Community regulations regarding approval for placing genetically modified products on the market**

Within the EC, the use of genetically modified organisms is regulated by a number of regulations and directives. The most important of these in the administrative sector of the Ministry of Agriculture and Forestry are the regulation on genetically modified food and feed, regulation

concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, directives on the open and contained use of genetically modified organisms, seed trade directives, directive on the marketing of forest reproductive material, directive on additives in feedingstuffs, directive on plant protection products, regulation on the transboundary movement of genetically modified organisms, as well as regulation on organic production of agricultural products.

The starting point in the legislation is that the use of genetically modified organisms is based on a prior approval system, founded on scientific risk assessment and the precautionary principle, labelling of genetically modified products as well as risk management with adequate monitoring and with general or case-specific follow-up.

Annex 2 gives further details about the legislation.

**Compensation for damages due to gene technology**

An important objective in the control of the use of genetically modified organisms is the advance prevention of the adverse impacts of the use of gene technology on the environment, health and property. In addition to prevention, the need for established rules regarding compensation for possible damages has been recognised.

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), the Act on Compensation for Environmental Damage (737/1994), the Product Liability Act (694/1990) and the Tort Liability Act (412/1974).

The Product Liability Act would apply to compensation to users for damage caused by products containing GMOs, but because product liability does not concern actual environmental damage, the Act on Compensation for Environmental Damage may be applied in this respect. In most cases, the Tort Liability Act would apply to compensation for 'purity accidents' of independent users such as farmers, but an act on the coexistence of GM and conventional farming would also be applicable if such an act were issued (see below).

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 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 meeting how to draw up 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.

**Activities of authorities in Finland in relation to genetically modified organisms**

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, Plant Protection Products Act and the Act on Trade in Forest Reproductive Material.

*Genetically modified foods and feeds*

Regulation (EC) No 1829/2003 on genetically modified food and feed is in force, as such, in all EU Member States, including Finland. To make the regulation effective, certain national amendments were required, issued by Government Decree 910/2004 (amended by Decree 135/2008). The decree covers, in addition to the sphere of competence and responsibilities of different authorities, the way in which the national position is to be appropriately coordinated in relation to the proposed Commission decisions. The control of genetically modified foods and feeds is also taken into consideration in the Government decree by recognising it as a part of general food and feed control, while the responsibility for it falls on the relevant control authorities.

*Activities under the Gene Technology Act*

The directive on open use, Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, is implemented by the Gene Technology Act (377/1995) (which also implements the directive on contained use, see Annex 2).The aim of the act is to promote the safe use of gene technology in accordance with the precautionary principle and in an ethically acceptable way, as well as to protect the health of humans and animals and the environment when using genetically modified organisms.

The Gene Technology Act lays down the rules to apply on hearing citizens when dealing with applications related to field experiments with genetically modified organisms. For implementation of the tasks under the Gene Technology Act, the Government appoints the Board for Gene Technology (GTLK) under the Ministry of Social Affairs and Health to sit for five-year terms, with representatives from the Ministry of Employment and the Economy, the Ministry of Agriculture and Forestry, the Ministry of Social Affairs and Health and the Ministry of the Environment. Scientific and ethical experts are also represented on the board.

The Gene Technology Act requires that expert authorities and specialist institutes are to be appointed to the board. These include the Finnish Food Safety Authority (Evira), National Institute for Health and Welfare (THL), National Agency for Medicines, MTT Agrifood Research Finland, Finnish Forest Research Institute (Metla), Finnish Game and Fisheries Research Institute (RKTL), National Supervisory Authority for Welfare and Health Valvira, Finnish Environment Institute (SYKE), Finnish Institute of Occupational Health and the Technical Research Centre of Finland (VTT). Valvira, (SYKE) and Evira are the control authorities referred to in the Gene Technology Act.

In accordance with the Gene Technology Act, the Government, on the recommendation of the Ministry of Social Affairs and Health, sets up a National Advisory Board for Biotechnology (BTNK) for a three-year term. The advisory board acts as an expert advisory body in questions related to biotechnology and gene technology.

*Control of genetically modified products and organisms*

Utilisation of gene technology imposes new demands on the control systems. This calls for well coordinated cooperation between the authorities and commitment throughout the production chain. Evira is responsible for the control of genetically modified seeds, plant propagating materials, forest reproductive materials, biocides and feeds. The role of the Employment and Economic Development Centres (TE Centres) is to function as local control authorities, steered by Evira. Evira also steers, manages and develops the control of genetically modified foods. The control is carried out in practice by the authorities responsible for food control in the municipalities and provinces. Evira is subject to the performance guidance of the Department of Food and Health under the Ministry of Agriculture and Forestry, and draws up annual control plans for different fields.

Genetically modified food and feed from third countries is controlled by the Finnish Customs in cooperation with Evira. The facilities for the analysis of genetically modified products and organisms are located at the Customs Laboratory, which has also been designated as the national reference laboratory for genetically modified organisms.

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 from 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 issues relating to the contained use of GMOs and their release to the environment and the impacts of this as well as the impacts on health arising from their use. The European Medicines Agency (EMEA) is responsible for the licences to sell GM products.

In addition, Evira's tasks include acting as the national focal point under Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. Another of Evira's obligations is to ensure that the public is made aware of the application process for new genetically modified feeds and foods.

*Coexistence of different forms of production*

The coexistence of different forms of plant production refers to the possibility of engaging in the production of genetically modified plants and other crop plants side-by-side in the same geographical area. Coexistence refers not only to the possibility for growers and consumers to choose between genetically modified, conventional and organically grown agricultural products but also to the actions needed to safeguard this freedom of choice.

From the viewpoint of coexistence, the key issue is how to prevent admixture. The presence of genetically modified material in other than GM products, GM production plants and GM production areas may have an adverse economic impact on growers, food and feed processors and retailers. Receiving compensation for such damage on the basis of the current legislation may prove a heavy, slow and uncertain process for the damaged party. To address this problem, in several Member States coexistence legislation has been drawn up to make access to

compensation for the damage sufferer simpler and lighter on bureaucracy. Of the Nordic countries, Denmark and Sweden already have their coexistence legislation in place.

In Finland, the Ministry of Agriculture and Forestry has prepared a Government proposal for the national Coexistence Act. The proposal is based on Commission Recommendation 2003/556/EC. The intention is to submit the proposal to the Finnish Parliament in 2009. It is recommended that the scope of the act should cover the cultivation of plant material in which the genetically modified material of a GM plant approved for the EU's or a national register of varieties is present in amounts that exceed the threshold value prescribed in Regulation (EC) No 1829/2003 on genetically modified food and feed. The scope of the act should also cover crop handling and storage as well as transport within and between farms. The act would apply to both seeds and plant parts and the yield obtained from these. It is proposed that the act should include an obligation for the grower of the genetically modified variety to notify of the cultivation in good time prior to sowing of the variety in question. The notification should be made to Evira or the municipal rural business authority.

To prevent admixture of genetically modified and other crop plants, the most important measure in the proposal would be the provision concerning the sufficient safety distance between the crops. The measures in this proposal and in the decrees based on it that deal with coexistence are harmonised in such a way that admixture would remain in accordance with the legislation related to the labelling of genetically modified products in feeds and foods.

A proposal has also been made for a procedure to be included in the act by which a grower engaged in the production of conventional or organically grown produce could be compensated for any monetary damage caused by unintentional admixture of genetically modified material. The compensation would be paid by the grower of the genetically modified crop plants who, either intentionally or by negligence, has failed to observe the law or the prescribed requirements based on it. In accordance with the proposed act, the compensation would apply to damage caused to a person engaged in the activity of conventional or organic production resulting from the fact that the threshold values for genetically modified material in these products are exceeded to such an extend that the products can no longer be marketed as, for example, an organic product or seed grain, but only under a label indicating the product as genetically modified. It is not intended, however, that the proposed damage compensation system would exclude other alternative or supplementary damage compensation systems, such as those based on the Act on Compensation for Environmental Damage.

**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, 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 in accordance with current regulations.

There are five national ethical advisory boards in Finland: the activities of the National Advisory Board for Biotechnology (BTNK) and the Board for Gene Technology (GLTK) were discussed earlier. The National Advisory Board on Health Care Ethics (ETENE) deals with the ethical questions relating to healthcare and the positions of patients, and the National Advisory Board on Research Ethics (TENK) with ethical questions relating to scientific research. The latter also promotes research ethics. The Cooperation Group for Laboratory Animal Science (KYTÖ) coordinates research using laboratory animals and training and other activities in the field and promotes the welfare of laboratory animals and ethical principles in animal testing. In addition, the Sub-Committee on Medical Research Ethics operates in association with ETENE. Besides TENK, ethical questions related to the release of information are also dealt with by the Committee for Public Information (TJNK).

# Preparation of gene technology issues at the Ministry of Agriculture and Forestry

### Gene technology issues in general at the Ministry of Agriculture and Forestry

In carrying out its tasks, the Ministry of Agriculture and Forestry and its entire administrative sector take an official stand regarding gene technology and its use and on the 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. Key tasks include plant and animal breeding, quality of agricultural inputs and foodstuffs and verification of this quality by means of control, organic production, and steering of research. The forestry and fishery sectors also address the role of gene technology in relation to these issues. For this reason, based on the Gene Technology Strategy report, the Biogen Working Group was established in 2003 for the Ministry's internal coordination of gene technology matters. The sectors of the Ministry involved in these matters have been represented in the Working Group. As found necessary, Biogen has conducted its activities through meetings or by hearing experts or other interest groups.

In addition, a cross-administrative ad-hoc working group on the control of the use of gene technology also operates under the Ministry of Agriculture and Forestry's Department of Food and Health. Represented in the group are the principal officials and authorities dealing with questions related to the control of the use of gene technology from the Ministry's administrative sector, from the Board for Gene Technology and from the environmental administration. The group's task is to keep track of developments in the control of gene technology use and to exchange information regarding actions undertaken and the events requiring actions in the national control of gene technology use. The group also harmonises the control programmes of different sectors.

### Decision making related to genetically modified food and feed in Finland

In accordance with Government Decree 910/2004, as amended by Government Decree 135/2008, the national position in decision making regarding application for a permit relating to genetically modified foods and feeds will be coordinated in such a way that the responsibility for

foods and feeds rests with the Ministry of Agriculture and Forestry and the Gene Technology Board carries the responsibility for questions related to environmental safety. The responsibility for appropriate implementation of the coordination rests with the Department of Food and Health of the Ministry of Agriculture and Forestry. The Department convenes meetings and prepares the national position on the basis of discussions held. In the case of food safety, the Novel Food Board, an expert body associated with the Ministry, will be heard. The expert in the case of feed safety is Evira, from whom statements will be requested case-by-case. To support its statement, Evira can consult experts in the field of animal nutrition. In addition, a feedstuffs sub-committee established by the Ministry will be heard on the decision.

# ACTION PROGRAMME

## General administrative measures

### Strategic planning

Gene technology is a rapidly developing field of technology involving all sectors of agriculture and forestry. The potential advantages and disadvantages of gene technology from the viewpoint of society and the individual, particularly with respect to its application in agriculture and forestry, divides opinions and is a subject of broad public debate. It is therefore essential for the Ministry to be broadly represented in the planning and implementation of the gene technology strategy in terms of both policy making and expertise. Thus it can be ensured that the aims and priorities of activities related to gene technology and attitudes taken in relation to the use of gene technology are consistent and congruent with the Ministry's other strategies and policies. For the Ministry, the objective is to be an active player in questions related to gene technology both within the administrative sector and in relation to the rest of society.

Administration of gene technology issues requires effective coordination between ministries and other national bodies. Currently, gene technology issues are dealt with by central government through several organisations and working groups in accordance with the statutory authority for gene technology regulations. The Working Group proposes to discuss how public awareness of the decision making process associated with gene technology can be enhanced and how to improve open and timely communication between various actors.

The Working Group's proposals are:

1) Awareness regarding legislation-based decision making related to gene technology issues must be increased, and open and timely communication in relation to this should be promoted among actors in the field.

2) The Biogen coordination group established for internal coordination of the Ministry's gene technology matters for the period 2003–2007 should continue its activities during the period 2009-2013. All the Ministry's sectors dealing with gene technology issues should be represented in the group. The group will keep track of international and national developments related to gene technology and, when necessary, state its position regarding questions of current interest

related to gene technology. The group will monitor the implementation of the proposals presented below. As necessary, the group will hear the representatives of non-governmental and other relevant organisations. Ad-hoc working groups are set up when needed.

3) The Ministry's Biogen coordination group together with the Ministry's Press and Information Unit shall be responsible for implementing the communication strategy for the provision of the public with correct and comprehensive information on the advantages and disadvantages of the use of gene technology, and on how the Ministry, in cooperation with the National Advisory Board on Biotechnology, for example, can actively participate in public debate on the issue.

**Regulation and control**

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 gene technology use in agriculture, food industry, game and reindeer husbandry, fishery and forestry 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 labeling 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 burdens or obstacles for enterprises.

The Community legislation currently in effect regulating the utilisation of gene technology places great additional demands for control. However, Community legislation and its administrative decisions should support the control work of the authorities so that the limited resources are focused on the control of relevant matters. In Finland, the responsibility for control is shared by a number of authorities. It would, therefore, be expedient to systematically develop and focus control activities jointly across the boundaries between administrative sectors.

The Working Group's proposals:

4) The Ministry will finalise the Government proposal for the Coexistence Act during 2009 and prepare the decrees pursuant to it.

5) Under the Ministry's guidance it will be ensured that Evira will keep the control strategy for the use of gene technology up-to-date and that Evira's cooperation group for gene technology will draw up, yearly, a coordinated control programme for genetically modified seeds, feeds and foods.  JK: onko ryhmälle vakiintunutta nimeä? Cooperation group ei oikein hyvää englantia.

6) The Ministry will put the activity of the ad hoc control group for the use of gene technology on a regular basis. All national authorities related to the control of gene technology use will be represented in the control group.

### Research

The objective of the Ministry of Agriculture and Forestry is to transfer biotechnology and gene technology knowledge to practice and to develop innovations. The Ministry aims to ensure that high-level sectoral research in biotechnology and gene technology is kept alive and strengthened and to promote the visibility and funding of multidisciplinary and cross-scientific research themes. Natural resources research institutes operate in a joint consortium for forest and natural resources. Several strategic concentrations of excellence industry have been established in Finland, where gene- and biotechnological research is conducted in close cooperation with the industrial applications. The Ministry of Agriculture and Forestry, in cooperation with the Academy of Finland, Tekes and international financiers, seeks to develop forms of financing for biotechnology and gene technology research.

Targeting research in the administrative sector of the Ministry of Agriculture and Forestry is founded - within the framework of the available resources - on key priority areas from the viewpoint of the strategy. The Environment and Natural Resources Consortium established by the Ministry of Agriculture and the Ministry of the Environment tightens the cooperation between the research institutes of the administrative sectors and provides opportunities to boost the efficiency of research also in questions related to gene technology. The implementation of the research agenda of the Advisory Board for Sectoral Research may also provide beneficial research with respect to the implementation of the Gene Technology Strategy, for example, in the area of mitigating and adapting to climate change. The emphasis of research funding is on international cooperation and cooperation with the Academy of Finland, Tekes and the existing and future strategic centres of excellence.

# Detailed measures for different sectors during the strategy period

## Agriculture

### Plant production

*Background*

The challenge for Finland and for the whole of Europe is to produce safe, high-quality and health-promoting food and other bioproducts in an economical and sustainable manner which saves the environment in a production environment where biotic and abiotic stress factors are increasing due to climate change.

The extensive ILMASOPU research programme (1st June 2006–30th September 2009), steered by the Ministry of Agriculture and Forestry, investigated the impacts of climate change on Finland's plant production. According to the studies, Finland's plant production will benefit from climate

change in the long run through a significantly increased crop yield potential. However, future growing conditions will mean that many of Finland’s current crop varieties will no longer be competitive. The studies also showed that the direct introduction to Finland of varieties currently cultivated in more temperate climates is not viable, as Finnish light conditions, especially during the growing period, differ significantly from those of other production regions. For this reason, new varieties must be bred within a short time frame in Finland. The studies estimate that, based on the speed of the advance of climate change, Finland will need new varieties by 2025.This presents a considerable challenge for Finnish plant breeding.

To meet these challenges in time, with the new varieties, requires the use of faster and more advanced breeding methods than those currently in use. Plant breeders must also be able to determine the genetic background of desired traits. This requires the use of genomics tools, as traits are often the result of the effects of several unknown genes. The task is complex and can only be effectively realised with international cooperation. Coordinated action on both national and European level is necessary for Finland to be able to meet consumer needs and cope with the environmental changes that can be expected during the next 25 years.

As genome research advances, plant breeders will be able to seek necessary genetic variability from gene banks and apply it in the breeding of new crop plant varieties. It can also be expected that the achievements in genomics will make it possible to extend the use of crop plants in the development of non-food products and the utilisation of crop plant biomass for the production of bioenergy.

*Objectives*

The objective is to develop technological solutions that provide effective tools and methods for the identification, isolation and utilisation of genes that influence key traits. The vital genes are those that affect the disease resistance of crop plants. Also important are genes that have an effect on abiotic stresses, such as genes for drought tolerance. In addition, many genes influence the development of crop quality and the formation of nutritional value (e.g. protein content and the amount of soluble fibre), crop reliability when using low inputs (nitrogen use efficiency), and efficient biomass production (starch synthesis, cell wall structure, suitability as a biofuel and suitability for the processing of bioproducts).

*Measures to be taken*

– selection, in cooperation with researchers and plant breeders, of the research subjects, i.e. crop plants and varieties as well as the traits, that from the viewpoint of Finland's plant production are important in the following priority areas: - adaptation to climate change - improved energy use of biomass – improved nutritional quality of food products
– promotion of coordinated cooperation between researchers and plant breeders in the key areas mentioned above, on both the national and international level.

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, MTT Agrifood Research Finland, Finnish Food Safety Authority (Evira)

*Other cooperation partners*

National Advisory Board for Biotechnology (BTNK), Boreal Plant Breeding Ltd, Board for Gene Technology (GTLK), higher education institutes, Central Union of Agricultural Producers and Forest Owners (MTK), agricultural advisory organisations, National Agency for Medicines, Potato Research Institute (Petla), Sugar Beet Research Centre, Ministry of Social Affairs and Health, Ministry of Employment and the Economy, industry and commerce, Customs Laboratory, Novel Food Board UELK, Ministry of the Environment.

**Animal nutrition**

*Background*

In feed additives used in animal nutrition gene technology has been applied for quite a long time to improve, among other things, the microbes which produce enzymes and amino acids. Certain GM crops used for animal nutrition have also been authorised for the EU market (soya, maize, rape). Use of GM rice may be approved in 2009.

*Objectives*

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

*Measures to be taken*

– support for gene technology research which aims to develop new, more rapid, accurate and economical methods to ensure the safety, quality and genuineness of feedstuffs and for the control needs

– increased cooperation with enterprises in allocating existing resources to gene technology research for the development of the quality and nutritional properties of feedstuffs and, through this, the improvement of foodstuffs of animal origin.

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, Finnish Food Safety Authority (Evira), MTT Agrifood Research Finland

*Other cooperation partners*

Board for Gene Technology (GTLK), higher education institutes, National Agency for Medicines, agricultural advisory organisations, Central Union of Agricultural Producers and Forest Owners (MTK), Finnish Environment Institute (SYKE), Ministry of Social Affairs and Health, industry and commerce, Customs Laboratory, Ministry of the Environment.

**Animal breeding**

*Background*

In Finland, methods based on genomics have been used in livestock research and breeding for cattle, swine, sheep and hens. The general objective of animal biotechnology is to investigate genome variations that affect livestock traits and which can be utilised in the breeding, production and planning of conservation programmes for gene resources. No gene transfers have been carried out on livestock in Finland.

Finland and the Nordic countries are pioneers in the collection of data on the health and fertility traits of dairy cattle for breeding value estimation purposes. The Finnish database collected on health and fertility traits offers researchers and those applying the research data a lead of about 15–20 years over their counterparts in other countries. The first gene mapping results of the health traits of Finnish dairy cattle have been published. The health and fertility traits database enables mapping of the genes responsible for these traits. This mapping data can be used, for example, to develop DNA diagnostics applications for the selection of maximally healthy and fertile breeding animals. Finland is well positioned to remain at the head of international research in health and fertility traits of dairy cattle well into the future.

In addition to genome mapping projects of cattle breeds, projects mapping the genomes of hen and swine have also identified numerous chromosome zones that influence key traits. The first selection marker taken into breeding use in Finland was based on a genetic sperm defect among swine, while the first to be brought into international use was the selection marker to eliminate fishy odour from hen's eggs.

*Objectives*

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

*Measures to be taken*

– the so-called Nordic breeding profile, focussing on health and structural properties as well as production properties, continues to be taken into account in breeding objectives by means of performance guidance

– supporting ethical and environmentally sustainable gene technology research aimed at healthier and more productive production animals which cause less burden to the environment, while paying heed to the requirements of climate change and its effects on the health, yield and the environmental effects of production animals.

– facilitating cross-scientific cooperation in livestock breeding between livestock nutrition research and technology research, on one hand, and food technology, on the other, to develop new applications in accordance with the breeding objectives mentioned above

– continued international cooperation in gene mapping and breeding of traits relating to the yield and health of production animals

- steering of extension organisations to active follow-up of development work and research results relating to gene technology, and to rapidly communicate new information to the farmers in order to achieve the possible competitive advantage.

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, MTT Agrifood Research Finland, Finnish Food Safety Authority (Evira), provincial veterinary officers, municipal veterinarians

*Other cooperation partners*

Board for Gene Technology (GTLK), higher education institutes, livestock breeding and advisory organisations, National Agency for Medicines, Customs Laboratory, Ministry of the Environment.

## Forestry

*Background*

European Union markets are free of genetically modified forest reproductive material. One of the key criteria of the Finnish Forest Certification System (FFCS) is that genetically modified reproductive material is not used in forest cultivation. Of the forests in economic use in Finland, 95% have been certified in accordance with the FFCS. Research underway in Finland on genetically modified trees, birch and hybrid aspen, is purely basic research. The research provides information on the functions of the transgene and the ecological interactions of genetically modified trees.

The most important special characteristic and the biggest problem in forest tree breeding is the long generation time. 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. Gene technology provides opportunities for increasing the speed and accuracy of forest tree breeding.

The challenge for forest tree breeding is, in addition to the long rotation period, to ensure the adaptability of forest reproductive materials to the changing climate. In this respect, it is important to know the genetic origin of forest reproductive material as precisely as possible, now that the identification of this origin is possible thanks to gene technology. Information obtained from research utilising gene technology can thus be used in selection based on genetic knowledge of breeding material or forest reproductive material. The most realistic first-stage gene technology applications in forestry relate, in fact, to the development of traditional forest breeding based on selection.

*Objectives*

Finnish gene technology research and expertise relating to forest tree species will remain at a high international level. The opportunities offered by the new technology will be taken into account in the efforts to improve the speed and efficiency of forest breeding and, as a result, also in the preparedness for climate change. 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 will be assessed and risk assessment methods developed, keeping in mind the long generation time of forest trees. Research, control and steering will ensure that possible gene technology applications are in harmony with the principles of ecological, economic and social sustainability of forestry.

*Measures to be taken*

– directing research resources to the development of methods of biotechnology and gene technology as a part of research of tree species and other organisms that are important with respect to forestry. The development of risk assessment and related methods are an integral part of this development work.

– facilitating the application of opportunities created by biotechnology and gene technology in the implementation of the forest tree breeding programme

– encouraging researchers and forest breeders to actively follow international development work and research results related to gene technology.

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, Finnish Forest Research Institute (Metla), Metsähallitus, Finnish Food Safety Authority (Evira)

*Other cooperation partners*

Board for Gene Technology (GTLK), higher education institutes, Finnish Forest Industries Federation, Central Union of Agricultural Producers and Forest Owners (MTK), Ministry of Social Affairs and Health, Finnish Environment Institute (SYKE), Customs Laboratory, Ministry of the Environment.

## Fishery

*Background*

The methods of gene technology and molecular biology offer new opportunities to develop the farming of fish and crayfish through, for example, contributions to genetic breeding, disease diagnostics and resistance, development of vaccines and feeds as well as the management of the environmental impacts of aquaculture. However, the development or production of genetically modified fish stocks in Finnish aquaculture is still not within sight. Finland's initial dealings with genetically modified organisms and products manufactured from these in relation to fishery will be in connection with the import of feedstuffs intended for fish farming and aquaculture. In Finland, molecular technology applications have been used in selective breeding of fish and in conservation of natural populations. The methods provide new opportunities for collecting data on normal genetic variation of individual fish and utilising this in breeding and cultivation. The methods offer, for example, a new cost-effective means of breeding new aquaculture species. Use of DNA marking techniques, for example, will enable a move away from, at least partially, the costly method of individual fish marking and the nursing stage involving hundreds of ponds. In the cultivation of food fish, selective breeding has progressed furthest with rainbow trout and whitefish.

*Objectives*

The use of gene technology in fish and crayfish husbandry will be promoted, taking into account issues relating to environmental protection and control of potential environmental risks, as well as consumer attitudes and wishes. The objective is to ensure sufficient preparedness in terms of both information and operations for the follow-up of development in the field, the development and utilisation of the technologies, and the assessment of their impacts. Expertise and techniques in molecular genetics will be developed in such a way that Finnish selection breeding programmes for farmed fish and diversity conservation will remain at the forefront of international development.

*Measures to be taken*

– supporting opportunities for the utilisation of new technologies in aquaculture by promoting the research and development of other methods, molecular genetics among them, that lend support to these technologies
– launching the assessment of positive and negative environmental impacts and ecological risks of gene technology applications in aquaculture

– developing safe production methods, particularly for the prevention of negative environmental impacts - one such method being the production of sterile fish
– continuing the collection of genetic information on the most important fish species for aquaculture (rainbow trout, whitefish) and certain other species (e.g. Atlantic salmon, trout, Arctic char, pike-perch, crayfish)
– continuing conservation activities for the genome of threatened and nationally important natural fish stocks (e.g. trout, Atlantic salmon, whitefish, grayling and pike-perch) with the help of milt bank operations and broodstocks in gene banks. In addition, fishing regulation activities will be developed to support the creation of special gene reserve water bodies for the conservation of fish species and stocks in nature

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, Finnish Game and Fisheries Research Institute (RKTL), MTT Agrifood Research Finland, Finnish Food Safety Authority (Evira)

*Other cooperation partners*

Board for Gene Technology (GTLK), Oy FIC Fish Innovation Centre Ltd, higher education institutes, National Agency for Medicines, Ministry of Social Affairs and Health, Finnish Environment Institute (SYKE), Ministry of the Environment.

## Game and reindeer husbandry

*Background*

Sylvatic rabies in wild predators has been prevented in Europe by means of rabies vaccine baits spread in forests. There is currently one live genetically modified bait rabies vaccine on the EU market, which has been tested on 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. 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.

In reindeer husbandry, there has been national and international cooperation, for example in the form of a Nordic reindeer breeding programme, in the gene mapping and breeding of traits relating to the yield and health of reindeer.

*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. Utilisation of gene technology in game and reindeer husbandry is based on the use of molecular biology methods in, for example, individual identification, measurement of genetic diversity, and the estimation of population size and individual range of movement.

*Measures to be taken*

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

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, Finnish Game and Fisheries Research Institute (RKTL), Finnish Food Safety Authority (Evira)

*Other cooperation partners*

Board for Gene Technology (GTLK), higher education institutes, National Agency for Medicines, Finnish Environment Institute (SYKE), Ministry of the Environment.

## 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, their raw materials and the production environment have also long been ensured through legislation and control, e.g. the prior approval procedure, quality and safety requirements for products and production, as well as quality assurance.

The foodstuffs available on the market are safe and of high quality, irrespective of the production technology used or location of production. The Finnish food industry is internationally competitive. Foodstuff production chains are transparent and reliably traceable in terms of the origin, type of production, composition and quality of foodstuffs. Consumers are able to choose freely between products on the basis of need or preference. The possibility to exercise choice is ensured by appropriate labelling and by improving other consumer information. There is active participation in the development of conditions and systems for consumer information at the Community level. 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 produce quality, clearly labelled foodstuffs.

*Measures to be taken*

– active participation in the safety assessment work of the European Food Safety Authority (EFSA) for genetically modified foodstuffs and feeds, making use of national experts and expert networks.
– developing the control of genetically modified products through closer cooperation between control organisations

– supporting research - within the resources available and using performance guidance - that utilises gene technology in order to develop new, more rapid, precise and economical methods for ensuring the hygienic quality of foodstuffs (various diagnostic methods for the detection of bacterial or viral contamination)
– concentrating resources on quality development and the health impacts of products on the basis of the gene technology research strategy of MTT Agrifood Research Finland (special products, functional foods, probiotics, etc.).

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, MTT Agrifood Research Finland, Finnish Food Safety Authority (Evira), Finnish Game and Fisheries Research Institute (RKTL)

*Other cooperation partners*

European Food Safety Authority EFSA, industry and commerce, Board for Gene Technology (GTLK), higher education institutes, consumer organisations, Agency for Rural Affairs (Mavi), Ministry of Social Affairs and Health, Ministry of Employment and the Economy, research institutes, Ministry of the Environment.

## Consumer aspects

*Background*

Different consumer groups have very different kinds of attitudes to food and GM products. Consumers are increasingly segmented into small groups with different needs and interests. Consumer choices are influenced by price, production method and origin, as well as by the ethical considerations and environmental impacts of food production. Consumers are also increasingly interested in the nutritional quality and health effects of foodstuffs. Emphasis is placed not only on safety but also other factors influencing choice-making are stressed, and there is a call for consumers to be considered as active actors in the food chain. Food production must serve all consumer groups.

Consumer confidence is a prerequisite for the production of genetically modified products. The key factors involved in building this confidence are quality products that interest the consumer, appropriate product labelling, product safety, and distribution of information. The increasing importance of environmental values may also be mirrored in consumer behaviour in the future.

*Objectives*

Foodstuffs and other products with good properties or high quality and a favourable price-quality ratio are developed for the consumer. Consumers expect that the foodstuffs available on the market and their raw materials are safe and of high quality. Consumers are able to choose the products they wish to buy. Different consumer groups, such as persons with allergies or special dietary requirements on health, ethical or religious grounds, are taken into account in the food production chain.

To ensure the consumer's right of choice, labelling of foodstuffs and other consumer information will be improved. Consumer demand for more accurate and detailed information on production practices and origin will be met. Genetically modified foodstuffs and feeds must be labelled appropriately as required by law. Consumer confidence must be ensured, meaning that that the public sector takes due care of the control of the production, processing, marketing and labelling of foodstuffs.

Consumers must play an active part in the discussion on the utilisation of GMOs in the administrative sector of the Ministry of Agriculture and Forestry and be able to follow the research and approval of products for marketing, for example, via the websites of the National Advisory Board on Biology, the Board for Gene Technology and Evira. Consumers must also be able to actively take advantage of their right to be heard when GMOs and GMO derived products are being considered for approval for deliberate release.

*Measures to be taken*

– consumer expectations and demands concerning safe and ethical production practices and high quality are to be taken into account in issues relating to the development and use of gene technology and related decision-making within the administrative sector of the Ministry. This control ensures the safety and good quality of food.
– labelling relating to the production methods of foodstuffs and feeds or the provision of information on these issues by means of other systems is to be improved on the basis of feedback received from consumers
– active participation in the discussion on the utilisation of gene technology, and the development of communication regarding GM products and the activities of the administration and food chain relating to these
– active participation in the development of preconditions and systems for consumer information at the Community level.
– encouraging researchers to participate in the public debate on gene technology and to present real, scientifically proven advantages and disadvantages of the application of gene technology in agriculture and the food industry, and implications for consumers and the environment
– scientific consumer research will be conducted to gauge consumer opinion regarding gene technology and to determine how consumer attitudes can be influenced and how consumer information can be improved.

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, Finnish Food Safety Authority (Evira), MTT Agrifood Research Finland

*Other cooperation partners*

National Advisory Board for Biotechnology (BTNK), Board for Gene Technology (GTLK), industry and commerce, higher education institutes, Ministry of Social Affairs and Health, research institutes, Ministry of the Environment

## 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 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 environmental impact assessments, are taken into account in risk management in accordance with the precautionary principle.

*Objectives*

Risk assessments founded on scientific information ensure that the environmental impacts of GMOs and processes used in the agriculture and food sector and their impacts on forest and water ecosystems are known. Uncontrolled release of GMOs to the environment is prevented. GM applications that improve the state of the environment are developed.

*Measures to be taken*

– case-by-case assessment of the magnitude of risk of spread of GMOs or modified genes to the environment and of their introduction to cultivated or natural populations, and the resulting, possibly harmful impacts
– supporting research relating to risk assessment and risk management needed particularly for GM applications developed in Finland, with particular regard to the special properties and ecological impacts of different groups of organisms (microorganisms, plant and animal groups)
– studying the possibilities for GMO use in reducing the negative environmental impacts of agriculture, such as fertiliser emissions and erosion
– studying the environmental impacts of the cultivation recommendations of herbicide/pesticide resistant genetically modified crops
– studying the total impacts of genetically modified foodstuffs and feedstuffs on environmental balances on the basis of life cycle analyses.

*Implementers in the administrative sector*

Ministry of Agriculture and Forestry, MTT Agrifood Research Finland, Finnish Food Safety Authority (Evira), Finnish Forest Research Institute (Metla), Finnish Game and Fisheries Research Institute (RKTL)

*Other cooperation partners*

Board for Gene Technology (GTLK), higher education institutes, Potato Research Institute Petla, Sugar Beet Research Centre, Finnish Environment Institute (SYKE), National Supervisory Authority for Welfare and Health Valvira, VTT Technical Research Centre of Finland, Ministry of the Environment

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# Annex 1. Glossary

**agrobacterium**
A common soil bacteria, the "tamed" form of which can be used to transfer a gene to a plant; a bacterial strain from which its disease-causing ability has been removed is used for gene transfer: instead of its own genes, this bacterial strain transfers the gene, which is to be bred in a plant, to a plant cell

**allele**
The alternative forms of a certain gene, which are always found in the same location on the chromosome – a diploid individual can have only two alleles of the gene at a time: two similar ones (homozygote) or two different ones (heterozygote) – often, however, plants are polyploids, which means that an individual plant can have many different alleles

**antigen**
A foreign substance that can cause formation of antibodies

**biocleaning**
Cleaning of the environment with the help of living organisms (e.g. microbes and plants) (synonym: bioremediation)

**biotechnology**
A technology based on the utilisation of the functions of organisms, cells, cell parts or cell molecules

**B.t., Bt †**
A naturally occurring soil bacterium (*Bacillus thuringiensis*) which produces Bt protein that is harmful to certain insects

**Bt variety**
A plant variety which is resistant to certain insect species due to Bt protein (generally the truncated form) that it produces

**DNA**
Deoxyribonucleic acid is the material containing and transferring genetic information in the cell – it occurs mainly in chromosomes in a form of a double helix

**DNA marker assisted selection**
A selection method in which an individual is selected for further processing based on the fact that there is a certain DNA sequence (selection marker) in its genome; previous research indicates that the presence of the selection marker in question in this plant material strongly correlates with the presence of the desired gene form

**DNA chip**
A base on which (up to tens of thousands) bits of DNA (genes) have been fixed; with the help of the chip it is possible to follow the presence and functioning of genes in a biological sample

**DUS**
The plant variety requirements (Distinct, Uniform, Stable) agreed upon in an international convention related to the protection of new varieties of plants (UPOV)

**phenotype**
The whole of an individual's all perceptible properties jointly made up by genes (genotype) and environmental factors

**functional food**
Food which, in addition to having traditional nutritional value, also has a positive effect on health

**functional genomics, functional genomics research**
Study of the function of the genome or its parts

**gene**
A DNA sequence that controls genetic traits and contains information for producing proteins or RNA molecules

**gene mapping**
Determining the locations of genes on a chromosome

**gene library**
A collection of cloned DNA sequences in bacterial cultures; the collection is made up of the fragments of chromosomal DNA and represents the entire genome of the species or a part of it

**gene modification**
Production of a genetically modified organism

**gene bank**
A collection of genes to conserve genetic natural resources; as representative a collection as possible about the genetic material, i.e. DNA, carried by organisms.

**gene technology**
A group of methods, with the help of which genes are isolated, analysed and transferred on a molecular level; gene technology includes, for example, gene transfer, determining the order of DNA bases, i.e. sequencing, the use of DNA markers in selection, production of genetically modified organisms and gene therapy; technology applying the methods of gene modification

**gene flow**
Gene migration within a plant population or from one plant population to another through sexual reproduction or asexual reproduction (vegetative propagation)

**genome**
The entire genetic or heritable material of a species, individual or cell

**genomics**
The study of the genome of a species, investigation of the structure of all its genes and their functions

**genotype**
The genome, the complete set of genes that an individual has inherited from its parents (cf. phenotype)

**GMO**
genetically modified organism

**herbicide-resistant genetically modified crop**
A cultivable crop, which has been made resistant of certain weed-killing pesticides

**stem cell**
An undifferentiated cell, which can divide and differentiate to several different cell-lines

**cloning**
1) Gene multiplication 2) Production of individuals with a similar genome (e.g. cells, antibodies, organisms)

**clone**
A set of individuals with an identical genome

**gene probe**
Chemically or radioactively labelled DNA or RNA sequence, which is used to find a certain nucleic acid

**LMO**
A living modified organism whose genome has been modified

**marker gene**
A gene with which it is possible to locate or identify another gene that has been transferred

**modern biotechnology**
New biotechnology methods; quite often used synonymously with gene technology

**molecular biology**
Study and modification of molecules thatare important for the cell's function or structure

**molecular genetics**
Study of genetic systems on a molecular level

**moratorium**
Period of time allocated for a further consideration of an issue

**mutation**
A structural change that has taken place in a gene, chromosome or in a set of chromosomes

**GM**
Genetically modified

**genetically modified vaccine for animals**
A vaccine that contains a living genetically modified organism or that has been produced from an inactive genetically modified organism

**substantial equivalence**
A property of food or its ingredient (e.g. composition, nutritional value or use) in which there is no perceptible or measurable difference when compared with traditional foods (a concept from the EU's novel foods regulation)

**PCR**
A method with which it is possible to quickly produce multiple copies of a desired DNA sequence starting with a very small amount of initial material (polymerase chain reaction)

**gene knock-out, gene inactivation**
Eliminating a certain gene from an organism with gene modification techniques

**primer**
A part of a nucleic acid (DNA, RNA) that is needed in its replication

**promoter**
The controlling element for the gene

**recombination**
Rearrangement of genes or parts of gene(s)

**recombinant DNA, rDNA**
DNA that is produced with the gene technology; a DNA molecule to which one or several foreign DNA sequences have been inserted

**resistance**
An organism's resistance or immunity against a disease, microbes, pesticides, medicine etc.

**sequencing**
1) Determining the order of DNA bases for a nucleic acid (synonym: DNA sequencing) 2) Determining the order of amino acids in a protein (synonym: amino acid sequencing)

**transgenic (organism)**
a genetically modified plant, animal or bacterium to which a foreign gene has been transferred

**contained use**
Performing gene technology experiments in an isolated space (a concept from gene technology legislation)

**deliberate release**
Open use; field experiments and cultivation for commercial applications in an environment without using special measures to prevent the release of the modified organism to the environment (a concept from gene technology legislation)

**terminator gene**
A gene that prevents the germination of crop seeds of a plant variety

**targeted improvement**
A form of breeding in which a desired modification of a gene, chromosome or a chromosome set is induced more accurately than in traditional forms of breeding

**novel food**
Food (or the processing method used in its production) that has not been used in the EU before 1997 (a concept from the EU's novel foods regulation)

**antibody**
A protein (e.g. gamma globulin) created by the effects of antigens in an organism during the immune reaction

**vector**
1) A plasmid of a bacterium ("gene taxi") on which the gene to be transferred is attached and which transfers the gene into a recipient cell 2) Carrier of infection (for example, a blood-sucking insect)

**recombinant DNA technique**
A group of methods used to create copies of recombinant DNA molecules in a suitable host cell; the objective is to produce a great amount of DNA or its products for analysis purposes or to be utilised in other ways

The definitions of the concepts mainly follow the Finnish Bioindustries glossary (in Finnish) (www.finbio.net/sanasto), but some of them are based on Tirri et al (2001): Biologian sanakirja, Otava, 888 pp.