ESGEMO

Research Programme on Environmental, Societal and Health Effects of Genetically Modified Organisms 2003–2007

Academy of Finland

Contents

1 Introduction

The use of genetically modified organisms (GMOs, organisms modified with gene technology) is a very topical issue which has given rise to a lively public debate in many European countries and internationally. Public concerns relate to the safety and sustainability of the new technologies as well as to ethical questions related to them. Therefore, questions concerning the ecological, health and societal effects of GMOs need to be addressed in a scientifically sound manner. A high level of expertise and information on the impacts of GMOs is crucial for their safe use and public acceptance.

Despite an extensive EU regulatory framework (Directive 219/90/EEC & Directive 2001/18/EC), consumer confidence in GMOs and GM food is not very strong in many European countries. Given the political sensitivity of the issue, no new GM products have been authorised in the EU since 1998. The so-called *de facto* moratorium in the EU has been criticised by many of its trade partners in which GM crops are already grown quite extensively. The EU is therefore lagging behind in research and development related to GMOs. The situation presents a challenge to research on the environmental effects and risk assessment of GMOs and calls for research into ethical and socio-economic concerns as well.

Much of the debate around GMOs and their use has so far concentrated on the risks of the release of GMOs to natural environments and gene flows between GMOs and natural populations in and/or between different organisms. Thus there is already some understanding of these risks and measures have also been developed to minimise them. However, much basic knowledge is still missing and there has been lack of research into indirect effects of the use of GMOs in particular. Indirect (and unexpected) effects may result from new practices in agriculture and forestry, as well as in environmental technology and be either positive or negative, but linked to the use of GMOs. For a comprehensive risk assessment it would be also necessary to cover these effects. To achieve this it would be crucially important to be able to fully exploit the modern ecological knowledge and research tools for this purpose. Collaboration of ecologists and those developing the GMO technology is therefore strongly encouraged.

In the social sciences there is an increasing concern about the social risks of modern life. Many of these risks relate to the human impact on nature, to deeply modified living environments, and to the sustainability of natural and cultural heritage. Research that helps environmental management and policies to minimise the social risks of the use of GMOs should be included in the Programme to foster multidisciplinary comprehensiveness. As regards public interest and good governance, the GMO issue has to be addressed in the framework of changing legislation and its implementation.

2 Background

2.1 Establishment of the ESGEMO Programme

In November 2002, the Board of the Academy decided to launch a Research Programme on Environmental, Societal and Health Effects of Genetically Modified Organisms (ESGEMO) and allocated EUR 3.5 million for the implementation of the Programme during 2004–2007, contingent upon funding from the Ministries of Agriculture and Forestry, the Environment, and Social Affairs and Health. Funding co-operation with other national and international organisations will also be sought.

The establishment of the Programme started by the initiative of the Advisory Board of Biotechnology in early 2001. An exploratory workshop "Genetically Modified Organisms – Impact on the Environment and the Society" for researchers and potential end-users of research results was organised by the Academy of Finland, the Finnish Environment Institute and the Advisory Board of Biotechnology on November 5, 2001. The workshop concluded that the present state of knowledge of the impact of GMOs on ecological processes is inadequate, and several essential research areas on this topic need to be strengthened in Finland.

In order to prepare a proposal for a Research Programme on risk assessment and risk control of GMOs, the Research Council for Biosciences and Environment appointed in May, 2002 a working group composed of representatives from the Research Councils of the Academy of Finland, from the Ministries of Agriculture and Forestry, the Environment, Social Affairs and Health, and Trade and Industry, as well as from the Advisory Board of Biotechnology. The working group heard the opinions of representatives from the Finnish Association for Nature Conservation and the Central Union of Agricultural Producers and Forest Owners who found the scope of the research programme important and warmly supported the programme.

The steering group of the ESGEMO Programme was appointed at the beginning of 2003. It is chaired by Director General Lea Kauppi (Research Council for Biosciences and Environment) and the members are Professor Marja Järvelä (vice-chair, Research Council for Culture and Society), Professor Riitta Keiski (Research Council for Natural Sciences and Engineering), Professor Lars-Axel Lindberg (Research Council for Health), Professor Pasi Puttonen (Research Council for Biosciences and Environment), Secretary General Markku Järvenpää from the Ministry of Agriculture and Forestry (with Senior Advisor Leena Hömmö as his deputy), Councellor Tuija Talsi from the Ministry of the Environment (with Senior Adviser Pasi Iivonen as her deputy) and Secretary General Irma Salovuori from the Ministry of Social Affairs and Health. Project Manager Petri Ahlroth (Ministry of Agriculture and Forestry), Professor Erkki Haukioja (University of Turku) and Research Professor Matti Sarvas (National Public Health Institute) acted as expert members in the steering group. Scientific Secretaries Jan Bäckman (Research Council for Natural Sciences and Engineering), Sirpa Huuskonen (Research Council for Biosciences and Environment), Riitta Launonen (Research Council for Culture and Society) and Jukka Reivinen (Research Council for Health) took part in the preparatory work. The Programme is co-ordinated by Programme Manager Reetta Kettunen (University of Helsinki).

2.2 European research environment

The Research Programme will be linked with the related research programmes and other activities presently running in Finland. In addition, it has links to several ongoing EU R & D activities. In the specific programmes of the EU FP5, there have been several key actions relevant to the Research Programme.

The EU FP6 has a priority area 'Genomics and biotechnology for health'. The emphasis in this programme is on research aimed at increasing basic knowledge to enable real and consistent progress in medicine, and to improve the quality of life. This kind of research may also have implications for research on areas such as agriculture and environment.

Another priority area in the FP6, 'Food quality and safety', aims at establishing the integrated scientific and technological basis needed to develop an environmentally sound production and distribution chain of safer, healthier and varied food. This priority area is addressing the health effects of GMO food and feed, as well as traceability and testing of GMOs, but not explicitly the environmental effects caused by them.

3 Objectives of the Programme

The objectives of the Programme are to

- create new knowledge on environmental and health effects and potential risks of GMOs used in agriculture, aquaculture, forestry, and environmental applications, particularly in boreal conditions; basic knowledge on related ecology and population genetics is emphasised
- develop novel tools for research and assessment of the potential impacts of GMOs on nature and its complex processes, and
- evaluate the socio-economic and technological impacts of the use of GMOs, including ethical considerations and public acceptance of novel biotechnology.

However, the Programme will not cover biomedical research or direct health effects of novel food or feed.

The objectives will be pursued by multi- and interdisciplinary research in biological, economical, social and technical sciences. The Programme is also addressed to researchers for health, well-being and quality of life issues concerning the impacts of GMO development and production.

The knowledge achieved through the Programme is necessary for strengthening the scientific base of risk assessment and risk management of the GMOs. The results can have potentially wide social and economical implications, and be of interest to several stakeholders: consumers, industry, agriculture, aquaculture, forestry, as well as the scientific community. Furthermore, the Programme would foster national and international research collaboration and support training of researchers and experts.

4 Research themes

Multidisciplinarity is strongly encouraged in the Programme. Research on different organisms (from microbes to vertebrates) and on interactions between them will be fostered. The research will cover natural and man-made ecosystems, as well as domestic animals and cultivated plants. Furthermore, research on ethical issues, risk conceptions and public acceptance of novel biotechnology will be encouraged. The research consortia/projects covering more than one of the theme areas are most welcome.

4.1 Ecological and health impacts of the use of GMOs

The use of GMOs may cause complex, beneficial or undesired effects in populations, food chains and ecosystems. We need better understanding of relevant biological processes and interactions between processes and organisms. This is implemental in developing better methods to predict and to assess environmental and health effects of GMOs, particularly in boreal ecosystems. Under this heading the following research fields are eligible:

- direct ecological impacts of the use of GMOs
- indirect ecological impacts, e.g. changing the functioning of food chains
- impacts of monocultures, e.g., clonal plantations, on biodiversity
- effects of introduced traits (not genes as such) on natural or cultivated ecosystems
- health effects caused by the use of GMOs in terms of new pathogenic traits and altered microbial flora of humans, animals and soil
- co-effects of environmental changes and the use of GMOs
- development and application of realistic ecological models for better understanding of ecosystem effects, which may result from new management practices in agriculture and forestry made possible by the use of GMOs

4.2 Gene flows and interactions

Possible spread of GMOs depends on gene flow among individuals and populations, and of transfer by vectors and susceptibility of recipient populations. Hence, the research should address the following topics, part of which can be studied with or without using GMOs.

- gene flows and interactions in and/or between different organisms (virus, fungi, microbes, plants, animals, and humans), populations, ecosystems including the analysis of health effects
- containment of GMOs
- interbiotic processes and the selective value of introduced traits in natural populations
- monitoring techniques of gene flows and interactions

4.3 Ethical and socio-economic aspects connected with the development and application of GMOs in nature

Development and application of GMOs may have a variety of new impacts on nature and society. The state and the civil society perceive these impacts as a matter of policies to be legimitated and pursued by a variety of actors. This topic is further elaborated by the following thematic research areas:

- ethical considerations and public perceptions on the use and development of GMOs
- political rhetorics, policy options and the role of experts in the development of GMO policies and practices
- the role of gene technology in inducing socio-economic changes and development of other technologies, in industrial as well as in developing countries
- drivers of innovation and diffusion of environmental technologies using GMOs
- analysis of legislation and policies, including domestic and EU legislation and international agreements, regulating the utilisation of GMOs

4.4 Risk assessment and management of GMOs

The objective of an environmental risk assessment is, on a case-by-case basis, to identify and evaluate potential adverse effects either direct or indirect, immediate or delayed, on the environment and human health of the deliberately released GMOs. The environmental risk assessment should be conducted with a view to identifying whether there is a need for risk management and, if so, the most appropriate methods to be used.

- methods and theory of predictive risk assessment
- evaluation of risk management practices

5 Application procedure at the Academy of Finland

The Research Programme on Environmental, Societal and Health Effects of Genetically Modified Organisms (ESGEMO) is scheduled to run for four years during 2004–2007. The Programme will be carried out jointly by the Academy of Finland (Research Councils for Biosciences and Environment, Culture and Society, Health, and Natural Sciences and Engineering), the Ministry of Agriculture and Forestry, the Ministry of the Environment, and the Ministry of Social Affairs and Health. The Academy's Board has earmarked a total of EUR 3.5 million for the Programme for the years 2003–2007.

The application procedure involves two stages. In the first stage a **plan of intent** with appendices shall be prepared in English and submitted to the Academy of Finland Registrar's office **by Thursday, May 15, 2003.**

Plans of intent shall be prepared on the Academy of Finland application form SA 1.2003E, with the programme acronym ‘ESGEMO’ marked on the first page. The form shall be completed according to the instructions given, with the exception that only the following documents are to be appended:

- a research plan of no more than three pages in length (text size not smaller than 12 pts)
- a curriculum vitae of the project leader with maximum length of two pages
- list of some 20 most relevant publications of the project leader and senior researchers

The research plan shall briefly describe the following:

- objectives of the project
- links to the research themes of the Programme
- main research methods employed
- links with other research
- time schedule of the project
- international co-operation
- significance and applicability of the research results
- plans for researcher training
- tentative budget
- description of the competence of the research team

If the application is filed in the name of a consortium, the project leader shall complete one consortium application form and one joint research plan which shall, in addition to what is written above, indicate the added value achieved by the consortium. In addition, each subproject shall complete its own form with a set of appendices (a curriculum vitae of the project leader with maximum length of two pages and list of some 20 most relevant publications).

When a paper version of the application is used, all application documents and appendices shall be submitted to the Academy of Finland Registrar's office in 20 copies (original and 19 sets of copies). The application can also be submitted online at www.aka.fi/eng > Electronic services.

A programme steering group will review the plans of intent and submit its proposal on projects that will be invited to file full applications. The final decision rests with a subcommittee nominated by the Academy of Finland.

The project leader going through to the second application phase will be informed in writing of the subcommittee's decision no later than Friday, June 27, 2003.

Projects selected to the second phase of applications will be invited to submit **full applications by Monday, September 15, 2003**.

Full applications shall be prepared in English on the Academy of Finland form SA 1.2003E, completed with appendices as specified in the instructions attached. The maximum length of the research plan is 10 pages (text size not smaller than 12 pts). The plan shall indicate:

- objectives of the project
- links to the research themes of the Programme
- main research methods employed
- links with other research
- time schedule of the project
- international co-operation

- significance and applicability of the research results
- plans for researcher training
- budget proposal
- description of the competence of the research group

If the application is filed in the name of a consortium, the project leader shall complete one consortium application form and one joint research plan which shall, in addition to what is written above, indicate the added value achieved by the consortium. In addition, each subproject shall complete its own application form with the required appendices (excluding the research plan which is prepared jointly by the consortium).

All application documents and appendices shall be submitted to the Academy of Finland Registrar's office in 20 copies (original and 19 sets of copies). The application can also be submitted online at www.aka.fi/eng > Electronic services.

6 Evaluation criteria for applications

The following criteria will be used for funding decisions:

- compatibility of the research with the objectives of the call
- scientific quality
- competence of the applicant and the research team
- applicability and policy relevance of the research results
- multidisciplinarity
- national and international co-operation, and
- research and training environment.

7 International co-operation

In order to foster research collaboration and networking among scientists, the Academy is looking for funding co-operation and other forms of co-operation with international and national funding bodies.

8 Programme co-ordination

Interdisciplinary research as well as national and international networking of scientists are important goals of the Programme. In order to facilitate the achievement of these goals, the Academy has appointed a Programme Manager, Dr. Reetta Kettunen (email: reetta.kettunen@helsinki.fi, tel. +358 (0) 9 1915 9666). The tasks of the co-ordination are to:

- manage the Programme according to the objectives, goals and themes of the Programme and the guidelines of the steering group
- participate in the processing of the applications
- seek for and negotiate on national and international funding co-operation
- foster national and international networking of scientists and information exchange through organising seminars, workshops, symposia and production of information material

- report on the progress of the Programme

The Programme Manager works in close co-operation with the ESGEMO Programme steering group, which is directing the Programme.

The project leaders are expected to:

- provide information about the scientific and administrative progress of the project as required by the co-ordination or funding organisations
- participate and ensure participation of project members in meetings, seminars, workshops etc. organised by the co-ordination
- contribute to producing overviews, synthesis, information material and other Programme products
- take an active role in dissemination and publication of the programme progress and outcome in scientific and public fora

9 Evaluation of the Programme

After the end of the Programme, its implementation and results will be evaluated by an international panel. The evaluation will consider the following issues:

- fulfilment of the objectives of the Programme
- success of the Programme in general (co-ordination, common scenarios, foci, achievement of results, impact, integration of results and synthesis)
- achievement of results and possible impacts of projects by consortia and themes
- researcher training and promotion of research careers
- influence on scientific and/or social development
- national and international co-operation
- impact of the Programme on advancement in science and management

10 Additional information

The call for proposals for this Programme, the Programme Memorandum, application forms and the Academy of Finland Guide for Applicants are available at the Academy's website www.aka.fi/eng > Application info and in the Academy of Finland Registrar's Office where the applications are also to be submitted.

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