

**Statement of the
Society of Ecology (*Gesellschaft für Ökologie*), Germany
on**

**Scientific Risk Assessment and Monitoring
in the Context of the
Deliberate Release and Commercial Application
of Genetically Engineered Organisms**

**passed and adopted on 15 September, 1999, Bayreuth,
by the General Assembly
of the Society of Ecology, Germany, at its 29th Annual Meeting**

Introduction

The deliberate release and commercial application of genetically engineered organisms (GEOs) is currently a controversial matter of debate in our society. This debate necessitates the participation of those scientists who specialize in ecological research, together with the organizations to which they belong. As early as 1989, the Ecological Society of America (Tiedje et al., 1989) published a position paper outlining the ecological hazards posed by the deliberate release of GEOs:

- the development of resistance in pests insect to transgenic toxins, and
- the unintentional spread and establishment of weeds following introgression of transgenic traits.

Since 1991, the Society of Ecology, Germany (*Gesellschaft für Ökologie*, GfÖ), together with scientists from other fields and representatives from both industry and administration, has included the identification and evaluation of the environmental impacts of GEOs on the agendas of its annual meetings and has established a working group to consider the issue further. Special attention is being paid to potential, undesirable and not immediately evident side effects in ecological systems.

The GfÖ holds that it is necessary to outline, review and evaluate the current state of scientific knowledge and scope of research on the ecological impacts of GEOs in order to formulate recommendations for further research and monitoring concepts. In this context, an examination of the extent to which the use of GEOs is in compliance with the principle of sustainability is essential. At its General Assembly in September 1995, the GfÖ adopted the resolution "Sustainable Development – Challenges for Ecological Research", which addresses central issues to be considered in assessing gene technology with respect to sustainability.

The Current Situation

To date, 444 sites have been approved for deliberate releases in Germany. According to information from the responsible German authority, the Robert-Koch Institute (as of Sept. 1999: <http://www.rki.de>), the EU has to date granted 18 market approvals for GEOs.

Owing to the novel combination of isolated genes that overcomes natural reproductive or recombinatory barriers, GEOs possess a new evolutionary quality (SRU, 1998). Moreover, the transition from short-term, small-scale deliberate releases to long-term, large-scale commercial applications raises new questions concerning the quantitative and qualitative ecological impacts of GEOs. This transition highlights other, more far-reaching ecological interactions that must also be addressed:

- evolution and breakthrough resistance phenomena,
- a development of secondary pests, and
- an increase in population numbers to attain a critical level for the initiation of invasive processes.

The advances that have been made in the development and application of genetic engineering during recent years have not been accompanied by a complementary increase in the scope of risk assessment research. Consequently, there are many ecological questions that remain unanswered. In comparison with the increase of GEO field trials, appropriate research efforts with respect to ecological risks have been sadly neglected.

In the light of the continuing uncertainty over the impacts of the release of transgenes into the environment, several EU member states (France, Austria, Luxembourg, Greece and Denmark) have, as a precautionary measure, decided on bans or moratoria for commercial planting and/or the importation of specific genetically engineered plants, products or seeds.

The need for restrictions on deliberate releases of GEOs at their centres of origin and the protection of biological diversity has been repeatedly raised in negotiations for an International Biosafety Protocol to be submitted to the UN Convention on Biological Diversity. The Draft Protocol on Biosafety acknowledges the crucial importance of these centres (UNEP, 1999).

Assessment of Ecological Impacts

The currently available risk assessments applicable to deliberate releases of GEOs show serious shortcomings. There is a lack of inventories and analyses in the following areas:

- dynamic processes in plant and animal diversity;
- dynamic processes in biogeochemical cycles;
- feedback effects within biocoenoses and ecosystems;
- the specific impact of traits introduced by genetic engineering, e.g., resistance to pests, diseases or abiotic stress factors on biocoenoses and ecosystems; and
- changes in agricultural methods linked to the application of GEOs and the resulting indirect ecological impacts.

Risk assessment in the form currently employed by leading authorities is far from adequate for appropriately addressing the scope and complexity of the problems outlined above. Owing to the numerous unanswered questions, current risk assessment is based on a vaguely defined concept of damages and hazards that nevertheless forms the basis of evaluation, as required under current legislation, of the purpose of, and justification for releases into the environment (Winter et al., 1998). In this context, the German Advisory Council on Global Change (WBGU, 1999) has called for the establishment of the necessary consensus within society and in Parliament.

Evaluations of the environmental impacts of GEOs are faced with the following dilemma: while it is possible to describe and analyse the short- and medium-term intentional effects of GEOs and their products, the long-term ecological impacts do not lend themselves to an analysis that yields quick and reliable scientific results. This applies all the more to the unavoidable, yet unpredictable side effects of the engineered modification.

Basic knowledge on the potential invasiveness and persistence of organisms in general, and of GEOs in particular, is still lacking. The precautionary principle adopted by the EU member states, as described above, makes it mandatory that efforts be made both prior to and during releases to combat our lack of scientific knowledge effectively. Here, a 'precautionary principle' not only aims at an avoidance of known, defined and roughly predictable undesirable impacts, but also implies the development of strategies for dealing with uncertainties. There is a need for assessment methods, procedures and criteria that can serve as early warning systems.

In this context, the principles and aims of environmental protection and nature conservation are of particular importance (e.g., protection of flora and fauna, productivity of natural processes and biodiversity, as stipulated by Article 1 of the German *Bundesnaturschutzgesetz* [Federal Nature Conservation Law]). The GfÖ considers it essential that these principles and objectives be strictly applied for deliberate releases and the planned commercial application of transgenic crops.

A Call for Action

- Ecological expertise must play a greater role, since central ecological research issues are addressed, i.e., the study, assessment and evaluation of environmental impacts, as well as the definition and evaluation of ecological risks posed by the use of GEOs.
- Expertise in ecosystemic approaches and population ecology, currently still neglected, must be given equal standing to expertise in molecular biology. The same applies to the integration of ecological modelling and theoretical development in applied, problem-orientated, experimental risk research projects.
- These are essential prerequisites for the development of long-term monitoring programmes, which must become an integral part of all commercial uses of GEOs.
- All risk assessment and monitoring activities should be co-ordinated by a new agency, the Central Agency for the Monitoring of GEOs, a demand voiced by the Conference of Ministers of the Environment and the German Council of Environmental Advisors (SRU, 1998).
- The identified gaps in our knowledge unavoidably lead us to the conclusion that case-by-case assessments are essential for every deliberate release and market placement. In parallel, a step-by-step procedure must be applied to ensure that the gradually increasing exposure of the environment to GEOs will only be maintained in the absence of unintentional effects.
- Moreover, it must also be possible to impose additional safety measures as preconditions for approval. These include risk assessments with a specific focus, accompanying studies, restrictions on approvals with respect to time and place, and effective monitoring.
- Ecological, ecotoxicological and health criteria must already be incorporated into risk assessment procedures at the stage of laboratory research and greenhouse experiments.
- Where undesirable effects are detected, there must be legal procedures and administrative structures in place to ensure that approval may be withdrawn at any stage of the evaluation procedure.
- Two specific problem areas have been identified that urgently need to be addressed:
 - GEOs containing resistance genes to antibiotics that are relevant for medical purposes, and
 - GEOs that have wild relatives in the vicinity of intentional or unintentional distribution.

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