

## **Environmental Report 2004**

### **Ensuring Environmental Protection Capacity**

Chap. 10 Genetic Engineering  
of the Summary

## German Advisory Council on the Environment (SRU)

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## 10 Genetic Engineering

**119.\*** As a result of a number of new EU regulations entering into force, the impending revision of the German Genetic Engineering Act and the foreseeable end of the de facto moratorium on approving new genetically modified organisms (GMOs) in the EU, the development of future uses of “green” genetic engineering will be greatly influenced. The Environmental Council deems the manner in which the stage is set in this context to be of great importance for the future of agricultural land use. Thus, in the following, the Environmental Council attempts to comprehensively describe the various aspects of the controversy surrounding “green” genetic engineering, and to direct the reader’s attention to the most pressing problems. This involves giving the controversy a slightly new focus, since a survey of the controversy has demonstrated that the most important open questions and the greatest risks, given the current state of knowledge, have less to do with human health than with impairment of the environment and impairment of non- GMO-based agriculture, especially organic farming.

### Potential Benefits

**120.\*** “Green” genetic engineering offers a broad spectrum of potential benefits, for example, the potential to increase the efficiency of agricultural production, the potential to reduce environmental burdens and the potential to improve the properties of foodstuffs. In particular, in addition to the herbicide- and insect-resistant GMOs already in widespread use, it offers the potential to produce very high-yield, disease-resistant organisms or organisms that are particularly adapted to unfavourable environmental conditions, to produce health-promoting foodstuffs and even to produce pharmaceuticals in genetically modified plants. For many of the potential applications still being developed, it is, however, still not possible to say when they will be marketable and what risks they will pose. Further, one has to take into account that many of the benefits being aimed at could also be achieved using means other than “green” genetic engineering.

### Categorical Objections

**121.\*** Often the use of “green” genetic engineering is rejected categorically, i.e., on principle. The Environmental Council argues that the rejection of “green” genetic engineering based on categorical arguments is merely a matter of personal worldview. When such categorical rejection is widespread, consumer protection policy has to take this adequately into account by requiring that products containing genetically modified material are labelled to this effect. Categorical arguments against “green” genetic engineering do not, however, give acceptable reason to establish legal restrictions. Rather, risk and impact assessments have to be the deciding factors.

## Health Risks

**122.\*** The ingestion of foodstuffs that contain genetically modified proteins can pose a health risk for humans. There is particular concern that toxic substances or allergens could occur in foodstuffs. Further, it is thought that microorganisms could gain selection advantages as a result of horizontal gene transfer and that this could lead to multiple resistance or new pathogens.

As regards controlling the quality of conventional foodstuffs and foodstuffs containing genetically modified materials, the Directive on the Deliberate Release of GMOs into the Environment (2001/18/EC – Deliberate Release Directive) prescribes a risk assessment and risk management scheme which is to be used to help detect potential health risks. Using relevant studies and experience gained in the food inspection sector, risk assessment methods have been developed whose application has led to the finding that the risks for human health are negligible. In spite of the fact that some methodological weaknesses remain and in spite of the fact that there are still some open questions, the Environmental Council is of the opinion that, based on the current state of knowledge, good food safety control is adequately ensured.

No final assessment can be made about the potential risks posed by products (functional foods and pharmaceuticals) stemming from second and third generation genetically modified plants. The Environmental Council is of the opinion that, with regard to the development of so-called functional foods, their benefits must be assessed individually and a differentiation between health-promoting and therapeutic effects must be made. The Environmental Council has reservations about the planned cropping of plants that produce pharmaceuticals which are then to be administered to patients. It is of the opinion that such plants can only be grown under controlled conditions and, furthermore, that it is imperative to conduct clinical tests of such pharmaceuticals to determine required dosages and, because there may be fluctuations in the expression of active agents, to continually monitor the proportion of active agents in such pharmaceuticals.

## Ecological Risks

**123.\*** Currently, there are great uncertainties as concerns ecological risks. These uncertainties are the result not only of the fact that there is a lack of reliable data but also the fact that natural systems are extremely complex. Lag phases in such systems, trigger effects (the occurrence of an impact only under particular conditions, such as under extreme weather conditions), and the ability of organisms to self-reproduce are examples of relevant factors. Decisions should thus always be based on the precautionary principle. Dealing carefully with GMOs requires that the environmental

impacts be assessed both before and after GMOs are released. As regards this, there are, however, far-reaching methodological deficits.

The Environmental Council recommends using an asset-related approach in defining ecological damage. Using this approach, valuable environmental assets should be understood to be biological diversity as specified by the CBD and the assets specified by Article 1 of the Genetic Engineering Act and articles 1 and 2 of the Federal Nature Conservation Act. With reference to the definition of ecological damage that the Environmental Council suggested in 1987, it suggests here that deviations from the natural range of variation (deviations that often manifest themselves only over long periods of time) should be the focus of attention when identifying ecological damage. Thus, changes that go beyond the natural range of variation for a particular asset of value would be considered indicators of damage to that asset and to the whole of the system of interactions in that asset's ecosystem. When this is the case, long-term studies would have to be used to determine the damage that has actually occurred.

Further, thresholds would have to be established below which ecological damage would have to be accepted. The marketing of GMOs would be prohibited only if these thresholds are exceeded. Such thresholds could only be determined politically. The Environmental Council recommends that, in addition to using deviations from the natural range of variation, the following criteria be used when establishing thresholds: the potential of a GMO to disperse, transgenic characteristics and the protection status of the assets concerned. The Environmental Council's concept for identifying and assessing ecological damage should be further developed expeditiously and made usable for the purpose of implementing monitoring. The basic prerequisite for assessing ecological damage is having baselines and GMO free reference areas. The Environmental Council thus deems the designation of such areas, in conjunction with commencing basic monitoring immediately, to be a priority task. The designation of such areas should take place within the framework of a national landscape concept.

#### Impairment of Non-GMO-based Agriculture

**124.\*** It is to be expected that farmers engaged in non-GMO-based agriculture might be disadvantaged by the use of "green" genetic engineering. Their production methods might be impaired (e.g., by the development of resistances in pest insects) and their ability to market their products might be lessened as a result of their products being contaminated with genetically modified material. Organic farming, whose regulations prohibit the use of "green" genetic engineering, will be particularly affected by the latter problem. Although numerous measures can be taken to minimize the above-mentioned impairments, they will surely not be able to prevent them completely.

It follows from the fact that farmers have a legitimate right to be able to produce non-GMO products and from the principle that consumers should have freedom of choice that organic farming needs to be protected. Above all, however, it particularly needs to be protected because it is the best type of agriculture as regards ecological sustainability and because it is, for this reason, a declared objective of the federal government to increase the proportion of organic farming to 20% by 2010. This all requires that the coexistence of GMO based and non GMO based farming must be ensured. In order to secure the continued existence of non-GMO-based farming and especially organic farming, specific good agricultural practice regulations are needed, first of all, to prevent cross-pollination and the adventitious presence of genetically modified material in non-GMO crops. The production of organic seed requires special protection.

The preferability of organic farming from the point of view of sustainability speaks for considering the users of “green” genetic engineering responsible for the damage which is to be expected. Accordingly, it would seem appropriate and necessary to allocate, in accordance with the polluter pays principle, the high transaction costs (e.g., for crop location registers, monitoring, analyses) and liability risks which “green” genetic engineering is likely to cause to its users, even when doing so means that in particular cases the introduction of this technology will thus be rendered economically unattractive. The details of any scheme to allocate costs should thus be explained as soon as possible. As regards the liability of the users of “green” genetic engineering, the Environmental Council considers the strict liability (“Gefährdungshaftung”) provided for in the revised version of the Genetic Engineering Act to be the best solution in spite of its having some disadvantages.

#### Development of Legal Community Framework

**125.\*** The EU has further developed the legal framework for the use of “green” genetic engineering in recent years to a great extent, with the objective of ending the de facto moratorium by establishing new approval basics for the release and placing on the market of GMOs and, at the same time, with the objective of preventing any further world trade law conflicts. The Deliberate Release Directive (2001/18/EC) regulates the approval and monitoring of releases of GMOs and distinguishes between procedures and competences primarily according to whether the purpose of release is to market a GMO or is merely experimental. Whereas the directive provides that approval for placing GMOs on the market will require comprehensive coordination with the member countries and that the Commission has the final decision-making competence, national authorities will remain largely responsible for approving and monitoring local release experiments. The Regulation on Genetically Modified Food and Feed (1829/2003/EC) introduced a largely centralized approval procedure for placing genetically modified

food and feed on the market. According to this procedure, a committee which assists the Commission (and which consists of representatives of the member countries) decides on whether to grant approval after consulting with the European Food Safety Authority. All agricultural products that are to be marketed as food or feed or that are to be used to produce food or feed are subject to this centralized procedure. The only thing left to the members countries to do in this area is participate in the European procedure. They do, however, remain responsible for certain supervision and monitoring activities.

Now that EU has finished regulating the use of genetic engineering (for the time being), the end of the de facto moratorium should be near and it is to be expected that “green” genetic engineering will be used in the EU as early as 2005. In spite of the above-mentioned EU legislation, however, the legal and administrative framework for “safe” approval and supervision in practice is nowhere near being finished. Rather, considerable specification and implementation are still necessary, at least at the national level. With regard to the approval procedure and the environmental and safety assessments contained therein, this is especially the case as concerns the legal criteria for the release and the placing on the market of GMOs, i.e., as concerns the central question as to what effects a GMO may have on the environment or human health that should be considered harmful and unacceptable and should thus speak against granting approval, or if approval has already been granted, speak for rescinding approval and stopping the release. This crucial question, which given the heavily Euro-centralized nature of the approval procedure actually requires a uniform Community answer, now has to be answered, at least for the time being, by the member countries, since no further regulations are to be expected from the EU for some time. Further, member countries will have to implement supervision (or monitoring) and enforcement on their own, as this has been left completely incumbent upon on them. Finally, European law does not address the problem of how GMO-based and non-GMO-based agriculture are to coexist.

Thus, national solutions will also have to be found for, and regulations established pertaining to, this problem so central to using “green” genetic engineering. On the whole, there is considerable need to adjust and supplement national genetic engineering legislation.

### Revising National Genetic Engineering Legislation

**126.\*** In order to address the above-mentioned need to change national genetic engineering legislation, the federal government has submitted a draft bill for a law on revising genetic engineering legislation which makes some welcome proposals and some less welcome proposals with regard to the above-mentioned implementation

problems. One central weakness in the bill is that it also does not specify any enforceable legal approval criteria as regards the effects of GMOs on the environment and human health, but rather merely provides for an empowering ordinance which leaves it to the discretion of the federal government to specify more closely which effects and effect mechanisms of a GMO are to be considered harmful and not tolerable. Without concrete risk assessment criteria, there can be no uniformly enforceable protection, or precautionary, approval standards. There are also no references that would allow enforcement of general monitoring and individual case monitoring. As concerns this, the Environmental Council recommends that a requirement to issue an ordinance that closely specifies approval criteria be added to the empowering ordinance, and that, accordingly, action-related risk assessment criteria be established as quickly as possible.

The Environmental Council is cognizant of the fact that, in a centralized approval system based largely on European legislation, the national assessment criteria recommended above will have to assimilate to, or make room for, European criteria sooner or later. Nevertheless, as long as there are no European criteria, national specifications of risk and harm thresholds to be used in granting approval and conducting monitoring will be essential in order ensure a minimum level of protection and precaution. Further, given the centralized nature of the approval system, special attention should be given to seeing to it that national interests are adequately included in the European decision-making process by having the competent national authorities participate in a suitable manner.

The Environment Council largely welcomes the draft bill's provisions for dealing with the coexistence problem, but would like to point out that provisions pertaining to the use of good agricultural practice as a precautionary measure against cross-pollination and contamination need to be more closely specified. The Environmental Council sees the liability provisions contained in the draft bill as a substantial step towards a fair liability regime that promotes coexistence. In particular, the Environmental Council deems it justifiable and appropriate to introduce strict liability for damage caused by the users of GMOs to their neighbouring farmers, but to restrict this liability to contamination levels that exceed the labelling threshold. The bill's provision for holding several possible "contaminators" jointly liable is, in the opinion of the Environmental Council, an appropriate distribution of the burden of proof.

## Labelling

**127.** EU regulations 1829/2003/EC and 1830/2003/EC regulate the labelling and traceability of GMOs. The labelling requirement applies to all genetically modified plants, all products that contain GMOs and all products made using GMOs but that do

not contain detectable amounts of genetically modified material. Regulation 1830/2003/EC specifies a threshold of 0.9% for GMOs in products that have been unavoidably contaminated. The Environmental Council recognizes the principle of consumer sovereignty and thus also the consumer's right to freedom of choice. The labelling requirement takes this freedom into account, albeit with a compromise, since unavoidably contaminated products are not required to be labelled as containing genetically modified material until the threshold of 0.9% is reached. Contamination is probably virtually impossible to prevent. This compromise will probably cause acceptance problems for organic farming, because a product labelled as containing genetically modified material is probably not saleable, in spite of the fact that it was not purposely contaminated. Nevertheless, the Environmental Council does not see any alternative to this pragmatic solution of setting a more or less arbitrary de minimis threshold. It is to be feared, however, that should "green" genetic engineering be used on a large scale, the threshold will be exceeded so often that label declarations will become meaningless. The threshold would then have to be adjusted to the actual situation. Thus, it is worth considering whether labelling requirements should not be based more on whether the use of genetically modified material is deliberate. It would be possible, for example, to declare the proportion of genetically modified material in a particular product while also declaring whether "green" genetic engineering was intentionally used in producing the product.

**128.\*** So far, the only proposal for a Seed Directive is SANCO/1542/2000 Rev. 4. In this proposal, various thresholds are established for seeds, whereby these thresholds lie above the detection thresholds. Since seed contamination stemming from the replication of genetic information during cropping is to be viewed more critically than the contamination of foodstuffs, the Environmental Council recommends that the federal government continue to try to have a threshold established which is based on the detection threshold.

### Monitoring

**129.\*** The monitoring (and its concomitant crop registers) provided for by the Deliberate Release Directive consists of general surveillance and so-called case-specific monitoring whose requirements are to be determined by previously conducted environmental impact assessments. The purpose of this monitoring is to ensure that ecological damage is detected as early as possible and thus to make it possible to initiate countermeasures as soon as possible. The data collected by means of monitoring are to be passed on to a special central agency where they will be assessed. The Environmental Council deems this system to be useful and necessary to minimize potential environmental risks. However, the monitoring requirements should be specified more closely. The methods for general supervision and case-

specific monitoring also definitely need to be standardized so that their data will be comparable. Well-chosen case-specific criteria and parameters should be established that can detect ecological damage with a high degree of accuracy and thus contribute to avoiding undirected detection costs.

The national coordination authority and the national crop register need, in the opinion of the Environmental Council, a counterpart at the European level if approvals are to be regulated Europe-wide by the European Food Safety Authority.

### Summary Recommendations

**130.\*** As explicated above, the Environment Council is of the opinion that there are good reasons that make comprehensive regulation of “green” genetic engineering necessary. The Environmental Council, taking the precautionary principle into account, is of the opinion that, in addition to the European regulations, or the particular implementation thereof, the following regulatory measures are appropriate and necessary to take account of these reasons:

- the expeditious implementation of monitoring and assessment of the current reference situation,
- the development of an enforceable damage definition to be used in approving or stopping the release and placing on the market of GMOs,
- the establishment of good agricultural practice standards for GMO cropping,
- the timely and transparent distribution, in accordance with the polluter pays principle, of all costs incurred by monitoring and measures taken to prevent contamination,
- the introduction of strict liability for damage caused by the users of “green” genetic engineering,
- the establishment of a requirement to label seeds such that each and every contamination that exceeds the detection threshold is declared.

**131.\*** The Environmental Council estimates that the regulatory effort (transaction costs) involved in introducing “green” genetic engineering will be considerable. Careful and forward-looking regulation is an essential basis for legitimizing the use of this technology. The potential benefits of this effort also have to be seen variously. In certain areas (efficiency increases in agricultural production, functional food, pharmaceuticals production) considerable benefits seem possible. However, exaggerated expectations (considerable reduction of environmental burdens, lower consumer prices) need to be seen in a more realistic light. When the risks and benefits of introducing this technology in Germany and the EU are weighed up, as is often

called for, the conclusion is not entirely in favour of “green” genetic engineering. The Environmental Council is of the opinion that this technology, which cannot be rejected categorically but for which there is also no pressing need, is not entirely desirable, especially in the context of the ecologization of land use. Overall assessments of this type are necessarily tentative. They can, however, be revised as a result of changes in the information basis or especially as a result of longer term experience with the technology if such changes or experience give rise to a new assessment of the risks involved or if it becomes possible to develop genetically modified plants that allow a true synthesis of ecological agriculture and modern genetic engineering.