> Biosafety in non-human gene technology

Results of the research programme 2004–2008

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> Summary

Starting point and mandate

The Gene Technology Act of 21 March 2003 stipulates that safety measures be taken when releasing genetically modified organisms.

However, the scientific bases for implementing the statutory provisions are insufficient, according to the theses of the Swiss Academy of Sciences (SCNAT) of May 2001. Numerous public surveys confirm that also non-scientists feel the need for more research. Genetically modified plants (GMPs), which are already cultivated on a large scale in other countries, particularly outside Europe, are a matter of public concern in Europe. In Switzerland, this led to a federal referendum in 2005 and to the decision for a moratorium on the commercial cultivation of genetically modified plants. This moratorium will remain in force until 2010.

In order to provide a scientific foundation for the statutory safety requirements, in 2003 the Federal Office for the Environment (FOEN) launched a four-year research programme entitled "Biosafety in non-human gene technology".

The research priorities were four topics and aspects for which relatively few or only unsatisfactory data are so far available.

The research priorities and their findings

Research priority:
Early detection of unexpected and long-term environmental impacts

Research priority 1 focused on the early detection of unexpected and long-term environmental impacts of genetically modified organisms (GMOs).

Two research projects were carried out within this research priority. In the first, *Methodological bases for the long-term monitoring of GMOs: protection goals – indicators – survey methods*, the protection targets were first listed, analysed and described from a legal point of view using existing legal texts. In the second part of the project, *Diabrotica*- and glyphosate-resistant maize and *Phytophthora*-resistant potatoes were selected as models. For each model plant, hypothetical scenarios were drawn up of undesired or adverse environmental impacts that could impair the protection targets formulated and set down in the law. These scenarios were then used to derive the indicators and survey methods (monitoring protocols), that might be used for early recognition of possible harmful impacts, including an estimate of cost.

The second project of this Research priority, Environmental monitoring of commercial Bt-maize crops – Approaches to detecting potential effects on butterflies and beneficial organisms, investigated how environmental monitoring should be designed to detect changes in biodiversity or number of individuals in butterfly populations, or in the biodiversity of beneficial organisms. Behind this investigation lay concerns that the

insecticide protein in Bt-maize might be toxic not just to corn borer larvae, but to butterflies and beneficial organisms as well. When designing environmental monitoring for butterflies it was shown that butterfly populations and their biodiversity display a natural spatial and temporal variability. Only in exceptional cases can this variability be attributed to particular agricultural practices or climatic factors. In most cases, the reasons for the fluctuations are unknown, or they are known to result from the sum of different factors. Any possible impact of GMPs on biodiversity could therefore be proved definitively only with great effort, and only if the changes are relatively large (over 30 %). Although a statistical correlation between cultivation of GMPs and changes in biodiversity would then have been demonstrated, a causal relationship would not have been proven. In view of the major effort required and the modest scientific value of the data obtained from the environmental monitoring of butterflies, the authors therefore conclude that risk assessment should be prioritised over environmental monitoring of cultivation. Should significant scientific uncertainty still remain after this extended study has been completed, a case-related monitoring might be indicated in order to test a plausible hypothesis (according to the EU legislation).

The second part of this project focused on the issue of suitable monitoring of beneficial organisms. The available results of the risk assessment (before marketing) do not provide a grounding for the hypothesis of the influence of Bt-maize on beneficial organisms that is scientifically sound enough to justify case-specific monitoring. As an alternative, the authors therefore propose monitoring the beneficial organism's ecological functions, i.e. natural pest control, as part of general surveillance (according to the EU legislation). These observations would be carried out by the farmers cultivating the GM maize and by plant protection services. Such surveillance methods are already being employed in the EU.

Research priority:
Analysis of ethical issues in risk assessment in biotechnology

Research priority 2 was devoted to analysing ethical issues of risk assessment. This research priority concentrated on making comprehensive overall risk assessments of GMOs that supplemented the perspective of the natural sciences.

The project was divided into two subprojects. The first, *Ethical risk assessment*, defined terms and drew up criteria to be used when making decisions in connection with ethical risk assessment. Independently of biotechnological issues, the study considered which risks are acceptable and which not, identifying the concept of threshold value as the single applicable criterion for decision-making when dealing with risk. An anticipated value is determined, based on the probability of damage and the anticipated extent of the damage. Only if this anticipated value lies below the threshold may a risk be taken.

The other subproject, *Significance of the damage definition for the risk assessment of GMOs*, investigated the role played by the definition of damage itself in risk assessment. It has been determined that the assessment of risk is based on two estimates: that of the value of the natural resource and that of the desired state. Damage occurs if a defined degree of deviation from the desired state of the natural resources to be protected is reached or exceeded. Here, in order to derive the criteria for risk assessment, the risks considered in three case studies were entered in a risk matrix. When both the

extent of the damage and the probability that it will occur can be estimated empirically, the risk can be presented quantitatively

The application of the criteria developed in the two subprojects proved to be difficult, particularly to cases taken from plant gene technology. The reason for this is that knowledge of both the extent of the damage and the probability that it will occur are needed for ethical risk assessment.

Research priority 3 focused on the risks to the soil ecosystem.

Research priority:
Risks to the soil ecosystem

Two research projects focused on this research priority. The first project, Burden on the soil ecosystem of natural and genetically modified organisms – effects, methods and definition of damage as a contribution to risk assessment, defined possible effects of biological pollution on the soil, collated methods for recording these effects and criteria for assessing the suitability of these methods, developed a procedure for selecting effect-related methods for the risk assessment of these organisms, and defined under which conditions a change represented damage to the soil. The project is subdivided into four modules. Module 1 contains the theoretical aspects, including work based on the evaluation of international strategies for determining soil quality, and an overview of the literature on GMOs and introduced organisms. Modules 2 and 3 put into practice the procedure drawn up for selecting effect-related methods, both in a model experiment in the greenhouse and in a field trial. The model experiment employed Pseudomonas fluorescens strain CHA0, and the field trial the bacterial product "Effective microorganisms". Module 4 contains the synthesis of modules 1 to 3.

The procedure developed in module 1 has proved to be suitable for recording possible effects of biological pollution on the soil ecosystem. Based on the criteria given by the definition of damage, neither experiment has been able to determine any changes in soil properties or functions indicating damage to the soil.

The second project, *Degradability of Bt-maize in the soil and impacts on earthworms and other soil macroorganisms*, investigated the degradation in the field of plant residue of various transgenic maize varieties containing the insecticide *Bt* protein and non-transgenic varieties. Differences in the speed of degradation were found only between different varieties, irrespective of their genetic modification. In the laboratory, the effect of the *Bt* toxin on various soil organisms such as earthworms, snails and fly larvae was investigated further. The organisms selected were followed for up to four generations, to determine longer-term effects and effects on fertility. Under the conditions investigated, no difference between genetically modified and conventional maize varieties could be detected. The study therefore concludes that there is no increased ecological risk to the soil from these transgenic maize varieties. By investigating soil organisms this second project forms a bridge to the fourth research priority, which studies possible impacts on non-target organisms.

Research priority:
Risks for non-target organisms

With a total of three projects, *Research priority 4* studied possible impacts of GMPs on non-target organisms. These projects investigated the influence of different genetically modified plants on organisms for which few or no studies are yet available in this connection.

The first project, *Impacts of transgenic plants on solitary bees*, studied wild bees. The effect of insect-resistant plants on honey bees has been investigated many times, but not the effect on wild bees, although these are indispensable for the fertilisation of countless flowering plants, including many crops. Bee larvae were fed with pollen mixed with three different proteins (OC-1, Cry1Ab and GNA). The influence of the transgenic plants was tested on the adult animals. Finally, the study considered whether honeydew from GMPs could represent a possible source of pollution for the animals that occasionally feed on it.

This study concludes that adverse effects of the transgenic plants on the stocks of wild bees tested can be practically excluded. The test procedures developed in this project can be applied to novel transgenic insect-resistant plants in the future.

The second project, *Impacts of transgenes that confer increased resistance to pathogens on the interactions of rice with symbiotic fungi*, considered the important question of whether resistance to pathogenic fungi can also hinder the interaction with symbiotic underground mycorrhiza. In the example selected, no difference between the genetically modified rice plants and their corresponding non-transgenic controls was detected. It was found that resistance to blast disease pathogen, inserted by gene technology, is ineffective in the plant roots: the roots of blast disease-resistant rice can be colonised by mycorrhiza, just like the controls. Thus the resistance mechanism of the specific genetically modified rice variety is no barrier to colonisation with the beneficial mycorrhiza fungi. The question of whether active resistance to pathogenic fungi in roots can also influence interaction with beneficial mycorrhiza remains open, and will therefore be integrated into the corresponding risk assessment.

A third project, *Influence of transgenesis on plant-insect relationships in the apple system, particularly on semiochemical interactions*, investigated the influence of scab resistance on the apple tentiform leafminer and on ichneumon wasps, which are attracted to the apple leaves by specific scents. In the cultivar "Florina", resistance to the scab-causing fungus is given by the *HcrVf2* gene. This was inserted into the cultivar "Gala" using transgenesis. Four varieties of apple were compared: the classic cultivars "Florina" and "Gala", and the transgenic "Gala" varieties with and without *HcrVf2*. In this case, too, the detection method developed proved to be sensitive and applicable to further investigations. In the case studies, differences between the cultivars could be determined, but showed no dependency on genetic modification.

The results of this research programme were presented to the public and discussed in a workshop on 17 June 2008.