TEXTE 45/01

EU-Workshop:
Monitoring of Environ-mental Impacts of Genetically Modified

A EU-Workshop of the German Federal Environmental Agency

9th and 10th November, Berlin

Summary

The German Federal Environmental Agency had commissioned the Federal Environment Agency of Austria to organise the EU-Workshop "Monitoring of Environmental Impacts of Genetically Modified Plants" taking specifically into account Annex VII of the amendment to the EU-Directive 90/220/EEC. The European Commission (DG Environment) as well as the German Ministry for Environment, Nature Conservation and Nuclear Safety financially supported the workshop, which was held in Berlin on the 9th and 10th of November 2000. In total 103 people from 17 different countries took part in the Workshop, among which there were representatives of the Competent Authorities of the EU-Member States, representatives of the European Commission and of industry as well as scientists from different disciplines. Meanwhile the EU-Parliament and the EU-Council have adopted the new directive 2001/18/EC regulating the deliberate release of genetically modified organisms in the EU and thus - in acknowledgement of the limitations of pre-release risk-assessment – have introduced mandatory post-release monitoring.

The main goal of the workshop was to initiate a discussion on how monitoring of GMOs should be - or can be – implemented. Monitoring shall help to detect in an early stage possible "direct", "indirect", "immediate" and "delayed" effects resulting from the deliberate release of GMOs into the environment, but there is still no consensus on the scope, the methods and the duration of such monitoring programmes. Since the term "monitoring", but also other terms in this field (e.g. general surveillance) are still subject to various interpretations, it was also necessary to deal with definitions. Moreover the intention of the workshop was an exchange of experience on monitoring projects already conducted in some of the Member States and an exchange of views on monitoring concepts developed so far.

In the first block of the workshop a short overview of the situation in the CEE countries Poland and Hungary was given concerning the adaptation of national legislation to European laws on biotechnology and their views on monitoring. France and the UK, which both have already gained some practical experience from monitoring projects conducted on a nation-wide scale, presented their monitoring concepts. In both countries committees dealing with questions of monitoring (protocols, methods and evaluation) have been constituted and various surveys are being carried out on specific questions relating to their monitoring projects. In addition,

data from Italian experiments with transgenic tomatoes and Bt-maize were provided. In Germany two monitoring concepts are being elaborated, one focusing more broadly on environmental effects of GMOs, the other on specific effects on the agricultural ecosystem. Moreover a list of priorities has been set up, in which transgenic plants are listed according to their status in placing on the market and their potential for ecological effects, to identify the focus of future monitoring programmes.

Two case studies were presented, one on Bt-maize in France and one on genetically modified herbicide tolerant (GMHT) crops, especially glufosinate-tolerant oil seed rape, in the UK. Within the cropping system of Bt-maize the question of resistance development is prevalent. An approach to address this risk is the application of the high dose/refuge model for resistance management in the case of one generation of corn borers (*Ostrinia nubilalis*) per year. Nevertheless data showing possible effects on non-target insects are rare and usually neglect effects of the interaction between the Bt-toxin, the plant and the herbivore. In tri-trophic feeding trials a significant prey-mediated effect of Bt on carnivores could be observed, which cannot be detected with direct feeding studies. So there are still more experiments necessary to elucidate effects on non-target organisms.

In the UK there is great concern that the recent decline in farmland wildlife due to the intensification of agricultural production could increase further with the introduction of GMHT crops. Therefore a three years programme (Farm Scale Evaluation Programme) has been implemented to assess the effects of the novel herbicide management regime associated with these crops on farmland wildlife.

Furthermore the Swiss Biodiversity monitoring programme (BDM) has been presented and commented, in order to show what can be learned from existing non-GMO monitoring programmes. In particular, the importance of clearly defined objectives, a result-oriented approach, compatibility with existing observation programmes and tests for the reliability of results were stressed.

As consistent definitions are a substantial prerequisite for the clarification of responsibilities and financing issues in connection with a widely accepted monitoring programme, the Federal Environmental Agency of Germany suggested definitions for the terms “biosafety risk research” and “release-related biosafety research” applicable to specific deliberate releases according to part B, and “case-specific monitoring” and “general surveillance” applicable for approvals for placing on the market (Part C and Annex VII of directive 2001/18/EC).

Throughout the discussions it became clear that various issues regarding the design and the methodology of monitoring programmes need further clarification. If the aim of monitoring programmes is the early recognition of damage and the application of measures based on discontinuance criteria, it is indispensable to define ecological damage. For this leading principles (such as sustainability) and protection aims need to be developed further and need to be given the appropriate significance. Moreover interdisciplinary discussions and clear political decisions will be crucial. In various presentations questions about the baseline for comparison, the suitability of indicators and the temporal and spatial extension of monitoring programmes were raised. Taking into account the dynamics of ecosystems it will be difficult to distinguish effects caused by GMOs clearly from effects caused by other developments (e.g. intensification of agricultural practices). Above all there is a common understanding about the need for further research concerning ecological risks, because of the possible long-term and scale-dependant effects of transgenic plants.

The organisers recommended that the results of this Workshop should be channelled into the development of Guidance Notes as laid down in Annex VII of the of EU Directive 2001/18/EC. This should be done very quickly in Working Groups by the European Commission and the Member States as they have to be developed until summer 2002. Moreover it was stated that the focus should be on the post-marketing monitoring according to part C of the Directive 2001/18/EC and the following definitions were proposed:

Case-specific monitoring: serves to confirm any assumption derived from risk assessment regarding potential adverse effects of the GMO or its use on human health or the environment. It deals with the observation of certain adverse effects, i.e. "immediate and direct as well as delayed or indirect effects which have been identified in the environmental risk assessment" relating to individual approvals for placing on the market over a limited period of time.

General Surveillance: is used for the long-term observation of GMOs and covers the observation of adverse effects of the GMO or its use for human health and the environment that were not predicted in the risk assessment for one particular product. To be able to identify these adverse effects, general surveillance should consist of elements based on effect-hypotheses and elements not based on clearly defined hypotheses. If changes in the environment are identified further examination is required. An additional component could be existing observation programmes which could be adapted to the needs of monitoring GMOs.