ANNEX 3: REVIEWS

AUSTRIA 1.

ECOLOGICAL MONITORING OF GENETICALLY MODIFIED ORGANISMS (2000) 1.1

BACKGROUND OF THE PROJECT

Context

On March 12th, 2001, the European Union (the Parliament and the Council by the co-decision procedure) adopted Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. As a significant part of this Directive there is a Monitoring Plan sketched to be further elaborated in Guidance Notes. These supplementing Guidance Notes have been adopted by decision of the Council on October 3rd, 2002.

The present research was realised and finished between these two dates and addresses the need for further elaboration of the monitoring system, presenting preliminary proposals to be discussed on a national Austrian basis and EU-wide, afterwards.

The Austrian situation in the domain of green biotechnologies is characterised by a quite restrictive legislation, regional efforts to completely forbid GMOs and a broad GM-critical consensus between the political parties, farmers, interest groups, NGOs and the public. Already in the 1990s with the Directive 90/220/EEC in force, Austria pushed for a monitoring instrument. Basically, there were and there are two fundamental positions on the EU-level: those who demand an extensive monitoring of the approved GMOs, arguing that it is impossible to know every relevant effect of the product in a risk assessment ex ante; and those who understand a product which is approved after an exhaustive risk assessment as fully admitted. The critique of the latter on monitoring is that it is not affordable and even if it would be one cannot know what parameters exactly to trace – one cannot detect and measure anything which possibly could be of relevance. Austria maintained its pro-monitoring attitude and the present paper has to be read in this stable policy-line.

Demanding institutions

This study was financed by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management. As documented in the Third Report of the Austrian Genetic Engineering Commission (Gentechnikkommission), the study was also demanded and partly financed by the Austrian Federal Ministry of Health and Women. The paper was published in the monograph series of the Austrian Federal Environment Agency. The authors are, partly, from this agency and, partly, scientists from outside (University of Vienna, Austrian Federal Office and Research Centre of Agriculture). The main author Andreas Traxler has no institutional affiliation.

Guiding questions

How can we deal with the uncertainty about potential environmental effects of GMOs? What proposals can be made for the guidance notes to amend and complete Annex VII of the Directive 2001/18/EC with a framework concept for ecological monitoring that satisfies the needs of the EU and the Member States?

BASIC DATA ABOUT THE PROJECT

Type of project:

This project is a survey on ecological monitoring and the translation (to present it to a larger audience) of an abridged version of a more extensive monography (containing more Austrian-specific details) of the Austrian Federal Environment Agency (published in 2000). The methods used are basically a review of the legislative texts and scientific publications on the subject, and an exposition of Austrian ecological protection targets. Two case studies (GM maize and GM oilseed rape) were used in the original German version to delineate the requisites of an ecological monitoring device. However, the focus lies on the elaboration of a method, more than on applying already established methods.

Topics:

At first, the survey presents the EU-wide legal provisions on GMO monitoring. Then, the framework concept and the guidelines for monitoring of GMOs are sketched. There are criteria elaborated, the questions of financing and public participation are addressed and a terminology is elaborated. In a next step, the authors introduce the monitoring parameters and test methods they recommend.. After suggestions for Austrian specific ecological protection targets, the authors conclude with some words on biogeographical regions in Austria.

Duration:

The longer version in German language was published and presented in the year 2000, this paper in 2001. The project work took approximately a year.

MAJOR OUTCOMES OF THE PROJECT

Central findings

The study's analysis of the respective legislative acts on GMOs brought the authors to the conviction that ecological monitoring is one of the few methods to increase GMOs' environmental safety. It is the only way to detect unforeseen effects, to possibly prevent adverse effects in time, and to get to learn about the ecological risks of GMOs. There is a broad agreement, also in the EU (see directive 2001/18/EC) and between the interest groups, that it is a necessary instrument to control possible risks of the release of GMOs. However, there is uncertainty on how to implement it. Representatives of the industry, on the one hand, and ecologists, on the other, have quite

divergent views on the nature, extent and duration of the investigations to be carried out in a monitoring tool.

From the authors' point of view, ecological monitoring must be planned and carried out by ecologists in co-operation with molecular biologists and cannot be accepted as a burdensome necessity involved in the release of a GMO.

In line with the EU directive's indications, there should be a case-specific monitoring (limited in time, hypothesis-based) and general surveillance (nation-wide long-term monitoring without time restrictions, designed to observe the effects of all consented GMOs). The present monography also suggests a monitoring of the state-of-the-art (collect and structure international monitoring results; periodically adjust current monitoring plans in terms of methodology and subject matter) and an ecosystem monitoring (because of the high costs, it would be feasible only at few locations; however, this could unearth important findings and initiate interdisciplinary environmental monitoring on an integrated basis). A list of guidelines for ecological monitoring for releases and for the placing on the market is compiled in the study. The paper votes for the participation of the public (to improve acceptance and increase objectivity) and a broader and interdisciplinary integration of scientific fields and interest groups.

There is a great amount of monitoring parameters and test methods proposed by the contributors, which reflect the inconvenience of not knowing what to detect and assess, exactly. It seems that with the recommended ensemble, there should be reached an integrated, holistic vision able to catch problematic effects on the ecobiological system on various points and as fast as possible: There are standard parameters (biomass, phenology, cover values, vegetation structure, etc.) and methods of plant ecology proposed, furthermore biochemical, ornithological and entomological monitoring methods, and soil analyses.

The ecological protection targets should be stipulated by each individual Member State – the present survey attempts this for Austria.

Options for action

Amend Directive 2001/18/EC in line with the aspects prompted by the Austrian position. Each notification for the deliberate release or placing on the market of GMOs must contain a detailed monitoring plan on a case-by-case basis.

Identified future issues

The survey claims that the following points have to be clarified for future GMO notifications with regard to efficient ecological monitoring:

- determination of the executing institutions
- definition of threshold values
- definition of ecological damage (the term is not sufficiently defined: is it "damage" if a native plant population is suppressed or already if there is a GMO-occurrence in ruderal biotops?)

- establishment of a national and international information network (with a central coordination office for the GMO-monitoring as collector and administrator of monitoring data and findings)

These issues should be discussed at the earliest possible stage:

- planning of a nation-wide, representative monitoring network for animals and plants
- definition of the ecological targets likely to be affected by GMOs
- financing

IMPACTS AND FOLLOW UP OF THE PROJECT

According to the press release of the Austrian Federal Environment Agency, the frame monitoring concept was developed to be placed at the EU-level in the discussion on the monitoring guidelines complementing directive 2001/18/EC. These guidelines were published in 2002 by decision of the Council of the European Union. Only a comparative study of the two documents and the positions of other Member States and the relevant interest groups could clarify the concrete influence of the Austrian proposal.

CHALLENGES IDENTIFIED

The development of this monitoring concept, according to the authors, does by no means give a "clean bill of health" for releasing or placing GMOs on the market. Moreover, ecological monitoring is necessary and a useful tool – however, it does not work wonders: it is expensive, time-consuming, and methodologically limited.

LITERATURE

Traxler, A., Heissenberger, A., Frank, G., Lethmayer, C., Gaugitsch, H. (2000): Durchführung von Untersuchungen zu einem ökologischen Monitoring von gentechnisch veränderten Organismen. Umweltbundesamt, Monographien Band 126, Wien http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1085490251342

English version (2001): Ecological Monitoring of Genetically Modified Organisms. Austrian Federal Environment Agency, Wien http://www.umweltbundesamt.at/fileadmin/site/publikationen/M147.pdf

AUTHOR OF THE REVIEW

Helge Torgersen

PRECAUTIONARY EXPERTISE FOR GM CROPS (2004) 1.2

BACKGROUND OF THE PROJECT

Demanding institution (initiator):

The research project "Precautionary Expertise for GM Crops" was funded by the European Commission, Quality of Life programme. It was the third in a series of EU funded projects on policy problems associated with the regulation of GMOs in several EU member states, co-ordinated by the Open University, Milton Keynes.

Context:

Background for this project was the increasing need of changes in regulatory procedures regarding GM crops. When Member States blocked the EU–level regulatory procedure in 1999, new legislations were adopted to meet their demands. New procedures were supposed to provide a mechanism to ensure full traceability and labelling of GMO crops and to enhance the application of the precautionary principle on a national level. Although the precautionary principle was widely invoked for dealing with uncertain risks by Member states, criticism remained considering the principle as a pretext for political agendas. One important reason was that largely, a generally accepted coherent view on the scope and modes of application of the principle was considered to be lacking.

The project analysed the different approaches to the precautionary principle and their consequences for regulatory measures as they appeared from regulatory actions by some Member States as well as from statements made by various stakeholders. Particularly the broader accounts leave the scope wide open for different interpretations. As a result, disagreements about the practical meaning emerged. The main goal of the study was to accommodate different views and give guidelines for the implementation of the principle. Thus it was an attempt to construct a comprehensive concept of the precautionary principle in the context of agricultural biotechnology.

The main guiding questions were:

- How do current European practices compare with different accounts of the precautionary principle?
- How are risk research, risk assessment and risk management linked in practice?
- How do stakeholder groups attempt to influence regulatory measures within or
- beyond formal procedures?
- How do expert advisory bodies mediate between regulatory science and public-scientific controversy?

BASIC DATA ABOUT THE PROJECT

Type of project:

The project was performed as an inter-disciplinary policy research exercise, aiming at comparative evaluations of national policy events, investigated by the national partners, and developments on the EU level researched by the co-ordinator.

The research activities mainly consisted of an analysis of relevant documents as well as interviews and workshops with key actors, involving a wide range of stakeholders.

Duration / start and closing date:

Work was performed within the years 2002 -2004, with the final report in 2004.

Topics of the project:

The investigation focused on the practical application of the precautionary principle in the member states with respect to transgenic crops.

Participants:

- D. Wield, S. Carr, L. Levidow, S. Oreszczyn, Open University, Milton Keynes, UK (Co-ordinators);
- H. Torgersen, A. Bogner, Institute of Technology Assessment; Austrian Academy of Sciences, Vienna, Austria;
- B. Gill, K. Boschert. Ludwig-Maximilians-Universität München, Germany;
- J. Toft, Roskilde University Library, Copenhagen, Denmark;
- C. Marris, P.-B. Joly, St. Ronda, Institut National de la Recherche Agonomique, Ivry, France; Ch. Bonneuil, Centre Koyré d'Histoire des Sciences et des Techniques, Grenable;
- L. Lemkow, D. Tàbara, D. Polo, Universitat Autònoma de Barcelona, Spain.

Subcontracts (consultants):

- P. Schenkelaars, Schenkelaars Biotechnology Consultancy, The Netherlands;
- J. Tait, University of Edinburgh, UK.

Events:

- National stakeholder workshops were held in all participating countries (UK, A, D, DK, F, SP, NL) and on the EU level. Workshops proceedings were distributed and, in part, published.

MAJOR OUTCOMES OF THE PROJECT

Central findings

The project places emphasis on the different understandings of the concept of precaution. As the different reports of the member states show, the concept is very contentious in its details and led to many conflicts among experts. In practise, the differ-

ent accounts have a strong impact on regulatory procedures. Narrow and broader accounts differ in three general respects – uncertainties in risk assessment, the trigger for management measures, and the scope of action (including alternative solutions). Despite institutional reforms regulatory disagreements continue, for instance, over the criteria for evidence, definitions of harms and means to manage uncertain risks.

One main outcome of the project is that different accounts should not be seen as fixed types but as dynamic tensions within the regulatory procedures. It is important to note that precaution has obtained its practical meanings through regulatory conflicts, more than by explicit interpretation or application of an a priori principle.

The project draws the conclusion that the diversity of views of member states is not considered impeding coherent policy or decisions. Through dynamic tensions among different accounts regulatory expert-procedures identified and addressed more scientific uncertainties than before. Thus, the precautionary principle helps to raise new questions about various unknowns in risk assessment. It shall be a flexible policy framework offering stronger means for shifting and clarifying regulatory criteria.

Options for action

The project analysed the need of common regulatory standards on EU level in order to handle existing expert conflicts. The establishment of the EFSA was an important step towards harmonizing the different understandings trough objective scientific advice. It is designed to override and reconcile national regulatory differences. However, the project made clear that on the EU-level different views are not being respected unless they are based on relevant scientific arguments. According to EFSA, Member States shall supply the necessary data and explain their scientific basis for different options within their risk management.

Identified future issues:

In future, this might stimulate more transparency in framing uncertainty and assigning a burden of evidence. Since many risks are not clarified yet, a great burden is born on science and expert judgements. Consequently common regulatory standards shall provide a more rigorous and transparent basis to deal with legitimacy problems.

Another future issue identified by this project is the broader participation of the public and stakeholders. The involvement of diverse stakeholders, including critical scientists and NGOs, can help to ensure that as many relevant questions as possible are addressed.

IMPACTS AND FOLLOW UP OF THE PROJECT

In every participating country as well as on the EU level a workshop with stakeholders such as regulators, scientists, industry and NGO representatives was held, where comments were collected and incorporated into the final report. These workshops took on different shapes in every country; in Austria, it was held as a “meeting on neutral grounds” between regulators from different ministries and scientists in order to explore policy future options.

The results of the project were published in a special issue of the scientific journal Science and Public Policy (32/4, 2005) and, individually, in various other scientific journals by several project team members.

CHALLENGES IDENTIFIED

The relation between scientific advice and political decision making on GM plants remains precarious despite agreed policy principles such as precaution. Rather than suggesting a once-and-for-all procedure with fixed and scientifically unambiguous criteria for the assessment of new GM plants, the authorisation, application and marketing of such plants and their products remain politically sensitive and open for negotiation. The issue turns out not to be able to be dealt with on the basis of science and law only, so that changes in the decision making due to political considerations will have to be taken into consideration in the future as well.

LITERATURE

Special issue on precautionary expertise for EU agbiotech regulation. Science and Public Policy 32(4), August 2005

AUTHOR OF THE REVIEW

Helge Torgersen

RISK ASSESSMENT OF GMO PRODUCTS IN THE EUROPEAN UNION. TOXICITY ASSESSMENT, ALLERGENICITY ASSESSMENT AND SUBSTANTIAL EQUIVALENCE IN PRACTICE AND PROPOSALS FOR IMPROVEMENT AND STANDARDISATION (2004) 1.3

BACKGROUND OF THE PROJECT

Context

Toxic and allergenic properties are considered focal aspects in the assessment of potential health risks of GM food. In contrast to other regulatory contexts such as chemicals, plant pesticides and food additives, detailed requirements for toxicity and allergenicity assessment have not been put into concrete terms until recently. During the time this study was carried out there was no detailed guidance available at all[1].

However, a number of genetically modified plants (GMPs) had already been authorised under Directive 90/220/EEC and the Novel Food Regulation. The authors state a distortion between the provided guidance for risk assessment and the complex situation characterised by rapid scientific progress, varying interpretation of EU regulation by the national authorities, and pressures from industry and public interest groups. The assessment practice resulting from this constellation is described as being time-consuming and inconsistent.

Demanding institution

The present monograph was funded by the Austrian Federal Ministry for Agriculture, Forestry, Environment and Water Economy and the Austrian Federal Ministry for Health and Women. The research that provided the basis for this document (two preceding studies in German language) was financed by the Austrian Federal Ministry for Work and Labour and by the Austrian Federal Ministry for Health and Women. Parliamentary documentation states that this compilation was carried out by order of the Austrian Federal Ministry for Health and Women.

Guiding questions

Which risk assessment practices exist regarding potential toxic and allergenic properties of GMPs? How would a consistent toxicity and allergenicity risk assessment approach look like? Which shortcomings can be identified in current risk assessment? Out of this review of the state-of-the-art, which proposals may be given in the context of recent regulatory developments for guidance documents etc.?

1 The authors mentioned the guidance document of EU's Scientific Steering Committee (SSC) that lists toxicity and allergenicity of gene products as issues to be considered. At present, there is the EFSA GMO panel's Guidance Document for the assessment of GMPs published in April 2004 (as an updated version of the SSC document) and actualized in 2006. This document more extensively addresses the aspects of toxicity and allergenicity.

BASIC DATA ABOUT THE PROJECT

Type of the project, methods

The present monograph is an abridged and condensed but updated English version of the content, conclusions and recommendations of two earlier research projects carried out in German language with the main goal to review the practice of risk assessment procedures on GMPs in the EU.

The practice of toxicity and allergenicity assessment was scrutinised in a range of Directive 90/220/EEC and Novel Food Regulation dossiers. Relevant dossiers were selected, investigated and their respective assessment procedure described. The different approaches to risk assessment were compared and evaluated. A literature review on the concept of substantial equivalence was also implemented. Based on this, the study elaborates proposals aiming at improvement and standardisation of risk assessment procedures. Surveys on toxicity and allergenicity assessment in regulatory documents covering GMPs in Europe and the US provided information which was included in the conclusions and proposals.

Topics

- current practice of toxicity and allergenicity assessment
- its shortcomings
- requirements for a comprehensive toxicity and allergenicity assessment
- proposals for improvement and standardisation of risk assessment regulation and practice

Duration

The two studies that form the basis of the present English version were conducted between 2000 and 2003. The English paper was first published in July 2004.

Participants

The current English version is authored by a subset of the original project team which consisted of scientists from the Austrian Federal Environment Agency, the Inter-University Research Centre for Technology, Work and Culture (IFZ) Graz, the ARC Seibersdorf Research GmbH, the Research Center for Biotechnology, Society and the Environment at the University of Hamburg and a range of individually contracted experts.

The subset of this team and, hence, the authors of the updated English version are: Armin Spök (IFZ), Heinz Hofer (ARC Seibersdorf), Petra Lehner and Rudolf Valenta (contracted), Susanne Stirn (University of Hamburg), and Helmut Gaugitsch (Austrian Federal Environment Agency).

Events

In the course of the investigation, various internal project workshops were held.

Prior to publishing the English version an international conference was held in autumn 2003 in Vienna, where the outcomes of the two preceding studies were discussed and a fundament for the updated English version was laid. Besides some of the studies' authors, a representative of the European Commission (Andreas Klepsch) and a member of the environmental NGO Global2000 gave lectures.

MAJOR OUTCOMES OF THE PROJECT

Central findings

With regard to the toxicity and allergenicity assessment procedures and the use of the concept of substantial equivalence, the study points out significant shortcomings in the dossiers based on Directive 90/220/EEC, as well as in the Novel Food Regulation dossiers:

- The formal structure of the risk assessment approach is not based on and does not clearly distinguish between exposure assessment and hazard assessment (which are both necessary). The claims of substantial equivalence are frequently based on trials and analysis that are not properly designed.
- Assessments and conclusions drawn often cannot be entirely verified given the lack of details.
- Although the overall approaches in risk assessment are similar in the dossiers, differences became evident at the level of details – this fact points to a lack of details in the guidance documents.
- Safety conclusions are often based on indirect evidence and/or assumption based reasoning, and they are partly based on questionable methods, approaches and assumptions.
- Unintended effects of genetic modification are usually not investigated and even dismissed. Significant differences found in compositional analysis are disregarded.

Options for action

Proposals were developed aiming at further improvement and standardisation of risk assessment:

- The structure of risk assessment approaches and dossiers should be standardised.
- The role of substantial equivalence for risk assessment should be further clarified.
- Significant differences in the results of analysis of the same GMPs should at least trigger repetition of the analysis.
- Dossiers should be "stand-alone" documents, including full reports of available safety studies, quoted literature, statistical evaluation sheets for compositional analysis, and thorough description of methods applied.
- The direct testing of toxic or allergenic properties should be preferred compared to indirect testing and assumption based reasoning.
- Testing should be extended to include whole-plant/whole-food testing.

Identified future issues

The authors mention that some of these proposals have already been included in most recent guidance documents. Others might require further discussion and even additional studies – the particular minimum set of toxicity endpoints, for example. Some proposals might require further improvement of testing methods or even the development of new methods.

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate

Austria refers to the study in an EU meeting of the Standing Committee on the Food Chain and Animal Health, claiming a comprehensive toxicological risk assessment as described in the study. In the Austrian Parliament there is no immediate discussion of the study. However, it details and shapes the Austrian position on GMP risk assessment issues.

Scientific recognition and public perception

An article based on the present study and written by some of its authors (together with other scientists) was published in the International Archives of Allergy and Immunology (137/2005).

Furthermore, the work is cited in Science, Technology & Human Values (32/1), in a Press Release of the Institute of Science in Society, and in a Nature Biotechnology correspondence. It was presented on the Third World Network's website and mentioned as additional material by the Third Meeting of the UNEP Ad Hoc Technical Expert Group on Risk Assessment.

CHALLENGES IDENTIFIED IN THE PROJECT

At the time of this English paper's publication, the 2003 SSC guidance document was the state-of-the-art standards on GMP risk assessment. As mentioned, it contains some of the proposals made by this study, as, for example, the need of complete dossiers containing all information required for a full risk assessment. Other aspects, however, remain unclear, ambiguous, or disregarded: Good Laboratory Practice is only demanded for toxicological studies. The SSC guidance is ambiguous with regard to the toxicological testing of the introduced proteins. The possibility of secondary effects is acknowledged, but in a more limited way than in this monograph. Further guidance for homology studies than the indications given by the SSC document is needed. Unlike the case-by-case basis favoured by the SSC guidance notes, this paper proposes compositional analysis for all processed products.

Taking into account these differences, this monograph sees the challenges in addressing the shortcomings still remaining. If this is not accomplished by further and better regulation, risk assessment practice on toxicity and allergenicity is still to be called deficient.

LITERATURE

Spök, A., Hofer, H., Lehner, P., Valenta, R., Stirn, S., Gaugitsch, H. (2004): Risk Assessment of GMO Products in the European Union. Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation. Austrian Federal Environment Agency. Wien

AUTHOR OF THE REVIEW

Helge Torgersen

FEASIBILITY STUDY ON »GMO-FREE« CLAIMS AND THE AVOIDANCE OF GMOS IN FOOD (2005) 1.4

BACKGROUND OF THE PROJECT

Context

The study bases its predications regarding to the feasibility of a correct use of the label "GMO-free", on the one hand, on the definition according to the Codex Alimentarius Austriacus and, on the other hand, on the EU-regulation 1829/2003 concerning the (not required) labelling of animal feed and comestibles as GMO.
The public debate on GMOs in Austria was a more critical one compared to other EU Member States. Moreover, it was characterised by an unusual common understanding between political representatives, social movements and significant parts of the agricultural sector. This constellation led to a more restrictive handling of the label "GMO-free" in Austria. For example, the Austrian label requires additional standards concerning the application of production facilities, the fabrication of additives, and feeding.
The study was carried out while the use of GM-seeds in Austria and other EU Member States was prohibited by regulations of the EU-Council. Hence, the possibility was excludable that in Austria and large parts of the EU there would be GM-seeds employed. In case of additives, the situation in the year 2005 was already different: some of them were almost exclusively accessible from sources involving GM-micro-organisms.

Demanding institution

The Austrian Federal Ministry of Health and Women, the Austrian Federal Ministry of Economics and Labour and the AMA Marketing GesmbH assigned the Austrian Agency for Health and Food Safety with the realisation and coordination of this feasibility study.
The study was realised in cooperation with the University for Natural Resources and Applied Life Sciences and was continuously evaluated by Prof. Maurer, head of the former Ludwig-Boltzmann-Institute for Organic Farming and Applied Ecology and now chairman of the new Bio Research Austria Institute.

Guiding questions

- Is there a transfer of GMOs from animal feed to derived food products?
- Are the raw materials and additives for feed production available?
- From the viewpoint of nutritional requirements, is the use of GMO-free feeds feasible?
- Does a GMO transfer happen via bee products?
- What strategies and efficient monitoring exist to avoid GMO contamination?
- From an economical viewpoint, is the use of GMO-free feeds feasible?

BASIC DATA ABOUT THE PROJECT

Type of project

The present project is a feasibility study that tries to estimate the existing possibilities (taking into account nutritional requirements, economical factors and constraints, etc.) to accomplish the requirements established in the legal frameworks in Austria and the EU. A broad inquiry into Austrian and international scientific studies and publications forms the basis of this study. The study investigates legislative texts and economical measures (market prices; amounts of consume and production of seeds, etc.), and undertakes some basic calculations to estimate the differential costs for the production of food applying GMO-free feeds.

Topics

The topics addressed by the study are basically the legal situation for the denomination of a product as "GMO-free" in Austria and the EU, the necessities to meet the legal requirements and control their compliance (monitoring) and the additional costs of gaining the "GMO-free" label. Besides, the world agricultural product market is taken into consideration regarding the availability of indispensable import products.

With these concrete topics the main problematic of the feasibility of GMO-free products appropriate to the current legal frameworks is addressed.

Duration

The study was commissioned in late autumn 2004, finished and published in November 2005.

Participants

- Austrian Agency for Health and Food Safety: Leopold Girsch (project management),
- Institute for Seeds: Natascha Balarezo (internal project coordination), Christine Kargl
- Institute for Animal Feed: Veronika Kolar, Thomas Kickinger, Herbert Würzner
- Vienna Institute for Comestible Testing: Rainer Bernhart, Klaus Riediger
- Risk Assessment: Roland Grossgut, Daniela Hofstädter
- Institute for Apiology: Rudolf Moosbeckhofer
- Biochemistry Competence Centre: Hermann Hoertner, Rupert Hochegger

Subcontracts

- University for Natural Resources and Applied Life Sciences (Institute for Marketing and Innovation): Siegfried Pöchtrager, Josef Penzinger, Stefan Großauer
- Evaluation: Ludwig Maurer

Events

The study was presented to a broad range of interest groups at the end of 2005. On November 2nd, 2005, there was a press conference at the Austrian Agency of Health

and Food Safety in Vienna. In the following weeks until February 2006 there were presentations, for example, for the Chambers of Agriculture of Austria, Upper Austria, Styria and Lower Austria and other communities of the agricultural sector.

MAJOR OUTCOMES OF THE PROJECT

Central findings

- No evidence was found in the international scientific literature stating that even traces of transgenic DNA were detectable in foods derived from animal production after feeding GM-feed.
- 90% of the imported soy used for feeding in Austria is transgenic. The global share of GM-soy is still increasing. However, following the requirements from the EU directive 1829/2003, in a short- and medium-term raw materials for animal feed production which do not have to be labelled as GMOs will be available. With respect to the provisions established by the Austrian Codex, protein substitutes for soybean extraction meal produced in Austria and the EU will be available. It has to be said that these substitutes can only be used to a certain limit and no forecast can be given for the development of the raw material markets. In terms of the additives for animal feed production, there are products available which do not require labelling in accordance with the EU-directive but would so according to the Austrian law.
- Feasibility of the usage of feed labelled as GMO-free: following the EU directive, it is feasible in a short- and medium term; following the Austrian Codex, it is feasible only for cattle but not for pigs, poultry and turkey (because of the necessary additives)
- The content of pollen in honey is usually noticeably below the labelling threshold levels in accordance with the EU-directive.
- Monitoring and strategies to avoid contamination: self-control of the companies; separated and closed production processes; appropriate cleaning; more provisions in monitoring and surveillance for the Austrian label
- The use of animal feed containing soybean extraction meal labelled as GMO-free or not requiring labelling leads to additional costs of up to over 8%. These costs vary considerably depending on the line of production (beef, pigs, etc.). In the future, by-products from bio-fuel production that contain protein and are available in Austria and the EU will be commercially employable as a protein supplying substitute for soybean extraction meal.

Options for action

- enhance the production of substitutes for soybean (for example, from bio-fuel production)
- try to assure a reliable labelling in the world market's production chains
- try to safeguard Austria's share of Brazilian and US GMO-free soybeans

Identified future issues

- monitor the world raw material market's development and the share of available and affordable GMO-free products
- integrate more aspects into the calculations of the additional costs

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate

The Federal Minister of Agriculture, Forestry, Environment and Water Management mentioned in a parliamentary inquiry presented by the Green Party in the year 2006 that the present study was presented to the ministerial working group on genetic engineering. Moreover, he cited the study's insights into the additional costs and technical needs for contamination prevention. In another parliamentary inquiry in 2004, also presented by the Greens, the same Minister explains the financing and planning of the study. He says, inter alia, that there was (as usual) an interchange on the planned contents with the relevant experts, on beforehand. Also in the regional Parliament of Salzburg the study was subject of a parliamentary inquiry.

Interestingly, the study was cited in a parliamentary debate in the German Bundestag by Christel Happach-Kasan (FDP). She exposed and interpreted the study's finding that GM-free pig and poultry breeding is quite impossible because of the additives needed. Not using genetic engineering technologies would lead to a higher mortality in the animal stocks. There was disagreement expressed by the German Greens.

Public perception

After the press conference on November 2nd, 2005, there was ample recognition of the study in local media and partially in the German-speaking world. The Austrian Press Agency published an article delivered by the Agrarian Information Centre. The ORF (the Austrian public news channel) reported, too.

Furthermore, the study was mentioned by the Austrian Federal Chamber of Commerce. Details were cited by the Austrian Chamber of Labour, Greenpeace, Austrian agricultural communities such as BioAustria, the German Information Service on Genetic Engineering (Informationsdienst Gentechnik) and other German citizen's action committees.

The public perception of the study is characterised by the conclusion that GMO-free production of comestibles is feasible, principally, but there are some costs to take into account. However, there are also new opportunities for the Austrian agriculture, especially concerning the production of GMO-free substitutes for soy from bio-fuel.

Scientific recognition

A research paper of the Austrian Federal Ministry of Health and Women on the need to label GMOs already pointed to the study in 2005, before its finishing.

CHALLENGES IDENTIFIED IN THE PROJECT

The development of the international market for reliable GM-free seeds and feed can not be predicted and lies outside the Austrian room for manoeuvre. The availability of GM-free additives is already quite limited.

LITERATURE

Austrian Agency for Health and Food Safety/University for Natural Resources and Applied Life Sciences, Vienna (2005): Feasibility Study on "GMO-free" claims and the avoidance of GMOs in food.

AUTHOR OF THE REVIEW

Helge Torgersen

COEXISTENCE (2005) 1.5

BACKGROUND OF THE PROJECT

The cultivation of genetically modified crops is growing steadily and fast in the ultimate years, mostly in North and Latin America. In the EU there is already an extensive set of legislation on the regulation, admission and limitation of GMO cultivation, import etc.

In 2003, the European Commission released the Recommendation No. 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. The Commission underlined that these guidelines should focus on economic consequences of GMO cultivation given that ecological and health aspects are already taken into account in the GMO admission procedure. The scope of the guidelines spans from the agricultural production to the first point of sale – higher levels of elaboration are not considered. In addition, national catalogues of measures, as to be defined by the member states, should allow for every country's specificities regarding topography, climate, the agricultural structures and the production systems. The Commission's Recommendation together with the country's implementation strategies should ensure that the compliance with the threshold values for non-GMOs is not impeded by the diversity of the producing regions, the productive systems and technical matters.

The Austrian situation in the domain of green biotechnologies is characterised by a quite restrictive legislation and a broad GM-critical consensus between the political parties, farmers, interest groups, NGOs and the public. Seeds in the initial examination have to be free of GM contaminations to be authorised in Austria. In the follow-up examination a threshold value of 0,1% is fixed.

BASIC DATA ABOUT THE PROJECT

The present study was conducted (under the guidance of Prof. Georg Grabherr) by Kathrin Pascher and Marion Dolezel from Vienna University's Department of Conservation Biology, Vegetation Ecology and Landscape Ecology between the end of 2003 and March 2005 on behalf of the Austrian Federal Ministry for Health and Women (Section IV). The overall goal of the document is to define rules and measures providing a general framework for coexistence of GM-, conventional and biological crops for the specific Austrian case as demanded by the Commission's Recommendation. The authors argue that measures for the cultivation of GM-crops would assure the farmers the possibility of planting just the crops they want to, as well as the consumers the security and freedom of choice they look for.

Following the Commission Guidelines which establish that the measures have to be crop-specific, the study focuses on maize, oilseed rape and sugar beet – for the authors primarily expect these crops to be commercially cultivated as GMOs in Europe.

Sources of GM-contaminations are outlined and evaluated, then the measure proposals for the reduction of these contaminations are given and experiences from other countries with coexistence of the mentioned crops are incorporated.

The project was realised in terms of a scientific study from an eco-biological perspective. In the course of the project, the authors attended a series of conferences and lectures, amongst others the 1st European Conference on the Coexistence in Denmark, a conference on GMO Risk Assessment in Vienna, other forums on coexistence in Austria and a Conference of the European network of GMO-free Regions.

There were basically two methods applied: Firstly, a theoretical evaluation of the problematic of coexistence and contamination by means of a review of existing studies of a European and non-European institutions and authorities (FiBL, Union of Concerned Scientists, BUWAL, JRC, MAFF, MAF), literature databases, organisational websites (saveourseeds.orf, transgen.de, biosicherheit.de, ucsa.org, etc.), personal contacts to Austrian authorities, organisations and firms (AGES, Saatbau Linz, ZAMG, Chambers of Agriculture, etc.), and conference attendance. Secondly, GMO-crop growing was simulated for different Austrian regions. The amount of field losses due to the necessary belts of isolation (to avoid exogamy) was simulated for random and clustered repartition of GM-crop fields in the cases of maize, oilseed rape and sugar beet.

MAJOR OUTCOMES OF THE PROJECT

The study's outcome is a catalogue of measures to prevent contamination with GMOs and to delineate the exigencies of a reasonable coexistence.

In the case of **maize**, the use of barriere-plants or of varieties with different flowering dates will not be sufficient to reduce GMO contamination rates to 0,9%. Isolation distances of at least 200m seem to be the only viable measure to guarantee this quota. However, if GM proportions grow beyond 10% and if a threshold value of 0,1% in the harvest is to be realised, cultivation, harvest and post-harvest processes have to be thoroughly separated and cross fertilisation completely avoided. Not even isolation distances of one to several kilometres could assure this due to other factors that until now couldn't be exhaustively studied – the establishment of large-scale GMO free zones would be the only possible way to guarantee these low threshold values.

Imports of basis seeds and possible cross fertilisation are the crucial points for contamination control in **oilseed rape**. Necessary measures for the consumption production are, therefore, a purity control of the imported basis seeds, long growing intervals of at least 8 to 12 years (to reduce volunteers of oilseed rape) and isolation distances of 4 kilometres (allowing for the flying distances of pollinating insects). Regional and continuous examinations of their effectiveness could facilitate more flexible isolation distances. The management of the segetal weed flora, barriers with non-GM oilseed rape and the removal of bee hives near the fields seem to be viable measures, too. Transportation routes should be as short as possible. However, the creation of a closed seed production area would be the most effective measure. Considering the specificities of agronomic and topographic structures, climatic particu-

larities, the necessary extent of the isolation zones, regional occurrence of volunteers, etc., the authors argue that coexistence of oilseed rape will not be feasible in Austria.

Sugar beet for consumption is not flowering. Hence, the unwanted hybridisation events affect seed production areas. To achieve a threshold value for GM contamination of 0,5% much larger isolation distances than the currently widespread 300, 600 or 1000m would be needed. The highest risk is currently posed by imported seed. Reliable choice and control is needed; moreover, suitable cultivars, coordination of farmers, at least 2 kilometres of isolation distance, control of bolters, weed beets, volunteer beets and Beta-forms. Pollen barriers should be used and a crop rotation of at least eight years guaranteed.

Beyond these crop specific arguments the study presents measures to avoid **technical contamination** at cultivation and harvest. The technical processes of GM and conventional or organic field crops should either be completely separated or strict guidelines for adjustment, operation and cleaning measures should be provided and demanded. Seeding and harvesting machines have to be cleaned before and after their application for GM crops. Losses during the transport must be prevented, hoppers cleaned and controlled, contracts established (e.g. between vicinal farmers on location of their fields or on the requirements and criteria for a joint use of machines), etc.

IMPACTS AND FOLLOW UP OF THE PROJECT

A Green Party's delegate to the National Assembly asked the Federal Minister of Health and Women and the Federal Minister of Agriculture, Forestry, Environment and Water Management in a written parliamentary request about the costs of coexistence in Austria. As an initial point he cited the present study which, in his interpretation, comes to the conclusion that the coexistence of GMOs and conventional and biological products is possible, if at all, only with high technical and organisational efforts.

The study is also cited by further studies of the Federal Ministry of Health and Women and the Austrian Agency for Health and Food Security, the network of GMO-free regions and an Upper-Austrian text introducing this region's characteristics and the structure of its economy. In a slightly different reading some of the study's findings are presented in an information letter of *Les Professionels des Semences et de la Protection des Plantes*, a French syndicate of the seeding industries. They mention that the study posits the possibility of coexistence always respecting the right isolation distances. It is just rape where coexistence doesn't seen viable in Austria.

CHALLENGES IDENTIFIED IN THE PROJECT

The study's tenor is that coexistence is possible in some cases but not in all. And even if it is possible this would lead to economical and social costs and much regulatory work on a national base. The mentioned feasible measures to assure coexistence

are presented in a sceptical light. The whole issue of coexistence seems to be a problematic one since it is at least an expensive endeavour and potentially impossible, at the end. The reader could get the impression that the study provides and tries to provide scientific arguments underpinning GM-critical positions.

LITERATURE

Pascher, K., Dolezel, M. (2005): Koexistenz von gentechnisch veränderten, konventionellen und biologisch angebauten Kulturpflanzen in der Österreichischen Landwirtschaft – Handlungsempfehlungen aus ökologischer Sicht. Bundesministerium für Gesundheit und Frauen, Sektion IV, Band 2/05, Wien http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1113391269254 English summary: http://www.bmgfj.gv.at/cms/site/attachments/6/4/4/CH0810/CMS1113391269254/summary_-_coexistenz.pdf

AUTHOR OF THE REVIEW

Helge Torgersen

THE ROLE OF PRECAUTION IN GMO POLICY (2006) 1.6

BACKGROUND OF THE PROJECT

Context

In the year 2000, the European Commission published the so called Communication on the Precautionary Principle. This document proposed guidelines for the handling of scientific uncertainty. Since then, precautionary language and criteria have been integral part of the respective legislation, for instance, in the Deliberate Release Directive concerning GM crops or the Biosafety Protocol. Today, the Precautionary Principle (PP) is firmly established in European law.

Notwithstanding, the principle has not ceased to be contentious and much less to be interpreted in different ways. Besides the narrow account of the European Commission's document, there are broader ones from other sources like the European Parliament, experts, member states and stakeholders. The project "Precautionary Expertise for GM crops" (see section 1.2) studied varying understandings and applications of the PP within and between 7 European States. The scenario in Austria could be sketched as characterised by a wide GMO-critical political consensus between government, stakeholders and the public, despite divergent concepts of precaution.

Demanding institution

The present conference was initiated jointly by the Austrian Federal Ministries of Agriculture, Forestry, the Environment and Water Management and of Health and Women. The Federal Environment Agency was responsible for realisation. The conference took place in the frame of the Austrian EU-Presidency in the first half year of 2006. The actual and possible development of the PP in GMO policy was examined from legal, scientific, and political perspectives as well as on the basis of case studies at national, EU and international levels.

Guiding questions

- What different interpretations of the PP exist?
- Is there room for the principle in the EU legislative framework and how is it specified?
- What are practical experiences with the principle?
- What is the scientific background to be taken into account?

BASIC DATA ABOUT THE PROJECT

Type of project and duration

The project was an international and interdisciplinary expert conference held at the Hofburg in Vienna with the participation of experts and stakeholders from a scientific and a political background. It took place on the 18th and 19th of April 2006.

Topics

Relevant aspects of the precautionary approach towards regulation of GMOs were addressed. The main topics discussed were possibilities and limits of precautionary measures within the existing legal framework, the scientific background of precautionary approaches, as well as the practical experiences of putting to use the principle.

Some of the contributions' subject areas were how EU legislation on GMOs relates to and gives room for the PP, how and where it is discussed controversially, how it is interpreted in the CEE countries and what were practical experiences with the use of the principle, as well as the question of risk assessment.

Participants

Approximately 135 scientists, state and interest group representatives

Speakers: (in order of appearance):

- Hugo-Maria Schally (Chairperson), DG Environment, European Commission
- Christine von Weizsäcker, Germany
- Kathryn Tierney, DG Environment, European Commission
- Liina Eek, Ministry of the Environment, Estonia
- David Wield, Open University, UK
- Eric White, Legal Service, European Commission
- Thomas Jakl (Chairperson), Ministry for Agriculture, Forestry, Environment and Water Management, Austria
- Brian Wynne, Centre for the Study of Environmental Change, Lancaster University, UK
- Jürgen Zentek, Freie Universität Berlin, Germany
- Christopher Pollock, Institute for Grassland and Environmental Research, UK
- Margaret Mellon, Union of Concerned Scientists, USA
- Katja Moch, Öko-Institut Freiburg, Germany
- Michel Haas (Chairperson), Ministry for Health and Women, Austria
- Brian Wynne on behalf of David Gee, European Environment Agency
- Harry Kuiper, GMO-Panel EFSA, RIKILT – Institute of Food Safety, The Netherlands
- Jan Husby, Norwegian Institute of Gene Ecology, Norway
- Simon Barber, Plant Biotechnology Unit, EuropaBio
- Helmut Gaugitsch, Federal Environment Agency, Austria

IMPACTS AND FOLLOW UP OF THE PROJECT

It was concludingly addressed by Helmut Gaugitsch that there is a need for a follow-up. A good starting-point would be the discussion on the PP and ways towards its application. Kathryn Tierney (EU Commission) enunciated that the debate on GMOs and the PP would continue at the EU Environmental Council in Luxembourg in June 2006.

There was no parliamentary debate on the conference. However, it was presented by the authorities as an asset in the Austrian EU-presidency 2006 to address the issue in such an international expert conference, bringing forward the respective EU-wide discussion. The national press (Der STANDARD, 20.4.2006) reported in a short statement. The Institute for Applied Ecology (Freiburg/Germany), the USDA Foreign Agricultural Service, biotrin.cz and the Biosafety Information Centre mentioned the conference on its website.

MAJOR OUTCOMES OF THE PROJECT

Central findings

As Helmut Gaugitsch in his closing remarks points out, there is broad consensus around an understanding of the PP as one of the central aspects of European GMO legislation. It was described as a tool that allows countries to adopt the level of protection that was felt necessary, even in the absence of scientific certainty. However, it remains questionable whether there is a common understanding of the PP and the way it can or should be implemented.

Regarding the question whether the PP is a risk management issue only, it became clear that risk assessment on its own is an important prerequisite for decision making but not enough as it is inadequate to assess uncertainty, by definition cannot assess ignorance and also falls short of acknowledging any benefits. As Bryan Wynne expressed it, precaution should rest on the recognition that knowledge is always limited. The assumption that the need for precautionary policy can be subjugated to preliminary risk assessment is misconceived.

The PP should contribute to protection and not protectionism and should be used to gain further scientific knowledge. It was stated that the PP can be a possible instrument of scientific innovation.

There were also voices who proposed a modification of EFSA's format and inner EU-communication on orientations toward the PP. Others, again, expressed the opinion that Europe-wide universalist approaches to the PP, maybe, will not work (considering that some regions see commercial benefits in being GM-free etc.). There will not be a single understanding and application of the PP. Particularly "ecologically sensitive" areas will have different approaches, for example.

Eric White from the European Commission's Legal Service claimed that the PP is alive and perfectly compatible even with the WTO.

Options for action and identified future issues:

- continue to discuss the concept of the PP in the national, EU and international level towards application and action
- discuss the different national and EU wide conceptions of the PP to get to a more common understanding
- elaborate mechanisms to include statements on the application of the PP in GMO product notifications

- improve, harmonize and standardize the risk assessment instruments nationally and EU wide (should include guidance on which kind of data should be included in notifications and the methodology to generate them), keeping a balance between clear guidance and case-by-case sensibility
- in order to gain further knowledge on GMOs and to address uncertainty and ignorance, research projects could and should take approaches as the PP more into account
- enter into a dialogue with stakeholders (and involve them) at the national and the EU level and between them; risk communication should be improved and a system for public participation needs to be set up

CHALLENGES IDENTIFIED IN THE PROJECT

A considerable challenge identified is to find ways from the PP to an applicable approach and action and to define its relation to the risk assessment framework. The PP should not be used as a technical barrier to trade and a tool for protectionism.

There lies a twofold challenge in the concept of PP as it is present in nowadays' legislation and practice: On the one hand, the PP has to be elaborated and discussed on general grounds, looking for ways to apply and regulate it. On the other hand, the various interpretations of the principle have to be consorted.

The EU legislative framework has to be fine-tuned to provide for a higher degree of transparency and thus to fulfil the expectations on decision-making.

It was argued that the "Sound Science" approach (firmly present in the US policies), with its accents on delaying safety obligations until causal chains of harmful impacts are fully proven, runs counter the PP – with this, originating a possible and already manifest conflict between the US and Europe (see the current WTO dispute). The EU could possibly use the "de facto coalition" with the developing countries in favour of the PP, to enforce its position and foster its understanding of protection.

LITERATURE

Federal Ministry of Health and Women (Ed) (2006): Conclusions of the conference "The Role of Precaution in GMO policy", 18.-19. April 2006, Vienna http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1145612477419

AUTHOR OF THE REVIEW

Helge Torgersen

DENMARK 2.

GENETICALLY MODIFIED FOODS (1999) 2.1

BACKGROUND OF THE PROJECT

The DBT- project *"Genetically modified foods"* from 1999 was carried out due to the apparent scepticism among the Danish population. At that time, genetically modified foods were about to enter the Danish market, but it seemed that the Danish consumers did not associate any direct advantages with them. However, it was impossible to reject that benefits would eventually emerge in step with the development of the technology.

At that time, legislation on genetically modified foods had not yet been completed within the EU and the potential benefits and risks considering GM foods were still associated with much uncertainty. Thus, the aim of the project was to provide a multi-faceted public debate on GM foods in order to enhance the dialogue between decision makers and the public.

BASIC DATA ABOUT THE PROJECT

The project was designed as a consensus conference that took place during three days. The Danish Board of Technology appointed a panel of fourteen citizens who were asked to consider genetically modified foods. Before the actual consensus conference, the citizen panel met twice and discussed GM foods based on some introductory information. At the conference, thirteen experts were invited to make a presentation of their knowledge and opinion considering GM foods. During the two first days of the consensus conference the experts answered questions from and discussed with the citizen panel. Conclusively, the citizen panel created a final document containing the evaluations and recommendations considering GM foods on which the panel could all agree.

Through the consensus conference ten questions considering genetically modified foods were addressed both by the experts and the citizens. In the final document, each question is evaluated by the citizen panel and followed by some recommendations. The main topics that characterized the ten questions concerned amongst others: environmental impacts, human health, market conditions, national and international regulation, information, and ethics.

MAJOR OUTCOMES OF THE PROJECT

The consensus conference concluded that the production of genetically modified foods undoubtedly affects nature's cycle. However, the experts strongly disagree about the seriousness of the effect and whether or not the effect is hazardous. Argu-

ments for and against GM foods were discussed among the citizen panel and resulted in some recommendations. These recommendations emphasize some of the challenges that the further development of GM foods involves.

The panel emphasized the importance of preserving the biodiversity of plants and animals and to protect the natural eco-systems. Thus, the citizen panel agreed that it should be possible to hold manufacturers of GM foods responsible for adverse effects on human health and the environment.

The laymen panel believed that authorisations for tests and production of genetically modified organisms should be subjected to severe regulations for risk evaluation and requirements of efficient control. Further, public regulation was recommended as a means to offset monopolistic companies from controlling the market for GMO's. It was also suggested that companies should lose their right of use for unapplied patents. The panel also supported the idea of a convention guaranteeing developing countries free access to utilising gene technology patents. Because biotechnological research to a wide extent is concentrated in the private sector, the panel recommended that public funding for research in the field should be increased.

The panel highlighted the importance of ensuring consumers still to be guaranteed a choice between genetically modified and non-genetically modified foods. It was further emphasized that dissemination of information is crucial and that comprehensible and informative declarations of contents are necessary.

The panel further recommended that ethical aspects should be given the same priority as purely technical aspects in relation to applications for testing, production and marketing of GM foods. Thus, the panel recommended that a committee charged with ensuring an ethical evaluation of the authorisation process should be established.

IMPACTS AND FOLLOW UP OF THE PROJECT

The consensus conference kick-started a more widespread debate on genetically modified food in the public. The Danish Board of Technology found that the political interest in the field increased in the wake of the conference. Both national and EU-politicians showed interest in the project and were curious to know what the citizens worried about.

CHALLENGES IDENTIFIED IN THE PROJECT

Different challenges considering genetically modified foods and how to handle them appeared throughout the project. First of all it became clear that there is a conflict between experts when it comes to assessing the risks and benefits of GM foods. Hence, the project showed that experts disagree whether GM foods are predominantly beneficial or if they pose a threat to the environment and/or human health. These disagreements pose a challenge to the further discussions considering GM foods. Another challenge that was identified considered the question of monopoly

highlighting that knowledge about GM foods is only available to very few people. The question of responsibility was further a challenge that appeared during the consensus conference; who can be held responsible if something goes wrong with GM foods? The challenge is to take such matters into consideration. The project further emphasized the importance of ethical considerations when dealing with genetically modified foods. Thus, the question is whether the utility value of GM foods matches up with the ethical issues.

LITERATURE

The Danish Board of Technology, (1999): Gensplejsede fødevarer. http://www.tekno.dk/pdf/projekter/p99_genspl.pdf; English summary: Genetically modified foods. http://www.tekno.dk/pdf/rtt_125_uk.pdf

AUTHOR OF THE REVIEW

Søren Gram

GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES – CHALLENGES FOR THE DEVELOPMENT AID (2003) 2.2

BACKGROUND OF THE PROJECT

The DBT project *"Genetically modified crops in developing countries"* were initiated based on the conclusions of the UNDP's Human Development report 2001, which focused on the role of ICT and biotechnology in the reduction of world poverty. The report stated quite a clear position in favour of biotechnology by emphasizing an opposition to put restrictions on technological developments. Instead, the report called on an examination of what it takes to control and exploit new technology in everybody's interest. The UNDP report gave rise to immediate counter-reactions emphasizing that the problems of hunger and poverty in the third world countries are a matter of distribution because we already produce enough food to feed the whole world. Based on these counter-reactions the DBT set out to assess the pros and cons of using genetically modified crops to fight poverty and hunger in the third world.

BASIC DATA ABOUT THE PROJECT

The project ran from 2002 to 2003 and involved an interdisciplinary task force appointed by the Danish Board of Technology. The task force consisted of six experts all with specialist knowledge within the field of biotechnology and development aid respectively. The objective of the task force was to consider if, and how, dealing with GM crops should be an integrated part of the official, Danish development policy.

The task force arranged three workshops where leading experts within selected areas presented and discussed experiences and the latest knowledge. The first workshop assessed the technical and environmental possibilities and risks regarding already existing biotechnologies. The second workshop assessed social, environmental, ethical and cultural issues. It aimed to assess the implications and desirability of using biotechnology in third world farming structures. The final workshop discussed the compatibility of GM food with the overall aims of Danish development policy in relation to using participatory methods, fighting poverty, the precautionary principle etc. During all three workshops the task force invited other leading experts to contribute with comments, ideas and their expertise on the matter.

Through the project, the task force was asked to answer a two-pronged question, which constituted the starting point of the DBT project; *Can Danish development aid be used positively to 1) incorporate genetically modified crops into the work of improving the living conditions of the poorest population groups in developing countries – and 2) can this be done without conflicting with existing Danish development policy strategies?* The task force approached the questions in view of the fact that the dissemination of GM crops is already taking place – just not considering Danish development aid. The first part of the question was considered to be too complex and

diverse to be answered by a simple yes or no, which is why the task force decided to take a diversified, more pragmatic and action-oriented approach. Thus, the DBT report does not contain arguments for or against GM crops as such but rather provides a basis for the assessment of benefits and drawbacks of the possible use of GM crops in specific contexts. Considering the second part of the question, the task force assessed that the use of GM crops in developing countries would not necessarily conflict with Danish development aid policy.

The result of the project was communicated through a report targeted at institutions and organisations engaged in agricultural development in the poor countries of the world, and further at politicians, researchers, corporate staff or others who, directly or indirectly, influence or are involved in agricultural development, legislation, commerce etc. in the third world.

MAJOR OUTCOMES OF THE PROJECT

The project was concluded by several conclusions and recommendations, which were further supported by a list of premises to constitute a framework for aid organisations when and if a developing country needs assistance in dealing with GM crops. The premises were:

- Each GM crop must be assessed individually.
- The same yardstick cannot be applied to all developing countries.
- Existing GM crops are primarily adapted to the needs of farmers in the rich part of the world.
- Development of GM crops is slow, i.e. there are relatively few GM crops on the market and relatively few on the way in.
- Safety approval of GM crops is expensive since the control procedures are extremely comprehensive.
- Many developing countries do not have the capacity required to undertake needs assessment and control and would find it difficult to make their own assessment of whether they would benefit from the crops, and whether they could comply with the control and safety regulations.
- Patents influence development, and this may cause developing countries major legal and economic problems when it comes to the use and development of GM crops.
- GM crops may have an adverse effect on developing countries' competitiveness and access to western markets.
- The consequences of introducing GM crops are uncertain. No-one knows for sure what their impact will be on the environment, nutrition and biodiversity.

The task force's main message was that GM crops represent one among many technologies that may contribute to solving food supply problems in developing countries, but this form of agriculture is no miracle solution – at least not in the short or medium term. The task force assessed that Danish development aid should continue to focus on a broad range of technological and institutional solutions in the agricultural area with focus on responding to the needs of the poor farmer. Thus, the task

force considered GM crops only to play a relatively limited role in the immediate future. The task force further emphasized that the question of how best to assist countries must be assessed specifically from case to case and from country to country. Besides these more general recommendations, the task force offered more specific recommendations within four focus areas: technology, political policy, institutions and society.

IMPACTS AND FOLLOW UP OF THE PROJECT

In the wake of the project, the Ministry of Foreign Affairs of Denmark, which is in charge of the Danish development policy, invited the Danish Board of Technology to give a presentation of the project. The Ministry does not usually consult external organisations, which is why the interest in the DBT report must be considered quite an acknowledgement of the project.

CHALLENGES IDENTIFIED IN THE PROJECT

Conclusively, the task force emphasized that developing aid organisations will be failing in their responsibility if they fall short to adopt a position with regard to GM crops and their use in developing countries while it is necessary to examine whether certain GM crops might assist developing countries in ensuring sustainable agricultural production and food supply in the future. Thus, the question is not whether Danish development aid should decide on the use of GM crops in developing countries. Instead, the challenge for the Danish development aid organisations is to help the developing countries prepare for the coming of the GM plants. The challenge is to frame some conditions that enable developing countries to deal with and decide on the use of GM plants. It is crucial that developing countries are assisted with the organizing so the given countries are prepared administratively for the GM crops and possess sufficient scientific knowledge on the matter. Further, it is important that the developing countries have developed the necessary control to handle GM crops. Such issues are exactly what development aid should focus on in relation to GM plants.

LITERATURE

The Danish Board of Technology (2003): Genmodificerede afgrøder i udviklingslande - udfordringer for udviklingshjælpen. http://www.tekno.dk/pdf/projekter/p03_genmodificerede_afgroeder.pdf; English summary: Genetically modified crops in developing countries - challenges for the development aid. http://www.tekno.dk/pdf/projekter/p03_gen_mod_crops_summary.pdf

AUTHOR OF THE REVIEW

Søren Gram

CO-EXISTENCE BETWEEN GM CROPS AND NON-GM CROPS (2004) 2.3

BACKGROUND OF THE PROJECT

During the summer 2003, the European Parliament and the Council decided on a regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. With this regulation the EU reopened for approvals on the growth of GM crops. Based on this regulation, the European Commission recommended some guidelines for the development of national strategies and best practices to ensure the co-existence of GM crops with conventional and organic farming. Thus, the Danish government introduced a bill on co-existence. The bill on co-existence was framed with references to a report from 2003 by the Danish Institute of Agricultural Sciences concluding that co-existence is possible in Denmark considering some crops, but that there are also some exceptions were co-existence seems to be problematic.

To discuss the bill on co-existence, the Danish Parliament (Folketing) committee of Food, Agriculture and Fisheries and the committee of Environment decided to make a hearing to clarify the experiences with the growth of genetically modified crops.

BASIC DATA ABOUT THE PROJECT

The Danish Board of Technology arranged the hearing on the experiences of co-existence between GM crops and non-GM crops (within the framework of BIOSAM, a collaborative forum addressing ethical questions considering biotechnology). The hearing was open to everybody and took place May 11th 2004. Around 90 people (mostly experts and stakeholders) attended the hearing.

The hearing was split up into five sessions with each their theme. The first session of the hearing addressed the risk of GM crops spreading by a presentation of available knowledge on the subject. The next session moved on to discuss how to handle the spreading by either preventing or minimizing the spread of GM crops to fields with either conventional or organic crops. The third session of the day focused on the positive and negative consequences facing the market in connection with a growing of GM crops in Danish fields. The fourth session of the hearing discussed the issue of compensation in cases of spreading. The last session of the hearing invited different stakeholders to present their view on the bill on co-existence. Each session consisted of three short presentations by different experts. After the presentations in each session there were time for questions and discussions from the panel of politicians (committee members). Also a few questions from the audience were allowed.

MAJOR OUTCOMES OF THE PROJECT

The aim of the hearing was to initiate discussions, generate knowledge, and collect experiences on the co-existence between GM crops and non-Gm crops. The hearing was recorded and later transcribed and published in a report. Due to the method of this project the report does not contain any overall conclusions but emphasizes, through the different viewpoints, the challenges that the growing of GM crops causes.

Since Denmark has no actual experiences with the growing of GM crops, several international experts were asked to speak at the hearing to share their experiences with the co-existence between GM crops and non-GM crops. In Austria, the agricultural structure (small farms and narrow fields) makes co-existence problematic. Further, Austria has passed a law that prohibits growing of GM crops in the northern part of the country - GM-free zones. In Spain they have more experience with GM crops and Bt-maize have been grown since 1998. The GM crops have been grown without any kind of precautions, without any control considering the agricultural results and the environmental impacts, and without information and transparency. According to Friends of the Earth, there are several examples of spreading and thus contamination of conventional and organic crops in Spain. Experiences from Canada further show that the growing of GM crops will have a negative impact on organic farming.

Economic potentials and costs of growing GM crops in Denmark were further discussed with reference to international experiences. So far, the growing of GM crops seems to bring both extra costs and savings. GM crops will no doubt become a factor of competitiveness, and in order for Denmark not to loose its competitive advantages it was broad forward that it is necessary that Denmark launch GM crops now. In the end, it all comes down to the individual farmer whether there are economic incentives to grow GM crops. Besides the potential economic benefits that GM crops will bring about, other possible advantages considering GM crops were discussed. The effects of shifting to GM crops vary from crop to crop. Some of the advantages that have been identified include increased yield and productivity, a reduction in the use of pesticides, a more efficient weed control, less erosion and leaching, and a better economy for the individual farmer. If the experiences from the US are transferred to Europe there is thought to be great benefits for the farmer as well as the environment, the consumer and society.

These claims was however dismissed by other experts who emphasized that we should not expect too much from the GM crops since they have not really shown any great potentials yet. Furthermore, some experts questioned the potential environmental advantages that are often highlighted in discussion on GM crops. Thus, the hearing showed that there are quite contradictory opinions considering the potential benefits and detriments of growing GM crops.

The Government’s suggestion for a bill on co-existence includes a system of compensation that guarantees farmers whose crops are polluted by GMO’s to receive compensation. During the hearing both governmental systems of compensation and

private insurance covers were discussed in this context. It was further discussed whether such a system of compensation would cover all losses in a case of spreading from GM fields to conventional and organic fields.

The hearing pointed to a passing of the bill on co-existence in Denmark. Throughout the hearing it further became clear that the provisional proposal for the co-existence were in need of some adjustments before the final decision to pass the bill.

IMPACTS AND FOLLOW UP OF THE PROJECT

Based on the discussions and experiences derived from the hearing, the original bill of co-existence was faced with some proposed amendments. Thus, after the hearing, the bill of co-existence went through two additional readings before the final bill on co-existence was passed in the beginning of June 2004. There were several amendments employed in the final bill on co-existence and the more prominent ones included changes considering the system of compensation in favour of organic farmers and the protection of their interests, and a system of publication that would make information (position, size and type of crop) about GM fields available to the public. The final bill on co-existence further enabled the minister to revoke approvals in cases where there is a danger that an approval might be misused.

CHALLENGES IDENTIFIED IN THE PROJECT

The greatest challenge considering the co-existence between GM crops and non-GM crops is that of spreading. To avoid the spreading of pollen it is necessary to keep a distance (dependent on the biology of the crop and the threshold value) between fields with the same kind of crops, and other cultivated plants that the crop might cross with. Intervals of growing are assessed as one of the most effective methods to avoid the spreading of seeds. However, it is impossible to secure a complete non-spreading. In order to minimize spreading it is necessary to take some overall principles into account. First of all, the methods used to prevent spreading should depend on the crop being grown hereby considering the different characteristics that the different GM crops have. Secondly, the given system of agriculture, whereto the rules of co-existence should be applied, needs to be considered; e.g. geography and landscape. Ultimately, it is necessary to consider the scope of GM crops. Thus, co-existence is assessed to be possible if the necessary precautions are taken.

Conclusively, the hearing emphasized that the ultimate challenge is to make a better and extended system of compensation and that the rules on co-existence are addressed at a EU-level that secures that all member states have common rules considering co-existence and compensation. Considering the widespread scepticism towards GM products that can be identified within the Danish population, it is crucial that consumers are given a genuine choice between GM products and non-GM products. This can be ensured through labelling of products that are genetically modified and through a securing of GM-free production; e.g. that organic alternatives are available.

LITERATURE

The Danish Board of Technology, (2004): Erfaringer med sameksistens: Høring om erfaringer med sameksistens mellem genetisk modificerede afgrøder og konventionelle og økologiske afgrøder. http://www.tekno.dk/pdf/projekter/p04_Erfaringer_med_sameksistens.pdf

AUTHOR OF THE REVIEW

Søren Gram

NEW GM CROPS – NEW DEBATE (2005) 2.4

BACKGROUND OF THE PROJECT

The DBT-project *"New GM crops – new debate"* was initiated with the purpose to investigate how the Danish citizens assess the use of new GM crops involving plants producing medicine and industrial chemicals and new ornamental plants. The project was suggested by the Danish Forest and Nature Agency (part of the Ministry of the Environment). Previous projects and debates had shown a public scepticism towards GM food and feed crops due to the fact that the benefits of this technology are not obvious or directly related to the public. Thus, it became interesting to investigate the public's attitude towards the use of GM plants with completely different purposes than those usually discussed.

Many of these new applications of GM plants appear to bring potential benefits to both human health and the environment. GM plants producing medicine are expected to be able to reduce the production costs of certain expensive medicines, and in other cases to create new possibilities for treatment. For industrial use, plants are genetically modified to be little biofactories that produce raw materials and thus contribute to a minimization of the use of chemicals. Finally, GM ornamental plants would create inventions such as blue roses or durable harebells. Still, these GM plants are grown under the same conditions as GM food and feed crops.

Based on this, the project set out to examine how Danish citizens assess the potential advantages and disadvantages of the new GM plants. The aim of the project was to present arguments for and against: how are the plants' potential benefits and detriments considering health and environment assessed, and what are the economic possibilities and consequences – considering both the societal and the consumer level.

BASIC DATA ABOUT THE PROJECT

The project was addressed through the use of a citizens' jury. 2000 Danish citizens were invited via the Civil Registration Number register to apply for participation in the citizens' jury. On the basis of the applications received, 16 citizens were selected. The aim was to assemble a citizens' jury that was relatively representative regarding gender, area of residence, age, education and job.

The sixteen laymen took part in the citizens' jury that was assembled from the 28th of April to the 2nd of May 2005. A planning group assisted the Danish Board of Technology in planning the project and formulating the questions that the citizens' jury was presented with. During the five days of the citizens' jury, the laymen met with experts and stakeholders and discussed advantages and disadvantages of the new crops. Based on this dialogue, the citizens' jury formulated arguments for and against the new GM plants and conditions for the possible growing of GM plants in Danish fields and general recommendations in connection with this.

Ultimately, the citizens' jury was concluded by a vote upon the arguments, conditions and recommendations that expressed their attitude the best. Thus, citizens were not required to reach a consensus, but asked to prioritise the arguments elaborated by them-selves and then vote for those that they considered most important.

The citizens were asked to consider the new uses of GM plants at three different levels: what are the arguments for and against GM plants within the category in question (medicine, industry or ornamentation); on which conditions can GM plants for medicine, industry or ornamentation respectively be grown in Danish markets; and which general recommendations are there for the future handling of new GM plants. These questions were addressed through 7 votes on which the recommendations and conclusions of the report are based.

MAJOR OUTCOMES OF THE PROJECT

Interpreting the voting results, the main conclusions of the report seem to be that the citizens' jury assessed the new uses of GM plants to be predominantly beneficial. Still, the citizens' jury had reservations considering some specific applications of the technology. Thus, the citizens' jury proclaimed a conditional yes to the new GM plants.

The main arguments *for* the GM plants included improvements with regard to the environment and public health, financial advantages (both for society in general and the individual consumer) and business opportunities. The citizens' jury assessed that Denmark should tap its potential for developing GM plants due to the fact that Denmark has significant knowledge and experience, not to mention effective legislation. The most important argument *against* GM plants referred to the risk of unintentional spreading of foreign or undesirable characteristics. But the majority of the citizens' jury assessed that existing regulations – including the act on co-existence – and approval procedures considers these problematic issues.

Considering the usage of GM plants for **medicine** the voting results showed that the arguments for received more votes than the arguments against them. However, if the production of medicine includes the use of human or animal genes, it was a high priority for the citizens that there are strict requirements for approval of new products, and that the production takes place in closed environments.

The citizens' jury received developments of **industrial** GM plants as positively as plants producing medicine. It was especially applauded that industrial plants have the potential for replacing present production methods with more environmentally sustainable ones.

The attitude towards GM **ornamental** plants was less optimistic than the two other usages. The vote showed that there was slightly more arguments against than for the growing of GM ornamental plants in Danish fields. The citizen's jury further emphasized that the main condition for the growing of GM ornamental plants is that herbicide-tolerant grasses are not going to be approved due to the significant risk of spread to cultivated areas as well as to other vegetation.

An important condition for allowing the new plants that was emphasized was, that the environmental consequences of irresponsible practices should be assessed. Further, the growth of the new plants should not pollute more than existing modes of production - particularly concerning fertilizer or pesticide usage. Thus, any negative impact on ground water and soil should be part of the risk assessment. However, the citizens' jury did not see any reason for alarm while the present legislation and administration is considered adequate to limit the risks. Instead, there should be more focus on public education and information about the new GM plants. In fact, the clearest message from the citizens' jury was not about advantages, disadvantages and conditions with regard to GM plants, but about the necessity of informing the population about these matters as part of an open and nuanced debate.

Conclusively, it appears that the public's estimation of use clearly differs depending on the use of GM plants. The debates on GM plants for food and feed showed that the public questioned these usages by asking: why? The purposes and benefits are not obvious to the public. On the contrary, this project on the use of new GM plants poses the question; why not? In general, the citizen's jury did not see any reasons to impede the further development of GM plants - at least for medical and industrial use - as long as this does not involve environmental or health hazards, that exceed existing or alternative modes of production.

IMPACTS AND FOLLOW UP OF THE PROJECT

The citizens' jury presented their results the 2nd of May 2005 at a conference at the Danish Parliament with the attendance of politicians, experts and various stakeholders. After the citizens' jury's presentation of the results, politicians representing different parties and different stakeholders commented on the assessments and discussed them with the jury. The results of the conference were subsequently mentioned in the media.

In November 2005 the Ministry of the Environment held a conference on the use of GMO's. Whether this conference was a direct follow-up of the DBT-project is difficult to say, but the themes discussed at the conference were, in particular, concerned around new uses of GM plants.

The results of the citizens' jury were furthermore mentioned in a report on a biotechnology strategy considering non-food and feed published by the Directorate for Food, Fisheries and Agri Business in February 2006.

In September 2005 the Danish moratorium (since 1999) on the growing and the marketing of GM crops were finally revoked. The reasons for this action were grounded in the implementation of rules considering labelling, traceability and co-existence. The results of the citizens' jury *might* have had an impact on these decisions, but it would be wrong to link the two incidents directly.

CHALLENGES IDENTIFIED IN THE PROJECT

The citizens' jury identified several challenges considering the use of GM plants for other purposes. One challenge is the retention of a free consumer choice in a way that genetically modified products are labelled. Another challenge is to strengthen public research to form a contrast to private research and development, as public research seems necessary to maintain sufficient control of the new GM plants. The far most obvious challenge considering these new GM plants is that usages do not pollute more than the corresponding traditional modes of production or better alternatives.

LITERATURE

The Danish Board of Technology, (2005): Nye GM-planter - ny debat. http://www.tekno.dk/pdf/projekter/p05_GM-planter_rapport.pdf; English summary: Contitional yes to new GM plants. http://www.tekno.dk/pdf/projekter/p05_gmp_rtt.pdf

AUTHOR OF THE REVIEW

Søren Gram

FINLAND 3.

DEBATE BETWEEN PUBLIC ADMINISTRATION, RESEARCHERS AND GENERAL PUBLIC CONCERNING THE PLANT GENE TECHNOLOGY

During last five years, the Finnish debate between public administration, researchers and general public concerning the plant gene technology can be divided in four types of activity:

- General and plant gene technology focused public hearings
- Public administrative information of field tests and product approval processes
- Special administrative processes which have taken into account the public opinion
- Scenarios concerning possible implications of plant gene technology

PUBLIC HEARINGS

In order to discuss the ethical dimensions of genetics, Ministry of social affairs and health arranged a seminar "Genes and values" in Hanasaari, Espoo in 2002. The audience consisted of over 100 invited participants, and the program consisted of presentations by experts and a panel guided by a media professional.

A booklet introducing in the subject had been composed in advance, and it was delivered for the participants. The booklet served mostly prejudices and popular beliefs concerning plant biology and agriculture circulated by GM critical political movements. The beliefs were discussed by philosophers specialized in ethical problems of gene technology. No scientific experts of plant breeding research were consulted in the booklet.

The popular beliefs were the foci of the meeting, too. The sole discussant representing the science of plant biology - an associate professor in plant breeding - was offered a very short time (5 minutes) to tell about new GM varieties. The media professional chairman had customarily little knowledge of science.

The leaders of the Finnish anti-GM society were invited. Their full handful of members trespassed in the seminar with video cameras and recorded the discussions. Such behaviour did not promote the free atmosphere of the discussions. As their response to the scientific presentations, the "activists" nailed up the ultimatum that the scientist lecturing on plant breeding shall be discharged.

It was no surprise that the seminar resulted in messages putting science under suspicion. But as a trade-off it also brought important science reporters in place. The presentation on plant breeding, albeit minuscule, gave many a first contact with the sub-

ject and its true possibilities. Hence, certain media columns were opened later on for the first time also for scientific facts regarding modern plant breeding.

Special contribution was made by philosophers. They analyzed also in the final report of the conference the quality of typical arguments given for and against gene technology. Logical analysis of superficial statements made by emotional opponents is a good way to promote rationality in the field. Besides that it is highly important that with careful scientific (and not only logical) analysis prejudices and real threats will be separated.

Other ministries have also arranged general seminars in the area. E.g. ministry of agriculture and forestry (MAF) have arranged many seminars as a part of the hearing process of their strategies or laws in preparation. Such seminars have been arranged concerning Gene Technology Strategy[2] (2003, wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2003/trm2003_18_en.pdf) and Co-existence[3] (2005, wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2005/Trm2005_9a.pdf). The bulk of the invited participants have been professionals from the field of activities of the ministry, but invitations also cover public interest groups such as societies and other NGOs.

In addition, seminars explaining the biological basics and topical situation regarding GM products in agriculture have been arranged by MAF for media people a few times, with fair success. Presentations are always given by top experts of science, legislation or administration in the field. Experiences of such focused seminars connected with preparatory work of administration and authorities are in general positive in Finland

PUBLIC ADMINISTRATIVE INFORMATION OF FIELD TESTS AND PRODUCT APPROVAL PROCESSES

Applications for GM product approvals are decided at Community level in EU, and all member states participate in the process. When the information concerning a product application arrives in Finland, a short Finnish summary and links to official documents dealing with the application are made publicly available. They are in the Internet pages of Finnish Food Safety Authority EVIRA, the authority ordered to take responsibility of the information delivery in these cases. In the pages, advice is also given how people can give their opinion of the application to EU authorities using Finnish language. In addition, a press release is given in a broad delivery in order to activate the media.

2 Gene Technology Strategy and Action Plan of the Ministry of Agriculture and Forestry 2003-2007. Working Group Memorandum 2003:18, Ministry of Agriculture and Forestry, Helsinki, Finland, 2003.

3 Enabling the coexistence of genetically modified crops and conventional and organic farming in Finland. Mid-term report. Expert Work Group on Coexistence, Ministry of Agriculture and Forestry, Finland, 2005

Finnish Gene Technology Act provides for the applications of GMO field tests to be communicated with public efficiently enough. The act implements Directive 2001/18/EC. Regarding a field test with GM white birch seedlings, public informative meeting was selected as the way of action.

The meeting was thoroughly advertised in local media, starting well beforehand. In spite of that, only two persons representing general public did arrive, the other of these was probably a local farmer. All other audience, a few scores of people, consisted of (mainly local) university scientists, many of whom participated in the GM research program (ESGEMO), and members of the Board for Gene Technology; plus the handful of activists (always the same few ones) from the specialised "GM-free" society.

For public discussion, far more important was the destruction of GM white birch seedlings made by plant GM opponents. As the result of extensive discussions in newspapers, the public opinion turned strongly against destructors. It was realized that there was no point in this destructive act because these non-flowering birches have no real way to diffuse their genetic material to non-GM birches or other plants. Instead, GM birches would have a real positive impact on town environments because of less allergic reactions. Actually based on their safety and positive impacts on health, an environmental organization (Ekosäätiö, Eco Foundation) gave its price to the developers of GM birches. Based on the destructive act, the public opinion is now much more favourable for the limited public information concerning the cultivation places GM plants. The irrationality of the GM opponents became much more evident for the general public.

SPECIAL ADMINISTRATIVE PROCESSES WHICH HAVE TAKEN IN ACCOUNT THE PUBLIC OPINION

We consider that it is highly important for a rational approach concerning the plant gene technology that the administration does not follow prejudices of the public opinion. This is especially important because of the feedback to the public opinion. Critics of gene technology with little science expertise can use the choices of the administration as an evidence for their opinions.

In Finland, the above problem was met related to restaurant criteria proposed for the Nordic Swan ecolabel. The aim of the ecocertificate is declared to be helping people "to choose the most environmentally-friendly products" and to avoid the use of the most environmentally burdening products (www.svanen.nu/Eng/default.asp).

Criteria for Nordic restaurants to fulfil in order to receive the ecolabel were proposed (June 2006). Without any statement of reason based on facts or science, all use of genetically modified constituents was categorically forbidden in the restaurants with ecolabels. That proposition excited Finnish life scientists to express their objections to the misuse of such populist prejudices which only damage true efforts on environmental protection. Among others, the traditional and most prestigious life science society in Finland (Societas Biochemica, Biophysica et Microbiologica Fenniae)

strongly criticized such anti-science attacks detrimental to environment in its statement. Applications of modern biological research, including gene technology and genetic modification, are fundamentally required for environmental ameliorating, and their impacts shall be properly assessed case-by-case.

Notable environmental benefits have already been obtained by producing the so-called traditional GM varieties for 10 years (Sanvido et al. 2006[4], Brookes et Barfoot 2006[5]). Yet essentially greater remedies could be anticipated from "second generation" GM varieties specifically designed for environmental enhancements. Such innovations include resistant plant varieties with better tolerance to drought, cold, flooding, salt as well as pests and diseases.

For example, blight-resistant potato was bred with gene technology by obtaining the resistance gene from a wild potato species. The healthy variety is in field tests for the third year in EU. Cultivating blight-resistant potatoes would save EU each year from 860 million kg of yield being wasted, and 7.5 million kg of fungicides to be sprayed (expressed as active ingredient). Of course that also means great reductions in oil use and greenhouse gas emissions in agriculture (Phipps et Park 2002[6], Gianessi et al 2003[7]). Organic producers could also benefit from the use of blight resistant varieties, because the risk of spreading the disease from other plantations to the fields used for organic production would be smaller.

---

4 Olivier Sanvido, Michèle Stark, Jörg Romeis and Franz Bigler (2006). Ecological impacts of genetically modified crops. Experiences from ten years of experimental field research and commercial cultivation. *ART-Schriftenreihe 1*. Fed. Dep. Econ. Aff. DEA, Switzerland, 108 p.

5 Graham Brookes and Peter Barfoot (2006). Global Impact of Biotech Crops: Socio-Economic and Environmental
Effects in the First Ten Years of Commercial Use. *Agbioforum* 9: 139-151.
Abstract: Genetically modified (GM) crops have now been grown commercially on a substantial scale for ten years. This paper assesses the impact this technology is having on global agriculture from both economic and environmental perspectives. It examines specific global economic impacts on farm income and environmental impacts of the technology with respect to pesticide usage and greenhouse gas emissions for each of the countries where GM crops have been grown since 1996. The analysis shows that there have been substantial net economic benefits at the farm level amounting to $5 billion in 2005 and $27 billion for the ten year period. The technology has reduced pesticide spraying by 224 million kg (equivalent to about 40% of the annual volume of pesticide active ingredient applied to arable crops in the European Union) and as a result, decreased the environmental impact associated with pesticide use by more than 15%. GM technology has also significantly reduced the release of greenhouse gas emissions from agriculture, which, in 2005, was equivalent to removing 4 million cars from the roads.

6 Phipps & Park (2002). *J Animal Feed Sci.*11**:** 1–18.

7 Leonard Gianessi, Sujatha Sankula and Nathan Reigner (2003). Plant biotechnology: Potential impact for improving pest management in European agriculture. Potato case study. NCFAP

The objections of the scientific community were accepted by the administration responsible for the Nordic Swan ecolabel. It was decided in autumn 2006 that genetically modified constituents are allowed in Nordic Swan ecolabeled restaurants.

SCENARIOS CONCERNING POSSIBLE IMPLICATIONS OF (PLANT) GENE TECHNOLOGY

Based on assessment project concerning social impacts of the human genome and stem cell research by the Committee for the Future, a scenario book was made. The aim of the book was to inform the general public about most important results of the assessment project. Beside that it illustrated possible future impacts of gene technology with three scenarios. The scenario book (Kuusi 2004)[8] got considerable publicity in media.

The names of the scenarios characterize their content:

- Safety first of all
- Wealth and employment from gene technology
- Gene information belongs to everybody

All scenarios were discussed as reasonable choices making different assumptions concerning future developments. After the presentation of the scenario story its probability was discussed. For example, in the first scenario the blight-resistant potato resulted in a lagged serious health problem. In the discussion part, the probability of that problem was discussed. It was considered that even taking into account the risk it is reasonable to accept the blight-resistant potato. The conclusion was the same as in the third scenario: Also in order to solve possible problems related to gene technology, the best choice is to make it commonplace.

Like the information technology, gene technology should belong to everybody. It requires an internet based "Gene Information Centre" providing its services to everybody. In a safe environment (compare banking services), it makes sense to integrate this type of personal gene information with one's personal electronic patient records.

AUTHORS OF THE REVIEW

DSc(Agr&For) Jussi Tammisola

PhD Osmo Kuusi

8 Osmo Kuusi (2004) Geenitieto kuuluu kaikille (Gene information belongs to everybody), Edita, Helsinki

FLANDERS 4.

PUBLIC FORUM »NEW IMPULSES FOR THE DEBATE ON GENETICALLY MODIFIED FOOD« (2003) 4.1

BACKGROUND OF THE PROJECT

On September 25th 2001 a hearing was held in the Flemish Parliament to discuss the advices published by five Flemish advisory bodies[9], by request of the Flemish Parliament[10], on the topic of genetically modified organisms(GM organisms). A recurring element in the five reports was the importance of organizing a public debate on this topic.

The Flemish Institute for Science and Technology Assessment, viWTA, established by Decree on 17/07/2000 provided the opportunity to respond to this advice. The Board of the viWTA decided in December 2001 to organise a pilot project on this topic. In Spring 2002 this topic was narrowed down to 'genetically modified food'. The project was officially launched in May 2002 with a pre-study. The goal of this study was to map the existing debate on genetically modified food in Flanders (actors, positions, legal situation,…). The report of this study was published in November 2002, in December 2002 the Public Forum was launched. On the 26th of May 2003, the 15 members of the citizens panel submitted their final report to Mr. Norbert de Batselier, President of the Flemish parliament.

MAJOR OUTCOMES OF THE PROJECT

The report of the Flemish lay panel contained 28 recommendations, centred around six major themes:

- Legislation, control and consultation
- Information
- Ethics
- Health issues
- Global and economic issues
- Environmental consequences

Most important of these recommendations, also in the light of European legislation, are:

9 De Sociaal Economische Raad van Vlaanderen (SERV), de Milieu en Natuurraad van Vlaanderen (Mina-raad), de Vlaamse Raad voor wetenschapsbeleid (VRWB), de Vlaamse Land- en Tuinbouwraad (VLTR) en de Vlaamse Gezondheidsraad.

10 Adviesvraag van 11/02/2001 van Trees Merckx-Van Goey houdende raadpleging van diverse adviesorganen over de problematiek van genetisch gemodificeerde organismen.

Legislation, control and consultation:

- Even after the discussion it is still not clear who is liable in case of problem (product liability as well as environmental liability). The reference persons did not know the answer. This leaves the initiative to politicians. The liability has to be regulated so as to be legally binding. It has to be unambiguous, leaving little room for interpretation and for dodging responsibilities.
- It is hard to choose between genetically modified foodstuffs or food without GM organisms: you cannot choose for something that is not available yet. But when genetically modified food arrives, there is a real danger that non-genetically modified food will be under pressure. The choice has wider implications than mere labels. If you want to sell both (labelled) genetically modified food and non-modified food, you need two completely separate circuits. Freedom of choice has to be guaranteed. This is a complex issue. Both those who want to purchase genetically modified food as those who do not, need to be able to make a choice. If nothing changes, the situation will not improve.
- The introduction of genetically modified food on the market might lead to increasing production costs for non-GM food, a.o. because of extra checks. The sector of genetically modified food will be able to compensate this extra cost because of cheaper production techniques.
- The European rules for permits are not bad; they are the result of hard work. The E.U has a procedure for quickly recalling GM products in case of problems. But the rules are not watertight: the evaluation of permits is left to scientists and politicians. The evaluation of permits ought not to be restricted to scientists, but extended to other areas of expertise (economists, sociologists, philosophers).

Information:

- The new EU legislation allows for public consultations, but the form in which this will happen is still vague (active or passive approach?) A large majority of the Flemish laypanel believes the government ought to provide clear and neutral information. A majority thinks the existing website of the Belgian Biosafety Server (http://biosafety.ihe.be) can fulfil this role, but is must be translated from English. The site can be expanded into a portal site.
- Labels must be uniform throughout Europe (using clear icons)
- Citizens prefer an active consultation of the public under EU legislation. This allows the citizen to voice his opinion. Participation can only be useful after an awareness-raising campaign.

Ethics:

- There is no universally accepted ethical position, but there are nevertheless clear ethical limits. The different scope of arguments (based on risks vs. based on duties) makes an ethical debate difficult. However, ethical considerations must play a role in allowing genetically modified foodstuffs.

Health issues:

- The health risk of genetically modified foodstuffs that are introduced in the market are negligible. Strict and reliable checks have convinced the lay panel that the health risks of regulated genetically modified food are negligible. Consumers can regain their confidence if they are informed in a reliable way about the health issues related to genetically modified food. But permanent checks and controls stay necessary for genetically modified food. Because of the complexity of the issues, this debate must be conducted in public.

Global and economic issues:

- The authorities have to provide a framework and the means for the transfer of knowledge and technology between North and South, and for establishing local research facilities in the South.
- The authorities should continue to support fundamental research and the technological development of genetically modified organisms. But the subsidies have to be made dependent on promises to share the relevant knowledge with the Third World.
- Research into traditional and biological agriculture must not be neglected, but should continue to exist as a full area of research.

Environmental consequences:

- Evaluation of the environmental hazards is extremely important. Each case has to be thoroughly investigated.
- Biotechnology must make a responsible choice, respecting biodiversity, the biotope of the crop and the ecosystem. These elements must be taken into account during risk analysis.
- Once genetically modified food is brought to market, environmental risks still need to be monitored. The present post-marketing plan does not provide for adequate control. The costs for more systematic controls have to be borne by the biotech industry.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic issues, that could be further explored in the questionnaire, seem very generally:

- Ways to engage the public in decision making processes on GMO's: active/passive?
- Importance of understandable, down to earth communication about GMO's
- Freedom of choice/possibility of creating complete separate circuits
- Effect on introduction GM-food on production costs for non GM food (extra checks and quality control systems)
- Multi-disciplinary evaluation of risks
- Challenges to labelling
- How to involve ethical considerations in future approvel procedures?

› How can the south benefit from European research?

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

FUNCTIONAL FOODS. STATE OF THE ART (2006) 4.2

BACKGROUND OF THE PROJECT

Functional foods represent one of the most intensively investigated and promoted area in the food and nutrition sciences today. Functional foods are fortified or enriched foods that provide health benefits beyond the provision of essential nutrients, when they are consumed at efficacious levels as part of a varied diet on a regular basis. Linking the consumption of functional foods with health claims should be based on scientific evidence. However, not all foods on the market today that are claimed to be functional foods are supported by enough solid data to merit such claims. What are the benefits and what are the risks?

In this comprehensive study, the consortium Food2Know (University of Ghent) and Flanders' FOOD (knowledge centre for the Flemish Food Industry) made an overview of different functional food products on the market in Flanders. Using a questionnaire, the societal issues were elaborated by 30 experts in this field (diet and nutrition experts, retailers, consumer and patient organisations, regulatory bodies, academic researchers and stakeholders from the Flemish food industry). Information was gathered on issues such as the scientific evidence linked to the health claims, the regulation in Flanders and Europe and the role of functional foods in the Flemish health policy.

The results were summarized in a report (only available in Dutch) and were presented during a debate with experts and policymakers in the Flemish Parliament. The project had no further impact on policy making.

MAJOR OUTCOMES OF THE PROJECT

The study focused on the following issues:

Scientific evidence for health claims:

There is a need for stricter control of the scientific basis of health claims on functional food products. Today, health claims are not reliable enough. More precise understanding of the mechanisms of actions of functional food and more scientific evidence is required.

Functional foods and health policy:

A frequently asked question is if functional food can be a part of the disease risk-reduction public health program? This study concluded that government policy and action must keep focussing on healthy lifestyle, balanced food intake and sport. Functional food cannot solve what has been damaged by ignoring these points.

Safety:

The products that are on the market today, are considered to be safe. Nevertheless, enrichment of food products with specific nutrients can imply much higher doses of intake by consumers. The experts in this study supported the idea of mentioning a maximum dose on the label of each functional food product. Another important risk is that functional food can give a false feeling of safety. Functional food could become an excuse to give less attention to sport and food habits.

Price of functional foods:

Functional food products are quite expensive. Experts recommend actions to make the possible advantages of functional food available for everybody.

Information overload:

News articles are often contradictory. It is very difficult for consumers to select the relevant and scientific based information.

Food and medicine:

Experts see a clear trend towards the use of food for medical purposes.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic aspects of functional food, that could be useful to the subject of GMO's, seem very generally:

- Scientific evidence for benefits of these type of food products
- Safety of the products
- Price of the products: Who can benefit? Who will pay for GM food?
- Challenges to labelling: information overload for consumer
- Consumers attitude towards GM food: experience of food, food culture.

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

INDUSTRIAL BIOTECHNOLOGY IN FLANDERS: STATE OF THE ART (2006) 4.3

BACKGROUND OF THE PROJECT

Industrial or white biotechnology is the application of biotechnology for the processing and production of chemicals, materials and energy. White biotechnology uses enzymes and micro-organisms, such as yeast and bacteria, to make products in chemistry, food, paper and pulp, textiles and energy. White biotechnology uses biomass as an alternative to fossil resources for the production of biochemicals such as biofuels and biopolymers. In the future, genetically modified crops could be developed, as a renewable source for non-food applications.

In this comprehensive study, the Laboratory for Industrial Microbiology and Biocatalysis (University of Ghent) made an overview of the applications and fields of expertise in Flanders. Using a questionnaire, the societal issues were elaborated by 30 experts in the field of industrial biotechnology. Information was gathered on issues such as Flanders' chances to evolve to a bio-based economy, the opportunities for a more sustainable production, the implications for the economy in Flanders, and more specific for the agricultural sector.

The results were summarized in a report (only available in Dutch) and were presented during a debate with experts and policymakers in the Flemish Parliament. The project had no further impact on policy making.

MAJOR OUTCOMES OF THE PROJECT

The study focused on the following issues:

- *Sustainability*:
  Industrial biotechnology offers opportunities for a more sustainable production. Enzymes can drive chemical reactions towards the desired end product in a very effective and efficient way, under circumstances of normal temperature and pressure. Less energy is consumed and waste production is reduced. However, only a complete life cycle analysis can asses whether the use of industrial biotechnology is more eco-efficient.
  Secondly, instead of fossil fuels, agricultural raw materials, such as cereals and coleseed are used. This reduces the emission of greenhouse gasses. Some experts expect that production of crops will be more geographically spread, in contrast to the concentration of power within the limited amount of petroleum producing countries.
  Thirdly, the agricultural raw material must be produced in a sustainable way, avoiding deforesting, erosion and soil impoverishment.
- *Safety of the use of micro-organisms for industrial applications*:
  The (genetically modified) micro-organisms are bred in a closed reactor. After

use, the micro-organisms are separated from the product and killed. This is called "contained use".

- *Perception of the public*:
  Recent Eurobarometer results show that more than half of the interviewees believe that biotechnology can improve the life standard. Especially the medical applications receive a lot of support. However, the European citizen is still very critical towards the modification of agricultural crops or green biotechnology. Experts fear that this negative attitude will also involve genetic modification of crops for non-food applications.
- *Implications for the agricultural sector*:
  The agricultural sector of the future will not only produce food, but will more and more become a producer of chemicals, industrial raw materials and biofuels. Because the area of land in Flanders used for the agricultural production is limited, some experts fear that this competition will threaten the production of food. Proponents argue that the Belgian and European agriculture suffer from overproduction and that the European agriculture requires a high proportion of the overall EU budget to subsidise it. Another argument is that a lot of area is available in the member states that integrated the EU in 2004.
  In the future green biotechnology could make a substantial contribution in the production of agricultural production such as cereals for non-food uses.
- *Can Flanders evolve to a biobased economy*:
  In a biobased economy, an increasing number of chemicals and materials will be produced in biorefineries using renewable resources. Biomass derived energy is expected to cover an increasing amount of the energy consumption.
  The agricultural sector in Flanders will be unable to meet the demand for biomass. Import from neighbouring countries, Eastern Europe, America and even Africa will be necessary. Because of its central location and extensive transport infrastructure, Flanders is well placed for import and transport of these raw materials.
- *Financial investment in research and development of industrial biotechnology*:
  The biotechnological research in Flanders is mainly focused on green and red biotechnology. Therefore the experts from the questionnaire propose to invest more in the research and development of industrial biotechnology in Flanders.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic issues, that could be further explored in the questionnaire, seem very generally:

- Sustainability of GM crops for non-food issues
- Perception of the public towards GM crops for non-food issues
- Implications for the European agricultural sector
- Europe and the biobased economy

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

FRANCE 5.

INRA PROJECT »CO-CONSTRUCTION OF A RESEARCH PROGRAMME« (2002)

BACKGROUND OF THE PROJECT

The French National Institute for agronomic research (INRA) has been working for many years on the elaboration of a transgenic rootstock potentially resistant to Grapevine Fanleaf Virus (GFLV), together with a private partner. In 1999, the private partner decided to stop its participation to this research, because of the hatred public discussion on GM grapevine. INRA decided to continue its research and passed on all material to its laboratory in Colmar.

However, in 2001, and because the public debate on transgenic was still going on, INRA decided to suspend the ongoing experiments and to initiate a discussion on their pursuit within a working group integrating researchers, professionals and consumers, using a participatory process.

The initial question the working group had to answer was about the opportunity to realise field trials of rootstock potentially resistant to Grapevine Fanleaf Virus (GFLV). However, the working group reformulated the demand in the following direction:

- Which are the philosophical, social, economical and technical aspects at stake in this field trial? Knowing that there are many research needs related to grapevine diseases, how to define priorities et how to choose the types of arbitration.
- Should INRA continue to research on GM-grapevine and, if yes, which conditions have to be met in order to pass to the stage of field trials?

BASIC DATA ABOUT THE PROJECT

The selected method was based on the so-called “Technology assessment through interaction”[11]. It consists in putting together various worldviews, so that deliberations are nourished from a variety of arguments and standpoints.

The number of participants was limited to 14, so as to allow deliberation on complex problems and heterogeneous questions. Whereas some participants had no special expertise in the topic (so-called “laypersons”’), the group also comprised researchers and wine-professionals. The selection process was based on the results of a sociological study, which displayed a social cartography of worldviews around the topics of grapevine, wine and GMOs. The conceptions of science have also been considered

11 See Grin, J., van de Graaf, H., Hoppe, R., (1997). Technology assessment through interaction. A guide. Den Hag, Rathenau Institute (available at http://www.rathenau.nl).

in the selection process, as well as attitudes towards research on a transgenic rootsock for grapevine. Based on this analysis, the organisers invited:

- Four researchers working on research on grapevine diseases, but who hold different worldviews.
- Six grapevine and wine professionals, stemming from different geographical regions and holding different worldviews.
- Four citizens, also invited for the variety of their worldviews.

The working group met 7 times, from April to September 2002.

Various instances were part of the experiment:

- The General Direction of INRA, which initiated the project.
- 2 project managers.
- One research assistant.
- A steering group (comité de pilotage), composed of the project managers and the INRA Direction.
- An evaluation committee, composed of personalities external to INRA, specialized in the analysis of controversies and of participation.
- A moderator for the working group sessions.

MAJOR OUTCOMES OF THE PROJECT

The working group came to the following conclusions:

- Wine has a strong symbolic dimension. As a consequence, a genetic modification done on grapevine dedicated to the fabrication of "wine-food" could have a negative impact on "wine-pleasure" and on high quality wines.
- There is a strong attachment to a system production based on biological, technical and cultural variety. With respect to the threats related to grapevine diseases, various fighting methods should be developed, so as to contribute to the various production modes of vinegrape.
- Considering research activities, there is a lack of integrated and transversal approaches. There is a necessity for a better understanding of the interaction between the plant and its environment.
- INRA should continue to do research on genetically modified vinegrape in laboratory and green house. Field trials should also be implemented. But, on this last point, all group members did not agree on the opportunity to have field trials (2 persons against). Opponents to the field trials considered that even the solution may be technically satisfactory, it is not socially acceptable. In this respect, it could prejudice the status and image of French wine. The other 12 members considered as acceptable field trials with transgenic grapevine. But their positive opinion is limited to a given experiment and no opinion has been formulated on a possible commercialisation.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report of the working group has been passed on to the INRA Direction in September 2002. In January 2003, INRA decided to ask for an authorization for the implantation of field trials in Colmar, to set up a local follow-up committe and to create a mix commission in charge of defining the major orientations of wine and vinegrape research.

CHALLENGES IDENTIFIED IN THE PROJECT

- role of public research.
- transgenic wine and vinegrape
- dialogue and interaction
- The issue of trust
- Ability of public resarch institutions to set a boundary between research and its applications

LITERATURE

Co-construction d'un programme de recherche : une expérience pilote sur les vignes transgéniques. Rapport final du groupe de travail et réponse de la direction de l'INRA.2003. INRA: Paris. http://www.inra.fr/genomique/rapport-final-ogm-vigne.html

AUTHOR OF THE REVIEW

Danielle Bütschi

GERMANY 6.

GENETIC ENGINEERING, BREEDING AND BIODIVERSITY (1998) 6.1

BACKGROUND OF THE PROJECT

The TAB-project "Genetic engineering and breeding from the viewpoint of biodiversity in agriculture" (short title: “Genetic engineering, breeding and biodiversity”) was based on a recommendation by the Committee on Food, Agriculture and Forestry and was approved in Autumn 1996 by the Committee for Education, Science, Research, Technology and Technology Assessment of the German Parliament.

Background for the project was the 4. International Technical Conference on Plant Genetic Resources of the FAO at Leipzig in June 1996, which approved the Global Action Plan and the Leipzig Declaration for the “Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture”. Further, the Convention on Biological Diversity – ratified by Germany in 1993 – had defined objectives for the protection and use of the global biodiversity. These international commitments, to be implemented on national level, were one starting point. The other starting point was the questions, which impacts on biodiversity results from modern biotechnology.

The goal of the TA-project was to investigate what negative influences the use of genetic engineering in plant breeding can have on biodiversity, what contributions breeding and genetic engineering can make to conserving biodiversity and finally, what potentials can be derived for policy-making. A restricted, technology-centred perspective was not adequate for this theme. Particularly for the issue of potentials for conserving plant genetic resources and biodiversity in general, the approach was expanded in order to cover the significance of genetic engineering and breeding in the overall context.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in one and a half year, and finished in 1998. Four scientific studies were awarded in the project. The draft final report of TAB was based mainly on these studies and was evaluated by a number of experts from science, government and stakeholders.

The investigation area was limited to the field of plant breeding and - as far as possible - was restricted to the agricultural sector in Germany, taking into account European framework conditions. The topics of the project were:

- biodiversity and plant genetic resources – status and development,
- plant breeding – its goals, economic development and legal regulation,

- direct and indirect impacts of new (conventional and genetically engineered) varieties on biodiversity – systematic analysis of impact chains,
- biodiversity conservation measures – ex-situ, in-situ and on farm measures,
- international agreements and implementation of international obligations,
- options for action in the areas of research, agricultural, environmental and development politics.

MAJOR OUTCOMES OF THE PROJECT

The results of the project showed that modern agriculture has made a considerable contribution to reducing the biodiversity of many crops and wild plants in Germany through intensification, rationalisation, specialisation and concentration of production. Impacts on biodiversity have in particular been generated by changes in fertilisation, plant protection, rotation and land reallocation and consolidation. Plant breeding and modern plant varieties are all part of the changed agricultural production system and their impact on biodiversity is more of an indirect one. The central conclusion of the project was that in Germany and Central Europe the use of genetic engineering procedures in plant breeding will not have a specific, significantly negative influence on biodiversity compared to conventional breeding practices in the short to medium term. On the other hand, however, genetic engineering in plant breeding will not make any significant contribution to conserving or extending plant genetic resources.

To achieve the goal of "conserving biodiversity", there was seen a particular need for action on direct conservation measures. To this end the ex-situ, in-situ and on-farm conservation measures must be improved and developed. As Germany did not have a coordinated procedure on the conservation of plant genetic resources which incorporates all conservation measures, it was recommended to develop a combined conservation strategy. This would simultaneously be a major contribution to conserving biodiversity in Germany. In order to implement international agreements at national level and to develop and apply a national strategy to conserve biodiversity (including plant genetic resources (PGR)), close coordination and cooperation was regarded as necessary between the various policy fields and levels affected. Interested and affected societal groups should be incorporated into the national strategy development and implementation process.

A matter of central importance for the sustainable conservation of biodiversity was seen in a full-coverage change towards sustainable agriculture, in which the promotion of agricultural diversity and the protection of wild flora and fauna is a major component. The principles of organic farming which, in contrast to the still predominant conventional farming, involve more extensive and diversified farming practices, could therefore provide significant guides. It was pointed out that changes in basic framework conditions for agricultural and environmental policy do not make specific conservation measures (as discussed in the project) become superfluous, but their scope and urgency would take on a relative basis.

A broad spectrum of options for action in the different areas of the project was identified and discussed. As future issues were identified:

- monitoring of the impacts of patenting on plant breeding and variety protection;
- research on the impacts of the introduction of new varieties (conventional and transgenic plant varieties) on biodiversity of agro eco-systems and adjacent eco-systems, with special attention to the issues of changes in cropping systems, resistance development and resistance management;
- long-term ecological impacts require comprehensive post-marketing monitoring, coordinated and combined with fundamental research activities on biodiversity and plant genetic resources.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report was published as parliamentary document (Bundestagsdrucksache 13/11253). In the following electoral term, the report was deliberated in the leading Committee for Nutrition, Agriculture and Forestry and two consulting committees. The result of the deliberation in the committees was a recommendation and report for the plenary (Bundestagsdrucksache 14/1716), with a detailed catalogue of actions based on the options for action in the TAB-report. This recommendation was approved in the plenary meeting of the German Bundestag on 16th December 1999, by the governmental majority and the PDS.

In the federal agricultural report 2000 (Bundestagsdrucksache 14/2672), the Federal Government had pointed out that measures for the national programme on plant genetic resources and a research programme on biodiversity has been prepared, in order to implement the above mentioned decision of the German Bundestag.

CHALLENGES IDENTIFIED IN THE PROJECT

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- preservation of plant genetic resources
- impacts of patenting on plant breeding and variety protection
- uncertain future of small and medium seed producers
- impacts of the introduction of new varieties (conventional and gm varieties) on biodiversity of agro eco-systems and adjacent eco-systems

LITERATURE

Meyer, R.; Revermann, C.; Sauter, A. (1998): Biologische Vielfalt in Gefahr? Gentechnik in der Pflanzenzüchtung. Studien des Büros für Technikfolgen-Abschätzung beim Deutschen Bundestag Band 6. Edition sigma: Berlin

English summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab55.htm

AUTHOR OF THE REVIEW

Rolf Meyer

RISK ASSESSMENT AND POST-MARKETING MONITORING OF TRANSGENIC PLANTS (2000) 6.2

BACKGROUND OF THE PROJECT

The TAB-project "Risk assessment and post-marketing monitoring of transgenic plants" was demanded by the Committee on Food, Agriculture and Forestry of the German Parliament.

Background for the project was the ongoing debate in the EU on the authorisation of transgenic varieties and the amendment of the Deliberate Release Directive 90/220/EEC. The development culminated in the summer of 1999 in a de facto moratorium on approval of transgenic plants for marketing by the Council of Environmental Ministers, combined with the demand that the reforms in progress be completed before any new approvals are issued.

During the project execution, the German marketing approval for the maize variety Bt176/ "Windsor" (about to receive variety approval from the "Bundessortenamt" – German Federal Plant Variety Agency) was suspended in February 2000 under Article 16 of the Release Directive, which constitutes a safeguard clause. This event has sparked off forceful political and scientific controversy in Germany, which has also involved the German Bundestag and its committees on a number of occasions. In June 2000 the German Chancellor announced an initiative seeking to agree a three-year transitional phase with the companies involved during which commercial cultivation of transgenic plants would be possible only on a limited scale and in combination with increased research into safety aspects, and particularly an intensive monitoring programme. This was not implemented due to the emerging of the BSE crisis in Germany.

The goal of the TA-project was to give a focused overview of the status of the scientific and political debate. It was not the purpose of the project to provide novel answers to the outstanding questions on biosafety or develop separate proposals for the post-marketing monitoring.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in fifteen months (July 1999 – November 2000). Five scientific studies were awarded in the project. The draft final report of TAB was based mainly on these studies and was evaluated by a number of experts from science and government.

The investigation was limited to a status report on risk assessment and post-marketing monitoring of transgenic agricultural crop plants. The main topics of the project were:

- the status in safety research (inc. post-marketing monitoring) and the debate on risks,

- the state of regulation and treatment of authorisation procedures in the EU for the release, marketing and variety licensing of gm agricultural crop plants,
- the state of implementation of the Novel Food Directive (licensing and labelling).

MAJOR OUTCOMES OF THE PROJECT

For the **scientific debate on risks**, it was worked out that controversies regarding both general and specific impacts relate primarily to three different levels:

- first, the fundamental likeliness of occurrence (e.g. of outcrossing or development of resistance by insect pests),
- second, the degree of possible damage (e.g. reducing biological diversity or adversely affecting organic farming), and
- third, the possible or necessary measures to avert risk (e.g. size of the protective zones around fields with transgenic plants or design of resistance management).

Generally, the state of data appeared deficient in many respects, as while there had been over 1,300 release experiments in Europe alone, fewer than 1 % of release experiments worldwide have been linked with accompanying ecological research (although in Germany the figure was 15 %). Another reason why there was virtually no "real knowledge about risk" is the safety requirements needed for the accompanying ecological research. Critical voices pointed out that the lack of evidence of adverse ecological impacts suggests more that the wrong questions are being asked (with a resulting lack of corresponding studies) than the absence of any risk. Conversely, it is true that conventionally bred plants (i.e. not using genetic engineering) have never been subjected to biological safety testing, so that the impacts of transgenic varieties are always more thoroughly researched than those of conventional varieties. Many scientists also stressed that the new characteristics of transgenic plants are in principle much more clearly defined – and hence more easily documented and researched – than the results of conventional breeding.

However, a whole series of questions will in any event be impossible to answer in research projects with a limited life. First, the results of scientific research always generate not only answers but also new questions, and second because long-term indirect effects can generally only be observed in the course of longer-term cultivation of transgenic plants on a significant scale. This realisation had led to virtual unanimity among all involved on the development and implementation of long-term monitoring of transgenic plants under cultivation.

For the **risk assessment in the approval procedures**, the report looked in detail at how far the status of the scientific risk debate, and specifically the ecological aspects, were taken into account in the opinions in the framework of the approval procedures for marketing under Directive 90/220/EEC of both the EU scientific committees and national agencies (in Germany, Austria, the UK and – in part – Sweden), and how differences identified in the opinions can be explained. The result was that

- scientific contributions and arguments have been very much selectively used and variously interpreted,

- diverging conclusions have been drawn from gaps and areas of uncertainty in our knowledge, and
- above all, the possible consequences have been very differently evaluated in terms of the scale of damage and resulting implications.

Even after the amendment, there is still no definition of damaging impacts, so that there will still be considerable scope for different assessments. Not least, the question will be which agricultural paradigm the impacts of transgenetic agricultural plants are measured against. It will not be possible to derive a normative framework for this paradigm simply from the debate about GE applications: instead, this will require a serious definition and specification of the term "sustainable agriculture" as a stated goal of European agricultural policy.

For the **post-marketing monitoring** was pointed out that three dimensions or distinctions have special relevance:

- monitoring based on cause-and-effect hypotheses (even if partly unexplained or uncertain) versus unexpected or rare events,
- surveys of the agricultural ecosystem (and adjoining marginal structures) versus surveys of the environment generally,
- monitoring for limited periods versus long-term or unlimited monitoring.

The **overall main conclusions** of the report were:

No excessive expectations should be raised for the amended Deliberate Release Directive 90/220/EEC and the introduction of post-marketing monitoring. Their potential for resolving problems will inevitably remain limited until such time as fundamental agreement is reached on definitions of damage and desirable agricultural practice.

Both the amended Deliberate Release Directive and the Novel Food Regulation require operationalisation and specific guidelines for implementing the safety assessment and approval procedures. This is the only way to reduce discussions about the scope, coverage, methodology and interpretation of the safety assessments. This should build on the current state of the scientific risk debate. To this extent it will be an ongoing task, rather than a one-time exercise.

New instruments – such as post-marketing monitoring or revised labelling regulations – should only be introduced when their integration into existing statutory provisions and their implications have been carefully considered and widely discussed. To avoid new areas of conflict and controversy, e.g. in post-marketing monitoring a distinction should be made as early as possible between this and pre-marketing safety research and risk assessment and the criteria for incorporating information from monitoring in the approval procedure should be clarified.

Finally, new areas of conflict should be identified at the earliest possible state and investigated in advance. Attention is drawn particularly to the announced second-generation transgenic plants, which are e.g. supposed to have a health-promoting effect as "functional food". These will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely

new and possibly even greater problems in safety assessment than the current transgenic plants.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report was published as a parliamentary document (Bundestagsdrucksache 14/5492). The report was deliberated in the leading Committee on Consumer Protection, Food and Agriculture and two consulting committees. Thereby, the report was discussed controversial. The governmental majority presented a motion which included the whole spectrum of the report issues, proposed a further development of the concept sustainable agriculture and demanded a consequent application of the precautionary principle. In contrast, the motion of the opposition (CDU/CSU) concentrated on the rapid implementation of the new Deliberate Release Directive 2001/18/EC and was demanding a strengthened research and use of transgenic crop plants.

The result of the deliberation in the committees was a recommendation (of the governmental majority of SPD and the Greens) and report for the plenary which was approved in the plenary meeting of the German Bundestag on 14th June 2002. The TAB report was once again unanimously noticed by the plenary.

The part on post-marketing monitoring of the report was used in a documentation of the Federal Environmental Agency (UBA 2001) which summarise the state of debate at that time.

The report had pointed out that TA should be started on the new generations of transgenic plants at the earliest state as possible because these will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely new and possibly even greater problems in safety assessment than the current transgenic plants. Following this recommendation, TAB was commissioned with a project on transgenic plants of the second and third generation in 2003.

CHALLENGES IDENTIFIED IN THE PROJECT

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- need for more accompanying ecological research to assess possible risks of gm plants
- missing definition of damaging impacts, so that there is still a considerable scope for different assessments
- missing normative framework for desirable agricultural practice or sustainable agriculture, against which impacts of gm plants can be measured
- insufficient implementation of post-marketing monitoring
- need for clear distinction between post-marketing monitoring and pre-marketing safety research

- development of criteria for the feed-back of information from the post-marketing monitoring to the authorisation agencies and for impacts on running approvals or re-approvals
- importance of the second and third generation of gm plants (in particular plant-made-pharmaceuticals, plant-made-industrials, functional food) with potentially a shift in the debate from ecological impacts towards health impacts and new problems in risk assessment

LITERATURE

Sauter, A.; Meyer, R. (2000): Sachstandsbericht Risikoabschätzung und Nachzulassungs-Monitoring transgener Pflanzen. TAB-Arbeitsbericht Nr. 68. Berlin http://www.tab.fzk.de/de/projekt/zusammenfassung/ab68.pdf

English Summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab68.htm

UBA (2001): Stand der Entwicklung des Monitoring von gentechnisch veränderten Organismen (GVO) – Materialsammlung. UBA-Texte 60/01

AUTHOR OF THE REVIEW

Rolf Meyer

DISKURS GRÜNE GENTECHNIK (GREEN BIOTECHNOLOGY DISCOURSE) (2002) 6.3

BACKGROUND OF THE PROJECT

The so-called "Diskurs Grüne Gentechnik" ("Green Biotechnology Discourse" was initiated by the federal Ministry of Consumer Protection, Nutrition and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, BMVEL) in 2001.

The situation in the starting year was characterised by the worldwide growing commercialisation of gm crops, the amendment of the EU regulation on genetic engineering, the abandonment of the three-year transitional trial phase of introducing gm crops in agriculture due to the BSE crisis (see review on the TAB project 2000), and the new direction of the German agricultural policy (so-called "Agrarwende").

The goal was to "establish a forum for clarification of facts and for debate among all relevant societal groups" (BMVEL 2003, p. 5).

BASIC DATA ABOUT THE PROJECT

The "Green Biotechnology Discourse" was started in December 2001 and finalised in September 2002. 30 stakeholder groups – industry, agricultural organisations, environmental and consumer groups, churches, trade unions – took part in the discourse. Further, representatives of different other ministries were present. The steering committee of the discourse consisted of representatives of the stakeholder groups and was chaired by a representative of the BMVEL.

The discourse was split in two phases, the starting phase (with a kick-of meeting, the selection of the moderator, the constitution of the steering committee and a hearing) und the phase of so called "discourse rounds". The stakeholder and representatives of the ministry met in five "discourse rounds" of two days duration und in a conference. At these meetings opinions of 53 experts were heard and discussed by the participants. Care was taken to have an equal proportion of "pro-GM" and "anti-GM" experts. The moderator had prepared in the starting phase a "basic reader" which gave an overview on scientific, economic, ethic, social and legal issues.

The steering committee agreed on the main topics to be discussed in the five "discourse rounds":

- preservation of biodiversity,
- innovation potential and future chances of green biotechnology,
- benefits and risks for consumer and producer,
- preconditions, chances and consequences of an abandonment of green biotechnology,
- information, participation of the public and freedom of choice.

The results were published in a final report written by the steering committee (BMVEL 2002). The BMVEL published in addition a booklet in which the results are resumed as seen by the ministry (BMVEL 2003).

MAJOR OUTCOMES OF THE PROJECT

For major points, a consensus was not achieved. The final report lists for the different topics the points of consensus and dissent, and open questions. Some major outcomes are (BMVEL 2002):

- Biodiversity: Consensus on the importance of preservation the biodiversity, but dissent on what is a negative impact on biodiversity (e.g. out-crossing); important open questions are seen in the definition of ecological damage and in the responsibility for damages on biodiversity;
- Risk assessment: Fundamental disagreement on the deliberate release and use of gm plants; as most important open question was identified the understanding of the precautionary principle;
- Benefits of GM plants: Consensus about the importance of plant breeding, the potentials of conventional breeding and the need of molecular-genetic and ecosystem research for successful plant breeding, but dissent on specific benefits from GM plants; important open questions are seen in the clarification of potential fundamental differences between conventional breeding and genetic engineering and in the regulation of intellectual property rights;
- Benefits of GM foods: Consensus on the high standards of food security and quality in the industrial countries, but disagreement on the consumer benefits from product innovation in the past and from gm food; as prior open questions are regarded the definition of improved foods and the possibilities of healthier nutrition through gm food;
- Freedom of choice and coexistence: Consensus on the freedom of choice for producer and consumer, the labelling of gm foods and that with zero tolerance coexistence is not possible, but dissent on thresholds, measurements and accountability; to the identified open questions belong feasibility of coexistence, coexistence rules and liability;
- Labelling: Clear and practicable regulation for labelling is demanded; a consensus for seed thresholds was not achieved.

IMPACTS AND FOLLOW UP OF THE DISCOURSE

All important stakeholders in the field of green biotechnology have participated in the discourse. But no changes in the German discussion on gm plants and foods resulted from this exercise – there was no successful mediation across the GM divide. The discourse is extensively documented on the "transgen" website (www.transgen.de). This official website declares: "In the end the discourse had little effect. The various views continue to stand opposed to each other. A number of questions that were discussed at the time have meanwhile been settled politically, but this has hardly calmed down the controversies." (Transgen 2007) For the in 2002 re-

elected red-green coalition government, freedom of choice and coexistence remained the leading policy goals for the area of biotechnology and food. Following the new EU regulation, an amendment of the German regulation on genetic engineering took place in 2004 [?]. Pro-GM participants regarded this new regulation as blocking the use of gm plants.

It has been suggested that the discourse had a built-in design to cement rather than to mitigate the controversy. A fundamental divide between two sides appeared due to the requirement of the pro/contra proportionality in the selection of experts. This arrangement offered organisations with more outspoken views greater leverage on the kind of expertise that would be presented. Any substantive debate between different experts was frustrated. Experts were used as strategic resources by the participating organisations. One effect of the discourse was apparently that cooperation and coordination within each side of the GM controversy was strengthened (Paula/van den Belt 2006, p. 32).

CHALLENGES IDENTIFIED IN THE DISCOURSE

In the discourse identified (future) challenges which are still valid (conclusions of the reviewer):

- definition of ecological damage
- definition and operationalisation of the precautionary principle
- regulation and impacts of intellectual property rights and patenting
- consumer benefits from gm foods as improved food products and healthier nutrition
- feasibility of coexistence, coexistence rules and liability
- working labelling regime for gm food
- thresholds for labelling of seeds

LITERATURE

BMVEL (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft) (2002): Diskurs Grüne Gentechnik. Ergebnisbericht, durch den Lenkungsausschuss am 27. August 2002 verabschiedet

BMVEL (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft) (2003): Diskurs Grüne Gentechnik. Hintergründe, Standpunkte und Erwartungen zum Einsatz der Gentechnik in der Land- und Ernährungswirtschaft

Heine, N.; Heyer, M.; Pickardt, T. (2002): Basisreader der Moderation zum Diskurs Grüne Gentechnik des Bundesministeriums für Verbraucherschutz, Ernährung und Landwirtschaft – BMVEL. Osnabrück, April 2002

Paula, L.; van den Belt, H. (2006): INES – The Institutionalisation of Ethics in Science Policy: practices and impact. Work Package 5: Ethics in Food Technologies. Final report

Transgen (2007): Diskurs Grüne Gentechnik: Wissen, Informationen, Meinungen. http://www.transgen.de/wissen/diskurs/ (27.02.2007)

AUTHOR OF THE REVIEW

Rolf Meyer

GENETIC ENGINEERING AND ORGANIC FARMING (2003) 6.4

BACKGROUND OF THE PROJECT

In December 2000, the German Federal Environmental Agency (Umweltbundesamt – UBA) held a professional conference on the subject of "Green genetic engineering and organic farming". During this conference, possible approaches for protecting organic production sites as the use of genetically modified plants increase in conventional agriculture were discussed with persons representing organic farming from the research, production and administration sector.

The experts participating in the conference agreed that the only way to minimise contamination due to introgression from genetically modified plants is to use suitable prescribed distances between organic farming areas and fields containing genetically modified plants. Additionally, the establishment of zones that are free of GMOs should be considered within protected areas.

At the starting time of the project, there was no basic legal stipulations in Germany or in Europe with regard to these calls for minimum prescribed distances and GMO-free protected areas.

The objective of the "Green genetic engineering and organic farming" project was thus to present different legal scenarios for establishing regulations on minimum prescribed distances between organic farming areas and fields containing genetically modified plants within the German und European legal systems.

BASIC DATA ABOUT THE PROJECT

The specialist report entitled "Green genetic engineering and organic farming" (Barth et al. 2003) was prepared on behalf of the German Federal Environmental Agency by the Forschungsinstitut für biologischen Landbau Berlin e.V. and the Öko-Institut e.V. in the time between June 2001 and August 2002. The report includes the results of two workshops held on 29 October 2001 and 16 January 2002 in Berlin during which the initial results were discussed with various experts.

MAJOR OUTCOMES OF THE PROJECT

There is a world wide consensus among organic farmers not to use genetically engineered organism (GMO). Initially implemented through the guidelines of organic farming associations, this rule now gained accession to consumer protection legislation in the USA, Japan and the European Union.

EU LAW PERMITS PROTECTIVE MEASURES FOR ORGANIC FARMING

At the European level neither the EU regulation on organic agriculture nor the seeds directives prescribe mandatory measures for the protection of organic crops against

pollination by GMO pollen. An evaluation of EU Directive 2001/18/EC on the Deliberate Release of GMO shows, however, that the permission to market GMO may include an order to take measures to avoid property damage through pollination as one of the "specific conditions of use and handling" of the GMO. This results from a systematic and parallel interpretation of the EU Directive on the release of GMO and the EU regulation on organic agriculture. Only inasmuch as the interpretation of the Directive on the release of GMO takes into account the legislative targets of the EU regulation on organic agriculture will a balance of interests between organic agriculture and the cultivation of GMO be accomplished.

PROPOSALS FOR ISOLATION DISTANCES

Currently the most widely discussed option for affording protection against property damages is to provide isolation distances between cultures with GMO plants and organically managed cultures; another is to demarcate GMO-free regions.

Isolation distances have for a long time been used in seed production to maintain purity of breed. The goal is to keep impurity to a minimum. Statutory minimum isolation distances are based on past experience with seed production and they do not completely rule out hybridisation. Nevertheless, the imposition of safety distances does offer itself as one possible way of protecting organic agriculture.

An analysis of empirical data with a view of defining isolation distances revealed many gaps and hence an urgent need for further research. Despite this shortcoming, and for pragmatic purposes, the present survey was based on what data were available to derive first recommendations for isolation distances.

Measures for protection against property damages through GMO pollination in organic agriculture, such as the declaration of isolation distances on commercial packaging of GMO seeds, could be imposed by way of commercialisation permits. Implemented through commercialisation permits such measures could even today have an effect on civil-law relationships between organic farmers and GMO farmers, under certain conditions entitling organic farmers to claims for damages caused by genetic introgression.

PATHS TOWARD CONCILIATION BETWEEN NEIGHBOURS

In Germany the private legal rights and spheres of interest of organic farmers and users of transgenic varieties are defined and delimited by civil law. The borderline is drawn by a system of legal claims governing neighbourly relationships. § 906 of the German Civil Code is the central norm of private environmental law. Under this paragraph users of transgenic plants can be required to avoid or minimise genetic modifications in neighbouring cultures. When an organic farmer suffers market losses due to the pollination of organic cultures by GMO pollen, the owner of the neighbouring transgenic cultures can be ordered to pay damages. At present it is difficult to assess the level of enforceable claims. The complex intercalating system of claims to desist or to compensate will have an inhibitory impact on the use of transgenic seeds, and the economic burden of having to avoid GMO pollination of

neighbouring cultures or pay compensation, will not be calculable in advance. However, organic farmers are so burdened with having to secure cogent proofs of causality that many will see this as an intolerable manacle. Under these conditions there will be little hope of arriving at a state of peaceful coexistence.

The idea of a self-organised mediation system for temporal and spatial isolation in connection with a compensation scheme financed by GMO producers and users is introduced.

PUBLIC REGISTER OF PRODUCTION SITES

All member states of the European Union are required by the Directive 2001/18/EC to establish public registers documenting GMO cultivation sites and the identity of cultivated GMO varieties for the purpose of monitoring environmental effects. This register could at the same time serve as a production register for GMO. The directive leaves it up to the member states to determine the details of register management. The directive contains no impediment to requiring farmers to provide precise information on the location of their GMO cultures for the register. Information concerning the precise design of the GMO and the analytic measures to detect it could be included along the lines of the draft of the EU regulation concerning traceability and labelling. However, this draft only requires that the codes of GMO sequences be published. Since organic farmers must be in a position to reliably detect GMO sequences, the cultivation register would need to contain precise information on their identity.

INTRODUCTION OF GOOD PRODUCTION PRACTICE IN GMO CULTIVATION

Protective measures to avoid GMO pollination could be imposed on users of GMO seeds through the introduction of a code of "Good Production Practice in GMO cultivation" (GPP). Such measures could include, for example, defensive cultivation planning and the maintenance of specific distances between transgenic and susceptible organic cultures. For the implementation of the GPP code the administration must be empowered to impose specific single protective measures. Non-observance of such an order must be penalised as a regulatory offence. GPP could be introduced by an amendment to the Gentechnikgesetz (German act on genetic engineering) or the Saatgutverkehrsgesetz (German act on the marketing of seed). Alternatively, it could be introduced through an amendment to a specific (organic) agriculture statute.

DAMAGE FUND FOR GMO POLLINATION

For pollination by GMO from non-determinable sources a system for compensating organic farmers for market losses is necessary and indeed feasible. Compensation could be provided by a governmental compensation system or a fund model based on a statutory regulation or a voluntary self-commitment of producers and users of GMO.

PROTECTION OF ORGANIC SEED PRODUCTION

The protection of organic seed production necessitates closed regional production areas. This requires the development of an appropriate legal basis.

IMPACTS AND FOLLOW UP OF THE PROJECT

Some points are incorporated in the amended German legislation on genetic engineering, but many other points are still discussed controversial.

CHALLENGES IDENTIFIED IN THE DISCOURSE

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- definition of isolation distances and Good Production Practice
- liability and compensation fund
- protection of organic seed production
- coexistence which does justice to consumers' right to freedom of choice is not easily to be arrived

LITERATURE

Barth, R., Brauner, R., Hermann, A., Hermanowski, R., Nowack, K., Schmidt, H., Tappeser, B., Meier, J. (2003): Genetic Engineering and Organic Farming. UBA-Texte 02/03, Berlin

AUTHOR OF THE REVIEW

Rolf Meyer

GREEN GENETIC ENGINEERING – TRANSGENIC PLANTS OF THE SECOND AND THIRD GENERATION (2005) 6.5

BACKGROUND OF THE PROJECT

The TAB-project “transgenic plants of the second and third generation” was demanded by the Committee for Education, Research and Technology Assessment. The term "second generation" was used to describe those genetically modified plants (GMP) which are in the pipeline (i.e. in industrial development and shortly before licensing), while “third generation” is applied to those in research or a very early stage of development.

The origin of this project can be clearly traced back to the previous TAB project "Risk assessment and post-marketing monitoring of transgenic plants", where the investigation of this topic was brought up as an important recommendation concerning future TA need (see review 6.2).

A second motivation was the (as well since a long time especially in the political debate repeated) assumption, that a shift in the European consumers' hostile attitude towards GMP can't be expected as long as no products from GMP with a convincing benefit are on the market. The TAB project to study the potential and risks of future transgenic plants was limited to the subset of GMP with modified use properties for the consumer (so-called “output traits”). The TA project aimed to answer the following questions:

- how the targeted additional benefits of these GMP are defined,
- how they are supposed to be achieved,
- what economic potential can be expected,
- what new (types of) risks should be assumed,
- what new questions of safety assessment result from these,
- whether existing safety measures appear adequate, or whether they need to be modified, expanded or supplemented,
- what regulatory challenges result, and also
- what effects on consumer acceptance are to be expected.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in 21 months (November 2003 – July 2005), subdivided into two phases. Eight scientific studies (expert opinions) were commissioned during the project. In the first phase (until August 2004), based on three of the expert opinions, an overview of research and development as well as concerning the economic potentials and the international debate on risk evaluation and assessment was worked out. The second phase of the project was devoted to an in-depth analysis of "molecular farming" which means the use of GMP for the production of industrial materials (so-called PMI or plant made industrials) and especially as a source of

pharmaceutical substances for human and animal medicine (so-called PMP, or plant made pharmaceuticals). The draft final report of TAB was based mainly on the commissioned scientific studies and was evaluated by a number of experts from science and government.

The main topics of the final report were:

- a detailed description of GMP for functional foods, for PMI and PMP[12]
- including an in-depth discussion of their economic potentials and
- their possible ecological and health risks;
- the possible performance of biological and physical confinement measures;
- the regulation of molecular farming (in the EU, compared to the U.S. and Canada):
- areas for action (with regard to the German national and the EU level).

MAJOR OUTCOMES OF THE PROJECT

OVERVIEW OF RESEARCH AND DEVELOPMENT – LICENSING AND RELEASE

GMP with output traits were divided into six groups:

1. improved contents in plants which are a source of food (functional foods - FF);
2. improved contents in plants which are a source of animal feed;
3. optimised or modified plants for production of industrial materials (PMI) or
4. for production of pharmaceutical substances (PMP);
5. GMP for phytoremediation (plants for the treatment of contaminated soils);
6. modified properties of decorative flowers (colour) or plants (e.g. lawn).

GMP with output traits play no role in global cultivation, which is still completely dominated by herbicide and insect resistance. Until 2005 eleven GMP with modified output traits have been licensed in various countries (2006: plus one), nine of them without relevance for the TAB report (tomatoes with longer shelf life, modified decorative flowers, tobacco with reduced nicotine content). The two remaining varieties, a rapeseed with high lauric acid content and a soy bean with increased oleic acid content, have been unsuccessful on the US market, and are accordingly not grown to any effective extent. In the *EU*, only the three modified carnations have been licensed (since 1997/98). The licensing pipeline contains (since 1997) 21 applications, including one PMI GMP, the "famous" potato with modified starch composition.

Among the releases in the U.S. (1988-2003), GMP with modified output traits account for c. 20% of the c. 10,000 applications, equivalent to 150-230 a year since 1994. In the EU, GMP with modified output traits account for c. 15% of all releases in 1988-2003 (over 270 of 1,850 applications). In line with the trend for GMP gener-

12GMP for animal feedstuff were not dealt with in depth, as their uses are more comparable with agronomically modified GMP, and hence do not open up new prospects for use in the same way as the other three groups, and because they play only a minor role in Europe, quantitatively speaking.

ally, there has been a very definite decrease in release applications since 1996/97. A breakdown by individual groups shows a much smaller significance of the feedstuff sector than in the USA.

GMP FOR THE PRODUCTION OF FUNCTIONAL FOODS OR THEIR INGREDIENTS

The range of functional ingredients produced or (to be) modified in plants by genetic engineering is still very manageable. The GMP developed so far are predominantly prototypes to demonstrate fundamental feasibility, which need further development for commercial use and must be tested not only in the field but also on humans in nutrition studies.

For most functional ingredients, the current genetic engineering approaches – overexpressing or reducing the activity of individual genes directly involved in the relevant metabolic pathways – are not sufficient to achieve commercially attractive content of the functional ingredients in the GMP. Hopes involve conceptual and methodological further developments in metabolic engineering, which seeks to affect entire metabolic pathways and regulatory networks in a coordinated way. Whether FF GMP can be established in the medium term as a source of functional food raw materials and ingredients depends crucially on whether the assumed cheaper production of functional ingredients in GMP can be actually achieved. This is not easy, as there are established production platforms already in existence (e.g. chemical synthesis, microbial production, isolation from natural sources) for most of the ingredients currently being researched in GMP, which FF GMP will have to compete with. The resource-intensive and comparatively long development period for new GMP varieties and the functional foods or ingredients produced from them represent a comparative disadvantage, as the regulatory requirements mean tying up resources in the long term in a dynamic market which actually requires a rapid and flexible response. In addition, GMP approaches generally have to be supplemented by other food technology options, as functional GMP for direct consumption can only meet a small segment of the possible entire supply of and demand for functional foods, for reasons of shelf life, seasonal availability, convenience and bioavailability.

PLANT MADE PHARMACEUTICALS

GMPs have been discussed for many years as a highly promising new production platform for drug production. The hope is particularly for low-cost production in large quantities. Products produced using genetic engineering methods account for the overwhelming part of pharmaceutically effective proteins and peptides, which are also called “biopharmaceuticals”. Significantly less important (and also in very early stages of development) are genetic approaches to influencing pharmaceutically effective so-called secondary metabolites, which were not discussed in the report.

To date, no PMP GMP has been licensed for placing on the market anywhere in the world. There are intensive research and release activities in the USA and Canada, while the activities in the EU come predominantly from two French firms (Meristem Therapeutics and Biocem). The plant species used are predominantly maize and tobacco, followed by rapeseed and soy bean. No PMP has yet been given “real” ap-

proval as a drug. Several proteins which also have pharmaceutical uses are already on the market, although so far they can only be sold as research or diagnostic reagents. They come from experimental releases (in the USA).

Of those PMP in development, so far only two have been recognised as having so-called orphan drug status (for treating rare diseases). In the EU orphan drug status (for use with mucoviscidosis sufferers) was granted in 2003 to a so-called gastric lipase (from maize). To date the protein comes from experimental releases in France, and could be the first PMP for application for approval as a drug in the EU. In the USA a so-called galacosidase was granted orphan drug status in the same year. 15 PMP were identified in various phases of clinical testing. In addition to gastric lipase, an antibody for caries prophylaxis and patient-specific antibodies for treating non-Hodgkin lymphomas are in an advanced stage of testing. Several PMP are currently being developed for veterinary use, with the option of extending these to human indications later if successful. Besides these concrete examples, there is a vast number of PMP in preclinical R&D stages. A key area is developing antibodies, presumably because possible specific advantages of production in GMP seem most within reach.

To assess the future potential of PMP GMP, comparison with competing production platforms is needed. To date, biopharmaceuticals have almost entirely been produced microbially or in animal cell cultures, and transgenic animals are rather more advanced than PMP approaches (although here again no drug has yet been approved). The various production platforms are briefly presented and described in the report.

Possible specific advantages of PMP GMP were considered in terms of freedom from human-pathogenic agents, correct glycosylation and of investment and production costs including scalability. These were found to be predominantly dependent on the product. For example, it is clear that glycosylation closer to mammalian cells (modification of the protein in the cell) from PMP has an advantage over microbial systems for many drugs, although this may also prove a pharmacological disadvantage for others. It is fairly certain that general cost advantages cannot be assumed for production from PMP – these are only plausible on the unrealistic assumption of only slightly regulated open cultivation (plus ideal yields). An in-depth investigation of the foreseeable potential of possible oral vaccines showed that oral vaccines do not seem very important for vaccine development, and particularly that the idea of ingestion in the form of unprocessed fruits (still frequently cited) is entirely unrealistic.

An overall assessment of the currently foreseeable economic potential concluded that in view of the major and growing importance of biopharmaceuticals generally, there is probably also growing potential for production in PMP, without the general cost advantages generally assumed. Their competitiveness is decisively determined by advances in competing production systems and development of specific regulations for cultivation and corresponding risk management measures.

PLANT MADE INDUSTRIALS

Use of PMI GMP seems comparatively further away. This is a little surprising, given the intensive work on relevant GMP concepts over many years, and the fact that the

first two such GMP were approved and commercialised years ago. The only currently foreseeable example here in the EU is the starch potato, which has been in the approval pipeline for years.

For all other approaches (whether in "designer oils" or "designer starches", production of industrial enzymes, biopolymers or other special ingredients) it is virtually impossible to assess how far the work has come in concrete terms. In some cases, this is in-house work, in other cases the development work – e.g. on bioplastics from GMP – seems to be taking significantly longer than hoped. The reasons for this differ, depending on the development goal and plant species, but the examples presented suggest possible general assessments (which also apply e.g. to development of FF GMP).

- In several cases, expectations particularly of attainable product yields have been not been satisfied even after many years of development. In the course of maximising content, apparently undesired side effects have emerged (are emerging) in many cases which then result in lower yields. While this does not make the concept (economically) unusable, it does affect the range of substances which can be produced on a commercially competitive basis.
- In several cases, the transition from the highly promising model plants to specifically usable ones did not proceed as hoped, as the genes failed to "function" accordingly.
- In other products, the alternative production systems (cell-based systems, transgenic animals) developed faster or more efficiently.

An assessment of the prospects for PMI concepts is accordingly (even) more difficult than for PMP. Production of bulk products seems unlikely in the foreseeable future, the production of renewable raw materials is more likely to be optimised through breeding of non-genetically-modified plants. Industry sees realistic prospects for high-price special applications, if these can only be produced in GMP and not in conventional varieties or the cultured varieties otherwise used. Dual use (e.g. bioplastic and feedstuff) depends on relevant approval, which is only conceivable for selected approaches. Transgenic trees for plantation farming could become more significant worldwide, but cultivation in the EU is unlikely for a long time.

POSSIBLE ECOLOGICAL AND HEALTH RISKS

Given the early stage of GMP modified for output traits, no risk discussion has developed for most sub-aspects, so that no presentation in detail was possible. This applied particularly to the possible ecological risks of FF GMP and the possible health risks of PMI GMP. The risk discussion for FF GMP is focusing on the basic question of safety evaluation of innovative and primarily functional foods, while for PMP GMP the emphasis is on possible release into the environment and food and preventing this. Therefore the risk debate on molecular farming (of PMP and PMI) generally has so far concentrated almost entirely on the question of reliable sequestration and containment of GMP.

Basically, GMP modified for output traits fundamentally change the situation for risk regulation (i.e. risk assessment, risk evaluation and risk management), because at least PMP GMP as well as some PMI GMP have an inherent risk because of the medical and physiological impact of their ingredients.

The current goal of risk regulation is to approve only GMP which are risk free as compared to "conventionally" bred plants. This concept must be at least modified by developing comprehensive and rigorous safety requirements for cultivation and processing e.g. for PMP GMP with their potential environmental and health risks (as is the case in Canada and the USA). It will probably be necessary to impose group-specific measures which imply moving away from the pure case-by-case principle, or at least supplementing it.

At the same time, the discussion of benefits is taking on new priority compared with the 1st generation of GMP, including risk evaluation and regulation. So far, it has been possible to ignore doubts about the benefits of the genetically introduced properties from the regulatory point of view (because no concrete risks to health and the environment were established as a prerequisite for approval), and to leave evaluation to market forces. In future, the desired benefit (e.g. production of life-saving drugs) is likely to play a greater role – at least in some cases – in risk evaluation, including in the approval decision.

BIOLOGICAL AND PHYSICAL CONFINEMENT MEASURES

In considering possible risk management measures for GMP modified for output traits, it is necessary to distinguish between two groups of GMP which pose very different requirements for regulation, namely those which can be regarded as just as safe as the approved 1st generation GMP, and all others.

The first group could include several of the conceivable PMI applications, e.g. if these involve modified food plants which are currently being used for industrial purposes in their conventional form. At least if the relevant GMP has explicit approval for food and feed, large scale cultivation is conceivable subject to the prevailing variety-specific coexistence regulations, and would not differ substantially in quality from the food sector. The second group presumably includes most PMP, together with a range of conceivable PMI plants for which special containment/confinement will be required. In the event of open cultivation, and possibly greenhouse cultivation, particularly strict biological and physical confinement measures must apply, as the current regulations in Canada and the U.S. require.

The report discusses in detail the question how reliable the various methods in preventing undesired dissemination of GMP are. The overall conclusion was that the present state of science and technology is unable to offer any system for confinement of transgenic nonfood plants which permits coexistence in open cultivation of GMO and non-GMO species completely free of any influence. But it was emphatically stressed that the extent to which such influence can be tolerated and under what conditions are matters for society to decide.

Only few biological confinement methods have reached a state of development where substantial studies on integrity and leak tightness can be carried out. An (almost) complete prevention of the escape of a transgene is up to now only possible in closed systems.

REGULATION ISSUES IN MOLECULAR FARMING

Consideration of the state of regulation of genetic engineering showed that the present regulations and procedures for molecular farming are not entirely appropriate or adequate. For molecular farming of "high price" products or ingredients on comparatively small areas, approval for release under Part B of European Directive 2001/18/EC is inadequate in many cases (because the relevant products may not be placed on the market), although approval for placing on the market under Part C would actually not be required, because free trade and unlimited cultivation are not goals of GMP development. At least in the medium term, there will accordingly be a need for change, particularly in the regulation of genetic engineering. By contrast, there is currently hardly any need for change apparent in drug and chemical regulation.

Activities and discussions in the EU (until summer 2005) showed that very little attention had been paid to the issue of molecular farming so far, particularly in comparison with Canada and the U.S. *[this has changed a little bit since then, as EFSA and IPTS have started several activities, both of them taking notice of the TAB report; see below]*. This implies a need at EU and national level for more intensive consideration of the opportunities and potential risks of GMP modified for output traits.

AREA FOR ACTION: OPERATIONALISATION OF VISIONS AND SCENARIOS

Although molecular farming has been described as a future option for many years in the debate on genetic engineering, it has mostly been presented in very vague terms, either as largely unsupported assumptions about possible benefits (and/or risks) or as visions of the future. The relevant documents typically focus on scenarios for the use of possible products from GMP modified for output traits, describing scenarios for production and cultivation which have little contact with reality, and completely ignore regulatory aspects and realistic coexistence scenarios. Such operationalisation accompanied by greater social opening seems very important for the coming debates on possible future use of transgenic plants. These tasks should be addressed with a view to the coming Framework Programme 7, together with more substantial links to the relevant policy areas, strategies and goals (including more extensive use of renewable raw materials, development of rural areas, sustainability of agriculture, healthier nutrition).

AREA FOR ACTION: GERMAN RESEARCH POLICY

Facing the new and complex questions regarding the benefit as well as novel risks and their management, for German research policy the development of interministerial promotional R&D measures for research into molecular farming was assessed

as being adequate. A viable and societally acceptable approach would require not only bringing together the ministries' technical points of view but also including various interest groups in developing such promotional programmes and projects.

No assessment was performed for R&D approaches in detail, e.g. deserving promotion or safety issues requiring particularly urgent investigation. However, a specific proposal was made for a “Progress report by the Federal Government on the status of publicly funded activities in connection with research, approval, cultivation and marketing of GMP”, which should in detail review the aims and outcomes of the last 10 to 15 years and draw conclusions for the future promotion and funding of R&D devoted to biotechnology and plant sciences (a proposal, which seems to be suited for every other country as well as the EU level). Such a report could possibly offer a basis or at least a point of reference for more constructive and sustainable further development of research policy on green genetic engineering and alternative strategies.

AREA FOR ACTION: MODIFICATION OF REGULATION AT EU LEVEL

The need for action concerning modification of regulation was clearly located at EU level. The regulation has to come under review if it is suited for the production of PMP and PMI (which seems not so; see results above). With regard to national regulations, it was concluded that they have to be revised in a second step according to the EU regulation.

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate and/or decision:

The proposal of the "Progress Report" was picked up several times in parliamentary debates (on GMOs, but not directly connected with the TAB report) and has been integrated in the official statement of the (together with the christian democrats governing) social democrats concerning the current amendment of the gene technology law.

Public perception:

Compared to other TAB projects, a relatively broad press coverage in print and web-based media began directly after the acceptance by the Committee for Education, Research and Technology Assessment and publication of the report in February 2006. In June 2006, TAB together with the Committee for Education, Research and Technology Assessment organized a public workshop in the German Parliament and invited stakeholders from industry, regulatory authorities and academia to answer to and to discuss the report's view. The workshop was very well attended, by all kinds of stakeholders. The usual heavily polarized debate was astonishingly moderate, in our view the outcomes of the report were completely validated, although "the industry" tried to proof a too negative judgement concerning the economic potentials (but failed to show any other perspective than was discussed by TAB).

Scientific recognition:

The performance of the report was appreciated a lot (there is up to now no publication of comparable comprehensiveness in Germany, maybe in Europe?), accompanied by heavy criticism from scientists who refuse to concede that the results of molecular farming up to now are in many respects of a poor nature (and probably are opposing the proposal of the reviewing "Progress Report"). The websites on GMOs and biosafety of the German research ministry refer to the report (especially concerning the risk regulation of PMP) and integrated links to TAB. IPTS invited TAB to a workshop on molecular farming which was then attended by Armin Spök from IFZ (Graz, Austria) who was responsible for two of the expert opinions on risk regulation, and who has published its results recently in TRENDs in Biotechnology.

CHALLENGES IDENTIFIED IN THE PROJECT

Due to the up to now very limited presence of the topic "molecular farming" in the debate on GMOs (at least in a detailed manner), an overall need at EU and national level for more intensive consideration of the opportunities and potential risks of GMP modified for output traits is obvious.

- Technical dimension: The possible performance of future GMP could be assessed in a more realistic way (via an in-depth "Progress Report"); with respect to the cultivation of PMP and PMI GMP, the development and assessment of biological and physical confinement measures are of special and fundamental importance;
- Social dimension: The possible acceptance of PMI and PMP GMP will (in my opinion, A. Sauter) depend on an early and transparent participation already in the R&D phase, beyond promotional communication activities like "Plants for the Future" (see "operationalisation of visions and scenarios");
- Political / regulatory dimension: The whole EU regulation has to be checked for appropriateness for molecular farming (EFSA has started a self tasking activity, IPTS is also working by order of the Commission).

LITERATURE

Sauter, A., Hüsing, B. (2005): Grüne Gentechnik - Transgene Pflanzen der 2. und 3. Generation. TAB-Arbeitsbericht Nr. 104, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, Berlin http://www.tab.fzk.de/de/projekt/zusammenfassung/ab104.pdf

English summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab104.htm

Spök, A. (2006): Molecular farming on the rise – GMO regulators still walking a tightrope. In: TRENDS in Biotechnology 25(2), pp.74-82

AUTHOR OF THE REVIEW

Arnold Sauter

GENTECHNOLOGIEBERICHT (GENE TECHNOLOGY REPORT) (2007) 6.6

BACKGROUND OF THE PROJECT

The “Gentechnologiebericht” (Gene Technology Report) of the Berlin-Brandenburg Academy of Sciences and Humanities is a monitoring project that focuses not only on GM plants or GM foods but includes also medical applications. The report assesses the entire field of gene technology, because unlike other technologies this particular field is affecting the basic principles of life, human existence and that of all other living beings.

The report surveys carefully all present facts and the latest developments in the field of gene technology and presents a critical study from an impartial viewpoint.

BASIC DATA ABOUT THE PROJECT

The report is edited by an interdisciplinary study group consisting of several members of the Berlin-Brandenburg Academy of Sciences and Humanities. The participating authors are impartial. They are experts on different disciplines of the subject, and they observe the subject beyond their own specific discipline as well. Acknowledged external experts are involved additionally for further detailed questions.

The report was published for the first time in 2005 (Hucho et al.). It consisted of four main chapters representing different case studies, which were chosen following public controversies at that time. One of these case studies is on gene technology applied to plant breeding, farming and foods (green gene technology). A separate supplement published in March 2007 updates the data and adds news topics (Müller-Röber et al., 2007).

MAJOR OUTCOMES OF THE PROJECT

The monitoring of the report consists of three parts: The first part is a documentation of today's state of technological development including scientific progress and the recent range of applications. The second part is a detailed overview of economic, ecological, social, political, legal, and ethical aspects. The third part is a system of indicators that are suitable to unravel and describe the topics connected with the application of gene technology to plant breeding, farming and foods.

The first part of the monitoring report, the documentation of technological developments, gives a detailed view on recent research and describes the aims of this research as well as the applied techniques. Cisgenic plants and smart breeding are examples for two newly invented techniques that were presented in the media as alternatives to transgenic plants, which is the “classic” way of modifying plants. The report draws the conclusion that both techniques could be useful extensions of the scientific methods. But they will not be able to replace the methods of genetic engineer-

ing transferring foreign DNA from other species since the available genes are restricted to closely related species.

Further topics are the DNA sequencing of plant genome, the use of genetic engineering in research on biodiversity and ecosystems, enabling technologies in modern plant breeding, new methods of selection and both the creation and phenotyping of genetic diversity. On top of giving an overview over current scientific progress, the monitoring report includes an overview of the input and output traits that are worked on in the field of GM plants. Several examples are being examined, including insect resistant maize, the cultivation of which has been started in Germany recently, “golden rice” that could arouse a great deal of interest especially for poorer people in developing countries, and “energy plants” which gain high yield of biomass and are being discussed in public as an alternative form of energy production.

The second part of the monitoring report examines different topics concerning GM plants and GM foods, which are debated controversially in the general public. Public opinion on GM plants and GM foods is a major factor and has to be taken into account, not only in Germany but in the whole European Union. The scepticism about these particular applications of gene technology is much higher in Europe than in the US, Canada or Argentina, where GM plants have been cultivated for almost ten years now. The report investigates the background to this poor acceptance. On the one hand, GM plants meet with criticism because of possible unforeseen negative ecological side effects, on the other hand GM foods are criticized because of the risk of unpredictable health effects. The report examines both argumentations. GM plants that are resistant against herbicides or insects are used as two examples to document the recent scientific findings on ecological and health effects. Furthermore, the report focuses on economic aspects being of particular interest to political debates. An overview over several studies on the economic potential of GM plants is being presented. The topics being discussed are the development of the areas cultivated with GM plants, the question who will profit from GM plants, the preconditions for benefiting of today's GM plants, the potential benefits of GM plants for the future, and the number of jobs being connected with the use of GM plants in agriculture and food production. Furthermore, a portrayal of the current situation of European and German laws on GM plants and GM foods is presented, which includes the topics coexistence and liability. Despite the fact that ethical questions might be less important for the agricultural use of gene technology than for medical use, the report even examines ethical problems that could be associated with the use of gene technology during the process of plant breeding.

The third part presents indicators that allow to describe the different current developments in the field of green gene technology clearly and easily to understand. A single indicator stands for a “measuring device” which allows to depict complex issues that cannot be measured directly and to assess these issues representatively. An indicator reduces complexity through which developments at long and at short intervals are less difficult to spot. A set of indicators makes it possible to back up subjective perceptions of developments or to falsify them. Proven developments can be analysed and interpreted with the help of further data. A misleading concentration on certain details frequently produces wrong results or misleading interpretations. The

report tries to prevent this serious risk by relating the indicators to one of the specifically defined problems that are connected strongly or weakly with the subject. All these defined problems seen as a whole should describe the issue of green gene technology entirely. This methodological step prevents observation loopholes if no suitable indicator could be found. In detail, the several defined problems take up again the different economic, ecological, social, political, legal, and ethical questions and also latest scientific research and current applications, which are presented in the second part of the report. In addition, connections between these aspects are pointed out and even problems connected to GM plants and GM foods less obviously are part of the overall picture. The definition of the problems is an important task of its own. The definition of what is seen as a problem is based on the public point of view on chances and risks, which might be diametrically opposed to an experts viewpoint. Nevertheless, this guarantees that the report does not deal with an experts debate only.

The following indicators represent some examples: The number of traits, the number of field trials and the number of traits in these field trials are used to examine the potential that green gene technology has developed currently. The sales and profits being made with genetically modified seeds, the worldwide area under cultivation with GM plants and several cultivation data for Germany are some of the indicators being used to determine the current economic relevance of GM plants and GM foods. The amount of money being spent on research on GM plants and the number of applied patents are two of the indicators that try to measure the scientific and economic importance of green gene technology. Ecological effects are observed for example by the number of proven cases, when a GM plant interbreeds with another plant outside the field, and the use of pesticides on GM plants compared to the amount used on non-GM plants. The dissemination of GM foods can be described for example by the number of GM plants being approved for food use in the EU and by the market share of these products. The consumers' and the farmers' acceptance of GM plants and GM foods are two indicators being used to measure the intensity of conflicts that the introduction of these products might cause. Generally, the indicators are used to describe the situation in Germany. The data is updated yearly. The report makes use of appropriate and valid sources like scientific studies or official databases of the government. The particular scientific work of the monitoring report is the selection of the indicators that has to base on intelligible criteria and that should cover all different aspects of green gene technology. Single results are linked with each other to achieve a more precise assessment and a balanced interpretation. Finally, the report publishes recommendations based on this work.

IMPACTS AND FOLLOW UP OF THE PROJECT

The monitoring report is not only addressed to the policy makers in parties, government, administration, non-profit organisations, scientific societies etc. but also to the general public interested in this particular issue. The report would like to make a good case for public discussions without taking a position for one side or the other. Thus the report wants to achieve a more objective public debate.

The next report is going to be published in 2008. Therein the issue of genetically modified animals will be dealt with additionally. Further and current information can be found at www.gentechnologiebericht.de.

CHALLENGES IDENTIFIED IN THE PROJECT

The annual update of the indicators does not only include the presentation and the interpretation of the recent data. It includes also a discussion if the indictors themselves. The main stress within the complex topics could have changed during the time and new additional data could be necessary for a conclusive interpretation. New topics have to be recognized as well, for example the debate about the consequences of the recent discoveries in the field of epigenomics.

LITERATURE

F. Hucho, K. Brockhoff, W. van den Daele, K. Köchy, J. Reich, H.-J. Rheinberger, B. Müller-Röber, K. Sperling, A. M. Wobus, M. Boysen, M. Kölsch (2005): Gentechnologiebericht - Analyse einer Hochtechnologie in Deutschland. Forschungsberichte der Interdisziplinären Arbeitsgruppen. Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

Bernd Müller-Röber, Ferdinand Hucho, Wolfgang van den Daele, Kristian Köchy, Jens Reich, Hans-Jörg Rheinberger, Karl Sperling, Anna M. Wobus, Mathias Boysen und Meike Kölsch (2007): Grüne Gentechnologie - aktuelle Entwicklungen in Wissenschaft und Wirtschaft, Supplement zum Gentechnologiebericht (mit Beiträgen von Volker Beckmann und Christian Schleyer). Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

AUTHOR OF THE REVIEW

Mathias Boysen

NORWAY 7.

RECONVENING THE LAY PEOPLES PANEL ON GM FOOD 4 YEARS AFTER (2000) 7.1

BACKGROUND OF THE PROJECT

The lay people's panel was commissioned in 1996, by the Norwegian Biotechnology Advisory Board (NBAB) and The National Committees for Research Ethics (NCRE), based on government grants. It consisted of 15 persons randomly chosen among 400 applicants. None of these had particular affiliations concerning the question of genetically modified food.

After several meetings to develop internal reflection on the issue of GM-food, the panel teamed up with a panel of experts to discuss central challenges regarding GM-food. After the conference, the lay people's panel delivered a consensus report with advice for action.

In 2000, the panel reconvened to discuss the issue with a new panel of experts, under the auspices of NBAB, NCRE and the Norwegian Board of Technology (NBT). In the meanwhile, some members of the panel had continued their involvement in the issue, thus establishing themselves as experts on the issue. Again, the lay people's panel delivered a consensus report.

The conference had the following aims:

- give a summary of central developments on research and use of GM food since the conference in 1996
- present a consensus report with advice on whether a moratorium on importing and marketing GM-food should be imposed and eventually on other relevant topics
- to strengthen the emphasis on lay people's insights in technology assessment and management

BASIC DATA ABOUT THE PROJECT

The project was a consensus conference based on a hearing of experts. The conference was undertaken on 15th-16th of November 2000. Participants included 15 lay people, 18 experts took part in the hearing. In addition there were a number of facilitators.

The hearing focused on the following topics:

- Status of knowledge about effects on health and environment
- Status of regulations and control: Are present regulations comprehensive and efficient?

- Is a moratorium feasible and legitimate?
- What are the interests of consumers, retailers, processors and producers?

MAJOR OUTCOMES OF THE PROJECT

The panel gave the following conclusions:

A moratorium should be imposed, prohibiting cultivation of GM food and feed with the exception for test purposes. Imports and marketing of GM food and feed should also be prohibited. The moratorium should only be lifted when certain criteria are met:

- - Knowledge of the long-range consequences of the technology should be improved
- - Laws and regulations should be coordinated internationally
- - Monitoring, control and traceability should be strengthened

A group representing broad interests should be convened to elaborate these criteria and evaluate when these are met.

Within health, no evidence of harm is given, but this cannot be excluded. Further, the technology has not contributed within promising fields of increased nutrition or lower allergenic effects.

There is no evidence that use of pesticides or herbicides have been reduced as a result of GM-cultivation. On the other hand, GM-agriculture has accentuated the use of monocultures and industrial approaches, which is harmful. There are indications that GMOs can disturb ecosystems, thus causing irreversible harm. There is an urgent need for better knowledge about effects on the environment.

Although the GM-plants marketed so far are not useful for Norway, they could prove advantageous in other regions of the world. However, despite promises that GM would especially benefit the poor, such applications have not been delivered. On the other hand, the development towards monocultures cannot be seen as serving the poor.

There is a mismatch between regulations on living matter and regulations on food and feed. While, according to the Norwegian Gene Technology Act, living matter is evaluated on criteria such as societal benefit, ethics and sustainability, these criteria are not considered in the Food Act which regulates food. Thus, food imports are not evaluated on the same criteria as domestic products.

The panel expressed disappointment that some members of the expert panel presented their own judgment of the consensus report, and that they were not able to distinguish between normative and factual topics/discussions.

Insights from experts:

There is no evidence of adverse health effects of GM food, but knowledge is insufficient. On environmental effects, knowledge is almost non-existent. Views on the

appropriateness of a moratorium vary, the strongest arguments against a moratorium is that it would challenge WTO rules. Further, the risk for GM contamination is limited to imports, and controlling this is dependent on systems for screening and tracing, rather than legal restrictions.

Acceptance of GMOs can be seen as a combination of risk, benefit and moral acceptance. While risk and benefit are quantitative factors, moral acceptance is a qualitative factor, constituting a veto. Opposition to GMOs up to 2000 can be based on perceptions of low benefits, rather than perceptions of high risk.

The Norwegian agricultural sector, including farmer unions and cooperatives, are sceptical towards GMOs, and practice a self-imposed restriction. This is based both on internal attitudes, but also on the lack of confidence among consumers. Although certain producers may be tempted to consider GM products, experiences with growth hormones and foreign cattle breeds indicate that producers are generally sceptical to growth-enhancing technologies.

Norwegians became more sceptical towards bio- and gene technology from 1996 to 2000, and are relatively more sceptical than the average European. As long as the consumers are sceptical, both retailers and food processing businesses try to avoid such products – also from imports. Thus, GM production is disadvantageous to Norwegian interests. Regulations that can be trusted by all parties will be advantageous.

To control products, methodology to reveal GM contamination is necessary. It is also necessary to establish a system of traceability to control products based on GM but where there are no trace of transgenes in the end-product. However, who shall pay for a system of traceability? If the businesses shall cover such expenses, can this be something that only the major actors can afford?

IMPACT AND FOLLOW UP OF THE PROJECT

The project got overall good coverage by the press and mass media and was looked upon as a valuable contribution in the further public debate. The project was described in detail in the Norwegian biotechnology journal “Genialt”, published by the Norwegian Biotechnology Advisory Board. Furthermore the facilitators were invited to present the major conclusions and recommendations from the project in the Norwegian Parliament on January 18th 2001.

In recent years, several of the challenges identified during the project (see underneath) have been met by the Norwegian Government. At present, routines for analysing imported food and feed for GM content are in place and running, legislation for traceability and labelling are established and there is a high degree of legislative harmonization.

CHALLENGES IDENTIFIED IN THE PROJECT

(The panel identified a number of challenges. The reviewer is not in a position to judge to what extent these challenges have been met through recent developments.)

- Systems for screening GMOs for adverse effects must be developed
- Systems for controlling GM-contamination must be developed. Existing schemes often only indicate GM-contamination, they cannot prove such contamination.
- Systems for labelling and traceability must be developed.
- Laws and regulations must be coordinated at the international level.

While health effects can be expected to be the same across regions, environmental effects may vary. Therefore, there is a higher need for independent Norwegian studies on environmental effects.

LITERATURE

Bioteknologinemnda, Forskningsetiske komiteer and Teknologirådet (2000): Oppfølgingskonferansen om Genmodifisert mat. Genialt nr. 4/2000. Web: http://www.teknologiradet.no/dm_documents/genialt42000_O6pbG.pdf

AUTHOR OF THE REVIEW

Jon Magnar Haugen

PUBLIC MEETING ON COEXISTENCE (2004) 7.2

BACKGROUND OF THE PROJECT

The Norwegian Biotechnology Advisory Board (NBAB) arranges a number of meetings and seminars to strengthen public reflection and debate on GMOs and to prepare hearings and statements on policies.

BASIC DATA ABOUT THE PROJECT

The meeting was held on 29th of April 2004. There were 94 participants, including a mixture of stakeholders, government officials and experts, with only a few lay people. The project did not intend to build consensus. Thus, outcomes presented underneath do not represent common understandings.

The debate covered the following topics:

- Case-study on gene flow between GM crops and their relatives – the case of canola
- Potential for gene flow in important crops for Norwegian agriculture
- Possible practical measures to reduce gene flow
- Possible political measures to minimize gene flow
- Specific co-existence challenges for organic agriculture
- Co-existence: strategies in a feed company
- How to ensure GM-free feed imports
- How to ensure GM-free seed

The presentations and key comments are documented in a report based partly on documents submitted by participants, and partly on transcripts from recordings.

MAJOR OUTCOMES OF THE PROJECT

Closing remarks:

- New regulatory frameworks for co-existence should not be used as a political instrument to introduce GM crops, but also to secure GM-free production.
- Co-existence is not only about biology, but also a question of commercial interests and economic compensation. Central stakeholders believe that the "polluter pays-principle" should apply and that the burden of proof should be placed on the producer.

Comments from participants (given without consensus):

- EU-regulation on co-existence is tailored to give consumers a choice. However, believing that GM may allow for choice may prove naïve. Separation measures either in cultivation or in transport and processing may be prohibitively expensive,

thus one type of farming will be harmed if the other is allowed. Which side to loose is a political question – and this should be what regulation is all about.

- Producers, feed industries etc. want to follow a restrictive line, but these sectors are dependent on imports of seed and feed. Imports from countries outside EEA raises particular challenges: Which can guarantee GM-free products? Can there be conflicts b/w objective of avoiding GM and other objectives such as contributing to income generation in developing countries?
- Norwegian producers, including fish farmers, avoid using GM feed because of consumer demand. However, this is not displayed on the final products. Wouldn't it be to farmers own interest to establish systems of labelling?

Perspectives on gene flow

The challenge of separation is not entirely new as organic products are already handled separately from conventional. However, the challenge of handling gene flow between crops/crop rotations is new.

There are a number of criteria on which the likelihood of gene flow can be evaluated. Gene flow through pollen is related to degree of out-crossing. The likelihood of gene transfer vary, dependent, inter alia, on the occurrence of related crops nearby. It also depends on whether the traits give a fitness advantage (for instance pest tolerance). Further, pollen flow is of highest concern when the seeds are the harvest of interest. For many vegetables, grasses etc., pollen flow is less relevant. Mitochondrial and chloroplastic DNA is not transferred with pollen, so transgenes within will be less susceptible to gene flow.

Particular challenges to particular sectors, some are also particular to Norway:

- For aquaculture, there is a challenge that soy meal and oils is gaining importance but GM-free soy is limited. On the other hand, the combination of fatty acids of today's soy is not entirely suitable for aquaculture – a challenge that could be solved by GM. Aquaculture therefore faces particular challenges in relation to GM feed, first by securing GM-free soy, and second by being tempted to adopt GM feed.
- In conventional agriculture, the strong position of agricultural cooperatives, alongside a high degree of regulation, favour a standard approach shared by neighbouring farms.
- Organic agriculture may have a higher diversity – both intentional and unintentional (weeds). This may allow them to be sinks of GM-volunteers – especially for Bt-crops and other GM-crops that may have a fitness advantage.

IMPACTS AND FOLLOW UP OF THE PROJECT

Insights from the meeting have been communicated in relation both to the development of general regulation, and in relation to specific submissions for deliberate release. The meeting marked the opening of the debate on co-existence in Norway. After the meeting, researchers and experts have been mandated to draft a bill for co-

existence, addressing crucial issues such as the risk for gene flow in different crop species, systems for compensation, and the right to information about GM fields.

CHALLENGES IDENTIFIED IN THE PROJECT

(Remaining challenges, based on judgments by the reviewer)

- What are the defining differences between GMOs and non-GMOs? The technology that is applied, or the traits that the organisms carry? While it is the (potentially harmful) traits that one wants to control, the regulations are defined by the techniques employed.
- Which properties/practical measures can reduce risk for gene flow? Can for instance mitochondrial/chloroplastic transgenes pose lower risk, thus be treated differently from regular transgenes?
- Systems for accountability, liability and compensation.
- The issue of organic farming becoming a sink of transgenes must be examined, including legal and economic aspects.
- Imports of meat, and of feed from 3rd party countries, increase likelihood of meat based on GM feed. This could create an urge for a labeling system for such products. However, should this be a mandatory labeling of meat based on GM feed, or should it be voluntary labeling of non-GM meat?

LITERATURE

Linnestad, Casper (ed) (2005): Co-existence. Report, The Norwegian Biotechnology Advisory Board. ISBN 82-91683-34-4.
http://www.bion.no/publikasjoner/20050905_Sameksisten_web.pdf

AUTHOR OF THE REVIEW

Jon Magnar Haugen

EVALUATING THE CRITERIA OF SUSTAINABILITY AND SOCIETAL IMPACTS IN RELATION TO GM FOOD – THE WORK OF THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD 7.3

BACKGROUND AND BASIC DATA

GM food on the market today is partly consisting of living entities, for instance intact corn grains or entire fruits or vegetables (containing viable seed). In Norway, such commodities must be evaluated not only in the food legislation context, but also in relation to the act relating to the production and use of genetically modified organisms. This act strongly emphasizes that the deliberate release of genetically modified organisms (GMOs) should have no detrimental effects on either health or the environment (at the same taking into account that we are not living in a risk-free society). This emphasis is fully in line with the legislation of other nations concerning the regulation of GMOs. Distinct from the regulations of most other nations, however, the Norwegian Gene Technology Act also stresses that the deliberate release of such organisms should represent a "benefit to the community" and enable "sustainable development". In general, the GM applications under directive 2001/18/EC or regulation 1829/2003 do not contain information that makes such a comprehensive GMO evaluation process possible.

It is not self-evident how "sustainability" and "benefit to the community" should be considered in terms of the practical application of the Act. The Norwegian Biotechnology Advisory Board is appointed by the Norwegian government with a mandate to give advice on these additional requirements.

The Norwegian Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board (NBAB) is an independent body established in 1991. The Board is founded in the Act relating to the application of biotechnology in medicine and the Act relating to the production and use of genetically modified organisms. The Board consists of 21 members, including 13 persons mandated by the government, and 8 persons mandated by different organisations. Representatives of six ministries have observer status. The Board's secretariat has seven to eight employees.

The main tasks of the NBAB are to identify and examine the ethical questions raised by applications of modern biotechnology on humans, animals, plants and microorganisms and to provide advice that can assist policy-making and stimulate public debates on the issues. The Board gives recommendations both concerning the development of general regulation, and in relation to specific submissions for deliberate release.

The work of NBAB can be described as a form of technology assessment done by a standing expert committee, with a specific emphasis on sustainability and societal

impacts. The activities involve meetings, dissemination, statements etc. Statements and advice are generally not based on consensus, but on majority votes.

This document explores how the NBAB interprets and addresses the issues of sustainability and societal impacts. The text is based primarily on conclusions from activities that were dedicated to discuss these issues broadly. However, insights from statements and advice in specific cases are also included.

MAJOR OUTCOMES OF THE PROJECT

The Norwegian Biotechnology Advisory Board finds that it is not clear whether the provisions relating to "benefit to the community" and "sustainable development" are to be considered as additional requirements or as a softening-up of the requirement for non-detrimental effects on either health or the environment. "Sustainable development" and "benefit to the community" can be understood as either:

- additional requirements to the absence of detrimental effects on health and the environment; or
- a softening-up of the requirement of non-detrimental effects; or
- an additional requirement that alone could be sufficient grounds for refusing approval or for a softening-up of the requirement of non-detriment.

According to the first alternative, the requirement would be that, in addition to having no detrimental effects on health and the environment, the "deliberate release represents a benefit to the community and a contribution to sustainable development". If the deliberate release fails to fulfil this requirement, the recommendation would be to reject an application for approval. Under this alternative, any softening-up of the requirement of non-detriment would be impossible.

The second alternative does allow for the approval of deliberate releases even when the possibility of detrimental effects on health and the environment have been established, if it can be demonstrated or argued that the "deliberate release represents a benefit to the community and a contribution to sustainable development". Consequently, the requirements of "sustainable development" and "benefit to the community" are being used as an opportunity for softening up or counterbalancing the requirement of non-detriment, but may not be applied as an additional requirement that alone could be sufficient grounds for rejecting an application for approval.

In the third alternative, the requirement of "benefit to the community" and/or "sustainable development" could constitute independent grounds for rejecting an application for approval. Furthermore, "sustainable development" and "benefit to the community" can be used to soften up the requirement of non-detriment. This could be considered as a combination of the first two alternatives and is the alternative the NBAB judges to be the best interpretation of the Act.

In the opinion of the NBAB, the Norwegian Gene Technology Act should be interpreted to mean that the requirements of "sustainable development", "benefit to the community" and other "ethical and social considerations" represent prerequisites that

alone could carry decisive weight against granting an application, but that should also be considered in relation to, and weighed against the risk of detrimental effects, when such risk is low.

Hence, an assessment of an individual GM application (also GM food, se above) will have the following structure:

1) Danger of detrimental effects on health and the environment:

   - what are the possible negative consequences?
   - what is the likelihood of such consequences occurring?

2) The precautionary principle:

   - is the risk assessment associated with justified uncertainty?
   - is there a possibility of substantial or irreversible harm?

3) Is it:

   - in compliance with the principle of "sustainable development"?
   - of "benefit to the community"?
   - "ethically and socially justifiable"?

Sustainable development

"Sustainable development" could be said to build on a series of ideas, including the following:

- the idea of the global effects of human activities;
- the idea of ecological limits and that these limits have been exceeded in several areas;
- the idea of meeting basic human needs;
- the idea of just distribution between generations;
- the idea of just distribution between wealthy and poor nations;
- the idea of a new form of economic growth.

This final point indicates that it is not a matter of just any form of economic growth. On the contrary, two types of qualification are required. Firstly, it should be economic growth involving an absolute – and not only a relative – efficiency improvement in the use of energy and other natural resources. Secondly, this economic growth must entail a more balanced distribution between poor and wealthy nations.

The six points listed above can serve as a structure for assessing whether the deliberate release of a genetically modified organism is in compliance with the requirements of "sustainable development". The same type of checklist questions could be asked for each of these points as those considered when assessing health and environmental risks and the precautionary principle. The responses to and the discussion of all the questions would, in this case, provide an overall picture of the extent to which there is compliance or non-compliance with the requirements set.

Furthermore, a clarification of the relationship between biodiversity (i.e. diversity of genes, species and ecosystems) and ecological sustainability is needed. Effects on

biodiversity would be assessed in relation to detrimental effects on health and the environment and the precautionary principle, thus be included in standard assessments also within the EU. However, relating biodiversity to the question of "sustainable development" implies a shift of focus in time and space. Assessments of the possible detrimental effects on health and the environment refer primarily to local, regional and national contexts. Assessments of the issue of "sustainable development" apply globally and also, to a longer time span (generations). When diversity is reduced, humankind's opportunities of promoting "sustainable development" are reduced accordingly. Preserving biodiversity represents a form of long-term life insurance – for the existence of species, ecosystems and humankind. Another aspect worth underlining is the type of ethical assessments associated with the notion of intrinsic value. The concept of "sustainable development" encompasses two different types of intrinsic value. The first is nature's own intrinsic value; the second applies to certain forms of humankind's absolute intrinsic value. In the opinion of the NBAB, assessments of this kind might be more usefully made in relation to the issue of "other ethical and social considerations" and not in relation to the issue of "sustainable development".

Global effects

- Is biodiversity affected on a global scale?
- Is the functional capacity of ecosystems affected?
- Do these effects differ between production and use?

Ecological limits

- Is the efficiency of energy use affected?
- Is the efficiency of other natural resource use affected?
- Is the distribution between the use of renewable and non-renewable natural resources affected?
- Are discharges of pollutants with a global/transboundary range affected?
- Are emissions of greenhouse gases especially affected?
- Do these effects differ between production and use?

Basic human needs

- Is the fulfilment of basic human needs affected?
- Do these effects differ between production and use?

Distribution between generations

- Is the distribution of benefits between generations affected?
- Is the distribution of burdens between generations affected?
- Do these effects differ between production and use?

Distribution between rich and poor

- Is the distribution of benefits between rich and poor countries affected?
- Is the distribution of burdens between rich and poor countries affected?
- Do these effects differ between production and use?

Economic growth

- Is economic growth's demands on energy and other natural resources affected?
- Are economic growth's global/transboundary environmental impacts affected?
- Is economic growth's distribution between rich and poor countries affected?
- Do these effects differ between production and use?

Comment

Compliance with the requirements of "sustainable development" will have to be based on an overall assessment and discussion of all these questions. However, not all the questions above may be relevant in all cases.

Benefit to the community

As mentioned above, the concept of "benefit to the community" appears in the Gene Technology Act as one of several criteria for granting an application. It is, in any case, a complex concept, for which neither the Act itself nor its legislative history provides any clear guidance as to how it should be understood. In the current context, the NBAB has opted for a relatively pragmatic approach, and try to ask some "check-list questions" that may be relevant:

Product characteristics

- Is it reasonable to say that there is a need for the product in terms of demand or otherwise?
- Is it reasonable to say that the product will solve or possibly contribute to solving a societal problem?
- Is it reasonable to say that the product is significantly better than equivalent products already on the market?
- Is it reasonable to say that there are alternatives that are better than the product in terms of solving or possibly contributing to solving the societal problem in question?

Production and use of the product

Among the relevant aspects to be considered are:

- Does the product contribute to creating new employment opportunities in general and in rural areas in particular?
- Does the product contribute to creating new employment opportunities in other
- countries?
- Does the product create problems for existing production whose existence should otherwise be preserved?
- Does the product create problems for existing production in other countries?

(This list of questions is not meant to be exhaustive, but is meant primarily to serve as an indication of the type of questions that should be considered).

Comment

Any assessment of benefit to the community must be based on a discussion of the responses as a whole. However, it should be emphasized that every question may not be equally relevant in all instances.

IMPACTS AND FOLLOW UP OF THE PROJECT

The statements made by the NBAB are generally regarded as high impact contributions by the competent authorities. Such statements are publicly available and quite often they spark a public debate. The statements are communicated to the decision-makers both through letters and by regular meetings, as the decision-makers have status as observers during the relevant NBAB discussions. NBAB is planning a conference on sustainability and GMOs late in 2007.

CHALLENGES IDENTIFIED IN THE PROJECT

Operationalizing the criteria of sustainability and societal benefit in relation, for instance, to specific submissions for deliberate release, remains challenging. Even more challenging than defining the "checklists", is to access relevant information regarding the products. As Norway appears to be unique in using these criteria, submissions within the EU do not generally include relevant data. And so far, applicants do not seem to find it worthwhile to provide such data just for Norway. Without relevant documentation, Norway cannot fully undertake the relevant assessments, and thus, based on this lack of information, Norwegian authorities may end up not authorising a given product. However, the EU might not consider such terms legitimate to reject an authorisation, which could be necessary under Norway's commitment as member of the EEA. Thus, a number of questions regarding the harmonization of regulation within the EU/EEA remain.

As described above, there also remains a question of whether criteria of sustainability and societal impacts should be interpreted as additional requirements to the absence of detrimental effects on health and the environment; or as a softening-up of the requirement of non-detrimental effects.

LITERATURE:

Linnestad, Casper (ed) (2003): Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms. Discussion Paper, The Norwegian Biotechnology Advisory Board. ISBN 82-91683-21-2. Web: http://www.bion.no/publikasjoner/sustainability.pdf

The Norwegian Biotechnology Advisory Board: http://www.bion.no

The Norwegian Gene Technology Act: http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031

AUTHOR OF THE REVIEW

Casper Linnestad

SWITZERLAND 8.

PUBLIFORUM »GENETIC TECHNOLOGY AND NUTRITION« (1999) 8.1

BACKGROUND OF THE PROJECT

The *PubliForum on Genetic Technology and Nutrition* took place in 1999, under the lead of the Swiss Centre for Technology Assessment, referred to below as TA-SWISS. This centre has been set up in 1992 by the Swiss Parliament and is attached to the Swiss Council for Science and Technology. Its mission is to support the political decision-making process, firstly by carrying out expert analyses, and secondly by canvassing the opinions of the citizens themselves through participatory projects. The *PubliForum on Genetic Technology and Nutrition* was the second participatory project ever organised by TA-SWISS[13].

The aim of the *PubliForum on Genetic Technology and Nutrition* was to set up an encounter between the people actively involved in the development of genetic technology (i.e. scientists, but also industry, public authorities and NGOs) and the public. Genetically modified organisms (GMOs) had already been extensively discussed about a year before, as Swiss citizens had to vote on an initiative demanding a halt to genetic engineering in Switzerland (the "initiative for genetic protection"). During the political campaign preceding the vote, all of the interested parties involved debated the issue at great length, but the fact that the rules of the game did not allow for a win-win situation (voters had to answer "yes" or "no") meant that it was difficult to get a real dialogue going. For the PubliForum on genetic technology in nutrition, the rules of the game were changed, to allow for win-win situations. The inclusion of ordinary citizens in the process would then provide greater awareness of their wishes, alternative solutions and needs. It would also provide an opportunity to learn about their argumentation patterns: how did they perceive and understand the implications of genetic technology in nutrition, what were their hopes and fears, and on which basic values and standards did they judge the issue?

Discussing these questions was considered as crucial, as the debate on GMOs was, at that time, far from being closed. As a matter of fact, when the Initiative for Genetic Protection had been first discussed by Parliament in 1996 and 1997, the Federal Assembly charged the government to fill all juridical gaps regarding genetic engineering in the non-human domain (Motion GENLEX). At the time of the PubliForum, government was working on this adaptation of the legislation[14].

13 TA-SWISS has been undertaking participatory projects since 1998.

14 The Swiss government presented its conclusions regarding the GENLEX motion in 2000, in form of a modification of the Law on environmental protection. This govern-

BASIC DATA ABOUT THE PROJECT

The *PubliForum on Genetic Technology and Nutrition* is a participatory project, using the "consensus conference" model developed by the Danish Board of Technology. This model has been adapted for the multilingual reality of Switzerland: instead of 15 citizens being invited to discuss the effects of new technologies, about 30 citizens from all parts of the country were invited to discuss and an interpretation service has been offered so that each participant could use their own language. All in all, the citizens met three times:

- In a first preparatory week-end, participants could meet and get to know each other, familiarize with the working method and inform themselves about the subject implications of genetic technology in food and plants. They also selected those aspects which they wanted to investigate more closely during the PubliForum.
- At the second preparatory weekend, the panel members defined their questions more clearly and chose the information persons who were to reply to these questions during the main PubliForum session. Their questions were related to research, environment, health, ethics and economics.
- The actual PubliForum lasted three days. During the first two days, which was open to the public, the information persons answered the questions of the citizen panel. Then the panel went behind closed doors and had 24 hours to draw up a report.

In order to create an as neutral as possible framework for the PubliForum, an accompanying group had been formed consisting of representatives from industry, research, administration, media, politics and various non-governmental organisations (NGOs). This accompanying group had the task of putting the content of the PubliForum into concrete terms and to make sure that the preparation and realisation of the event took place in an as balanced as possible way. The accompanying group was also responsible for the preparation of information sheets meant to help the Citizen Panel familiarise themselves with the subject. Another assignment was that of helping find reference persons to answer the questions and, finally, influence could be made on the composition of the Citizen Panel.

MAJOR OUTCOMES OF THE PROJECT

In its report, the Citizens' Panel acknowledged that today's level of scientific knowledge does not permit the existence of specific risks resulting from genetically modified organisms to be ruled out. And, as one cannot quantify these risks, the Panel was not in a position to make any judgement on their acceptability. Half of the Panel,

mental proposal addressed many issues, such as biodiversity preservation, civil responsibility regarding GM crops, authorization procedures and the introduction of a declaration for GM products. But the Parliament, after having examined this proposal, decided to write a specific law on genetic engineering. It took more than two years of political debate for the Parliament to come to a final text.

however, was of the opinion that genetic technology is an encroachment on life-processes, whereas the other half saw no difference between genetic technology and traditional production methods. This gap could be seen in the notion of imposing a moratorium on the production and marketing of genetically modified organisms[15], which was endorsed only by a slender majority of the Panel. Despite these differences of opinion, the Citizens' Panel agreed that freedom of choice for consumers should be maintained and that GMOs should thus be clearly labelled. It also demanded more research on risks and monitoring studies and showed some concern about the financial independence of public research.

IMPACTS AND FOLLOW UP OF THE PROJECT

The *PubliForum on genetic engineering in nutrition* caught a great deal of attention of the media and political groups, mainly for its proposal of a moratorium made by the Citizens' Panel. TA-SWISS could also present the PubliForum's results in the Parliamentary commission for science, education and culture. Many articles also were published in specialized magazines and journals.

Interestingly, what was a minority position at the time of the publication of the results of the PubliForum (the idea of a moratorium was in fact only defended by ecologists groups) became, with time and the support of farmers' representatives (who became conscious, through the PubliForum and other surveys, that consumers didn't want to consume GMO crops), a potentially majority position. Indeed, during the discussions on the new law on genetic engineering by the relevant Parliamentary Commission, a slender majority amended the law with a moratorium of 5 years (excluding field trials for scientific purposes). This proposal was ultimately rejected in the final vote in Parliament, where the Commission's slender majority was unable to gain enough support for its proposal. Interestingly, groups in favour of a moratorium tried a second time to anchor a 5-year moratorium on GMOs in Swiss legislation. This time, they tried to integrate it in the agriculture law, which was revised in 2003. And for a second time, they just failed[16]. Parallel to all these parliamentary debates, environmental groups, consumer associations and farmers group have launched an Initiative demanding a five-year moratorium on the farming GM crops for use in food (the use of GM crops for research purposes would be authorized under strict conditions). The group collected over 120'000 signatures in only seven months[17].

This initiative was contested by the government and Parliament (whereas a minority of the representatives had been supporting it), as well as by research and industry

15 Clearly defined field trials (specifically by public institutions) should, however, be permitted and supervised in order to obtain extended knowledge on any risks.

16 The proposal was in fact accepted by the lower chamber of the Parliament (National Council), but rejected by the upper chamber (State Council). In an ultimate vote, the lower chamber decided to align its position to that of the State Council in order not to bring down the whole revision.

17 To be valid, an initiative must be supported by 100'000 citizens and have to be found in a period of 18 monthes.

representatives. In November 2005, 55.7% of the Swiss citizens accepted the initiative demanding the five-year moratorium[18].

CHALLENGES IDENTIFIED IN THE PROJECT

In its report, the Citizen's Panel gave its opinion on several topics and formulated several recommendations. From these, we can consider that the challenges for GM plants and food, seen from a citizen perspective, are the following:

- The freedom of public research must be guaranteed and public funding should remain assured.
- The current supervisory mechanisms are sufficient, but citizens call for an intensified dialog between the general public and research.
- GMO-specific risks cannot be ruled out. Therefore, monitoring is absolutely necessary, in order to be able to estimate risk potential in a better way.
- Switzerland needs to have trained personnel, able to carry out monitoring research into GMOs.
- Backing out of genetic technology in the sense of a unilateral Swiss policy doesn't seem to be an option any more, since this would lead to important economic disadvantages, primarily in the Swiss research area and secondarily because of the dependence of Switzerland on imported raw materials, which could in the future contain GMO-components. Nevertheless, the question on how far a need for the use of genetically modified organisms exists in Switzerland must be answered.
- The existence of traditional, genetic-technology-free agriculture as well as organic farming must be guaranteed, in order to provide consumers with a free choice, both today and in the future. Moreover, instead of GMO production, organic farming could be a chance for Switzerland, as at the moment of the PubliForum no contamination is to be feared.
- The smaller seed producers may disappear in the long term because they will not be able to compete with large multi-national industry, which would mean that dependence could develop.
- The patenting of living organisms is for many of the members of the panel not acceptable. On the other hand, patenting creates more transparency, as the applicant has to publish his research results before the patent is granted. It is also understandable that the high costs of research have to be made to pay for themselves somehow.
- The unequivocal tracing of damage back to a GMO is very difficult. If such evidence exists, it must in all cases be possible to prosecute those responsible (e.g. the producer).

18 A survey conducted just after the vote showed that among those who voted against the initiative, 13% were actually convinced to vote against gene technology. In other words, these persons didn't correctly understand that the question they had to answer ("do you agree or not with the initiative and, eventually, the initiative should have been accepted by about 68% of the voters – an extremely high score for a popular initiative (Hirter and Linder 2006).

LITERATURE

PubliForum «Genetic Technology and Nutrition». Citizen Panel Report, Centre for Technology Assessment, TA-P1/1999e, Bern, 1999 (http://www.ta-swiss.ch/a/erna_gent/1999_TAP1_gentech_e.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

RIBIOS FORUM »THE FUTURE OF PLANT BIOTECHNOLOGY IN SWITZERLAND« (2003) 8.2

Excerpts from the report: "The Future of Plant Biotechnology in Switzerland", Les Cahiers du RIBios, No7

BACKGROUND OF THE PROJECT

The Forum entitled « The future of plant biotechnology in Switzerland » took place at the University of Lausanne on November 3rd, 2003. It was jointly organised by the RIBios (Biosafety Interdisciplinary Network, based at the Graduate Institute for Development Studies of the University of Geneva) and by the Interface sciences-société of the University of Lausanne.

The aim of this Forum was to bring together stakeholders involved in the decisions about experimental field releases of transgenic plants in Switzerland.

BASIC DATA ABOUT THE PROJECT

The participants of the Forum were representatives of three main groups of stakeholders: public scientists involved in plant biotechnology research, the governmental bodies involved in the decision-making process, and other institutions directly involved in science policy at the national level. All the participants had been invited personally, in order to make clear that they should speak in their own name rather than in their institution's name. This sensitive issue was dealt with by agreeing with the participants that no material would be published on the content of the debates without their prior review of the documents.

Before the forum, the participants received a position paper written by the organisers. This paper was divided into six sections corresponding to important topics that would be discussed during the forum. It was aimed at giving some factual information, but also some analytical overview to stimulate the debate.

The forum lasted one day. The debates were organised by topics. In the morning, three questions were discussed: «Risk negotiation», «Coordination at the level of assessment and decision» and «Coherence between research and environment policies». In the afternoon the debates focused on «"Socially robust" research policies», «Biotechnological research in Switzerland» and «Decision-making under uncertainty: the controversial implementation of precaution».

The organisers decided to adopt a non-directive strategy for the debate regulation. Three persons were assigned to that task. One was in charge of handing over to the participants and to keep the schedule. The two other persons acted as facilitators by introducing factual or analytical elements pertinent to the debate, and by redirecting the discussion when it was clearly out of the topic of this forum.

MAJOR OUTCOMES OF THE PROJECT

Following the forum, a document restituting the main discussed points have been published in the "Les Cahiers du Ribios". The core of the text is made of participants' quotations, which are introduced by a short summary.

CHALLENGES IDENTIFIED IN THE PROJECT

The richness and diversity of the discussions during the forum show that many open questions are remaining with respect to research on GMOs. The lecture of the report shows that there is a certain frustration from the side of researchers, or at least a difficulty to cope with the social and political dimension of the issue.

CHALLENGES IDENTIFIED WITH RESPECT TO PUBLIC RESEARCH:

- To regain the public's confidence, it is necessary to define research priorities that correspond to agronomical problems which have been clearly identified and which benefit from political support.
- The distinction between fundamental and applied research must be taken into consideration. There is a sharp difference between commercialisation and experimental releases. The frontier between these two facets of research is nevertheless difficult to draw. This distinction is however important as soon as risk assessment is concerned. The standards and procedures used in the assessment do indeed depend on the nature of the trials, experimental or commercial.
- The position of Switzerland on the international scene in terms of knowledge and competitiveness in plant biotechnology is an issue to consider. There is a risk to see the competitiveness of Switzerland in the field of plant biotechnology decrease, as a result of industrial delocalisations and disinterest on behalf of students. While Switzerland has still a good knowledge base in the field of plant biotechnology, research is locked in, in part because of the difficulty to make field tests experiments.
- Research is facing important economical, political or administrative constraints. These difficulties have prevented researchers from accumulating the knowledge needed to perform an adequate risk assessment of the plants under development.
- The time lag between the application for an experimental release and the decision of the authority may be incompatible with the scientific rationale.

CHALLENGES IDENTIFIED WITH RESPECT TO RISKS:

- Rather than talking about the risks of doing research, one should also take into account the potential benefits, namely benefits that will derive from this research in the future but are still not known. In other words, the risks of doing research should be balanced with the risks of not doing it.
- Risks related to a new technology such as GMOs must not be discussed in isolation but rather in comparison with the risks of the technology it is replacing.

CHALLENGES IDENTIFIED WITH RESPECT TO PUBLIC DEBATE:

- The perception of risk by the public may sometimes be irrational. Risks related to GM food are typically over-estimated in comparison to other risks.
- Some participants pointed out the fact that communication policies have not been able until now to reverse this trend, and thus generate a positive picture of plant biotechnology in the public.
- It is more difficult to find support in the public for innovation, than to exploit the fears of the public related to these innovations.
- There is clearly a lack of communication in the field of plant biotechnology. The scientific community should do more grassroot work. However, the social acceptability of GMOs does not onlydepend on the level of information. In other words, more information does not necessarily end up with more people accepting the technology:
- There is a need to find new forms of public debate. Moreover, people and groups concerned by new technologies shoudl be included upstream (i.e.when a technology is still at the stage of research), so as to make research policies "socially more robust".

CHALLENGES IDENTIFIED WITH RESPECT TO DECISION-MAKING PROCESSES:

- There is a risk that scientific arguments are "instrumentalised" by political authorities in the decision-making process.
- Science should be more able to recognize the limits of its knowledge. This would surely be a way to improve society's confidence in science.
- Any decision in the field of risk mangement is somehow political, since a zero risk level is not achievable. Political decisions consist therefore in determining an acceptable level of risk:

LITERATURE

The Future of Plant Biotechnology in Switzerland", Les Cahiers du RIBios, No7, RIBios and IUED, Geneva, 2005.
(http://www.ribios.ch/en/documents/docs/Brochurespdf/Brochure7Forum.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

REPORT ON THE COEXISTENCE OF DIFFERENT GM AND NON-GM AGRICULTURAL CULTIVATION SYSTEMS (AGROSCOPE RECKENHOLZ-TÄNIKON RESEARCH STATION ART, 2005) 8.3

BACKGROUND OF THE PROJECT

Worldwide GM0 cultivation is increasing year by year. Even though there is little likelihood of such cultivation in Switzerland at present, cultivation of GMOs in the future cannot be excluded. According to the Gene Technology Law (GTL), when GMOs are grown, non-GMO production and consumer's freedom of choice must be safeguarded. So-called "coexistence" must be guaranteed by segregating production flows (Warenflussstrennung) during the whole productions chain (from the field to shelves of the stores), by regulations and by technical measures. In this respect, legal threshold values were defined because it is impossible to rule out mixing completely no matter how much care is taken. They specify the percentage of genetically modified material which can be included in food and animal feeds without having to label them as «genetically modified». In line with the EU, a threshold limit of 0.9% is set in Switzerland. This limit is for approved GM crops. For non-approved GM crops there is, theoretically, a zero-tolerance.

Agroscope Reckenholz-Tänikon Research Station ART was commissioned by the Federal Office for Agriculture (FOAG) to carry out a study on whether GM and non-GM agricultural systems in Swit-zerland can coexist from a scientific and technical point of view within the present legislative framework. Maize, wheat and oilseed rape were selected as model crops.

BASIC DATA ABOUT THE PROJECT

The aim of the project was to present a concept for a coexistence of GM and non-GM cropping systems in Switzerland. In a first step mechanisms were analysed which can lead to a mixture of agricultural products during cropping. Subsequently, technical and organisational measures were listed which can minimize or prevent mixing. The study was limited to the agricultural production, i.e. from planting to the delivery of the harvest to storing or processing facilities. The cost of segregation of different cropping systems varies according to the specific biological characteristics of the crops and according to the level of segregation required. Three model crops (maize, wheat and oilseed rape) have been chosen as case studies to show what specific measures are needed in order to maintain the legally binding GMO threshold for food and feed.

The study was entirely funded from the Agroscope Reckenholz-Tänikon Research Station own resources, with no third party funding that could have cast doubts upon their independence. The scientists based their statements on objective foundations.

MAJOR OUTCOMES OF THE PROJECT

The investigations on the possibilities and limits of the «coexistence of GM and non-GM cultivation systems in Switzerland» reached the conclusion that, with the requisite crop-specific distances, discussion and agreement between farmers, and careful segregation during product handling on the farm, the cultivation of GM maize, GM wheat and GM oilseed rape in Switzerland would be technically possible.

This assessment was based on the threshold limit of 0.9 % GM content and covered cultivation up to the delivery of the harvested material at the collection point. Additional time and costs related to coexistence was not examined. The measures necessary for coexistence are detailed in the "Schriftenreihe der FAL" No 55[19]. They are for example:

- Usge of certified seed
- Optimal soil preparation after the harvest and cultivation of non-GM crops before subsequent GM planting.
- The degree of out-crossing between fields with GM and fields with non-modified plants of the same species can be reduced through isolation distances and "buffer zones" between GM an non-modified crops.. Moreover, it is possible to avoid that cross-pollination happens at the same time.
- The intermingling of GM and non-modified crops in various machines can be avoided by carefully cleaning them after having used them for GM-crop fields.
- Segragation during harvest, transport, storage and processing of the crops, as well as a documentation of these processes is essential to minimize intermingling.

IMPACT AND FOLLOW UP OF THE PROJECT

In June 2005, a conference named "Coexistence of GM and non-GM crops - scientific data, practical applications and perspectives for the next decade has been organised by the authors of the study. About 120 Swiss and international experts discussed the issue of coexistence (more info on the conference on: www.coexistence.ethz.ch/). The group took part in many other conferences dedicated to the issue of coexistence, in Switzerland or at the European level. But, at the time being, it doesn't carry any project on the theme.

In June 2006, The Federal Office for Agriculture adapted the legislation on coexistence (ordinance on coexistence) and considered some elements analysed in the study. There is, however, no evidence on how far the study influenced the legislative process.

19 Study summary as pdf (http://www.reckenholz.ch/doc/en/publ/schrift/sr55vz.html): To order Study (http://www.reckenholz.ch/cgi-bin/sql/order.pl?ref=4&lang=en&sort=-feld_0).

CHALLENGES IDENTIFIED IN THE PROJECT

- How to guarantee coexistence? This implies regulatory, technical and organisational aspects.
- The probability of intermingling depends on the biological properties of the various plants. The necessity for coexistence measures must then be separately assessed, for each cultivated plant.

LITERATURE

Olivier Sanvido, Franco Widmer, Michael Winzeler, Bernhard Streit, Erich Szerencsitz, Franz Bigler, 2005, Koexistenz verschiedener landwirtschaftlicher Anbausysteme mit und ohne Gentechnik, FAL-Schriftenreihe Nr. 55, edited by: Agroscope Reckenholz-Tänikin Research Station ART, Switzerland (http://www.art.admin.ch)

AUTHOR OF THE REVIEW

Danielle Bütschi

COORDINATION MEETING OF INSTITUTIONS OFFERING BIOSAFETY-RELATED TRAINING AND EDUCATION PROGRAMS (2004) 8.4

Excerpts from the "REPORT OF THE COORDINATION MEETING OF INSTITUTIONS OFFERING BIOSAFETYRELATED TRAINING AND EDUCATION PROGRAMS",(http://www.biodiv.org/doc/meetings/bs/bscmet-01/official/bscmet-01-01-en.pdf)

BACKGROUND OF THE PROJECT

The first Coordination Meeting of institutions offering biosafety-related training and education programs was held 4-6 October 2004 in Geneva, Switzerland. It was organized by the Swiss Agency for Environment, Forests and Landscape (SAEFL) in collaboration with the CBD Secretariat, the UNEP/GEF Biosafety Unit and the Geneva Environment Network.

Thirty-seven (37) participants from 28 institutions attended the meeting, including representatives from academic and other organizations. The participants came from all over the world (Belgium, Namibia, Switzerland, Mexico, New Zealand, USA, England, Netherlands, China, Kenya, Norway, Cuba, Thailand, Canada, Austria, Chile, Italy, Japan).

The meeting was a follow-up to the offer made by the Government of Switzerland at the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOP). In its decision BS-I/5 on capacity-building, the COP-MOP emphasized the need for a coordinated approach towards capacity-building at all levels and accordingly established a Coordination Mechanism to promote partnerships and maximize complementarities and synergies between various capacity-building initiatives contributing to the effective implementation of the Protocol. In this regard, the Government of Switzerland offered to sponsor a coordination meeting for representatives of academic and research institutions actively involved in education, training and research programs in biotechnology and biosafety in the autumn of 2004. The Swiss Government contracted RIBios – Réseau Interdisciplinaire Biosécurité – (Biosafety Interdisciplinary Research Network), which is part of Institut Universitaire d'Études du Développement (IUED), to organize the meeting.

The primary objective of this meeting was to bring together representatives of institutions involved in biosafety training and education to share information and compare notes regarding their ongoing programs and to learn more about the about the Protocol and the capacity-building needs and priorities for its effective implementation. The specific objectives of the meeting were:

- To review the current status ("state of the art") regarding training and education programs in biosafety, including consideration of the draft compendium of existing programs;
- To review the needs and priorities of countries and discuss ways and means for enhancing training and education programs to respond to those needs and support effective implementation of the Protocol;
- To identify and discuss key components of biosafety training and education programs;
- To explore mechanisms to enhance coordination, networking and collaboration among institutions offering biosafety training and education programs.

BASIC DATA ABOUT THE PROJECT

The agenda of the meeting consisted of two parts. The first part (day one) included presentations on: overview of the Cartagena Protocol and the COP-MOP decisions; the capacity building needs of countries and the role of training institutions in addressing those needs; the experience from the UNEP-GEF projects on capacity-building in biosafety and overview of the draft compendium. These were followed by short presentations by participants on their ongoing and planned programs.

The second part of the meeting included three plenary session discussions and one session of group discussions. The deliberations focused on the compendium; ways and means to improve biosafety training and education programs to address the needs of different target audiences; possible mechanisms for future networking/ collaboration and the next steps.

MAJOR OUTCOMES OF THE PROJECT

Overall, the meeting was a big success. It provided the first opportunity for institutions offering training and education in biosafety to meet and interact and laid a good foundation for their future collaboration and active involvement in biosafety processes at international, regional and national levels.

The meeting represented an important first step in preparing education and training institutions to play an effective role in building capacity for effective implementation of the Cartagena Protocol on Biosafety and other relevant instruments. It provided them with an insight into what the key training need are from the point of view of the countries that are now in the process of establishing and implementing their national frameworks and an the opportunity to learn more about what other institutions are offering and develop ideas for improving their programs.

The main outcome of the meeting was the development of a common format (questionnaire) for the compendium of existing biosafety training and education programs. The meeting also developed a set of draft recommendations for consideration by COP-MOP, governments, education and training institutions and other stakeholders in order to enhance biosafety training and education in support of the Protocol implementation.

IMPACT AND FOLLOW UP OF THE PROJECT

No concrete action has been implemented after the coordination meeting. Nevertheless, the meeting created a dynamic, in the sense that Malaisia University decided to organise a second meeting in April 2007, in Kuala Lumpur. The RIBios network (which organised the first meeting) will be participating and hopes that it will be able to interact and create synergies with african universities, so as to establish education programmes on biosecurity.

CHALLENGES IDENTIFIED IN THE PROJECT

While the meeting had resulted in fruitful deliberations, it also raised many new important questions. For example, questions were raised regarding:

- how to effectively to involve the newly trained experts in biosafety activities of their own countries;
- how to insure the sustainability of the biosafety training and education programs,
- how to mobilize adequate funding for biosafety training programs and for scholarships to support students from developing countries;
- how to insure the availability of technical infrastructure in all countries for the effective delivery of biosafety education and training programs and
- how to fill the gaps in the existing courses. All these questions underline the arduous challenge ahead.

LITERATURE

Report of the coordination meeting of institutions offering biosafety related training and education programs, 4-6 october 2004, by the Swiss Agency for Environment, forests and landscape, the CBD secretariat, the UNEP/GEF Biosafety Unit and the Geneva Environment Network.
(http://www.biodiv.org/doc/meetings/bs/bscmet-01/official/bscmet-01-01-en.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

UNITED KINGDOM 9.

PROJECTS SINCE 2000

BACKGROUND

The most important activities concerning GM crops and food carried out in the UK since 2000 are

- the government commissioned dialogue on GM issues (GM dialogue)
- the Farm-scale evaluations (FSEs) of GM crops

As the latter study is scientific, this review will focus on the GM dialogue. However it should be noted that the FSE's were one of the pieces of information used by the government to inform its policy on GM crops in 2004 – see section on Impact and follow-up. POSTnote 211 *GM crops in the UK* (2004) gives an overview of the GM dialogue and the FSEs and discusses the issues raised. It was published prior to the Government setting out its policy on GM in March 2004. Other POSTnotes in this area published since 2000 are POSTnote 172 *Labelling GM foods* (2002) and POSTnote 146 *GM farm trials* (2000).

GM DIALOGUE

The GM dialogue ran from May 2002 to January 2004 and consisted of three main strands:

- GM science review –an assessment of the state of current scientific knowledge on GM crops and foods;
- economics review - an evaluation of the potential costs and benefits of GM crops in the UK;
- GM Nation? - a nationwide public debate to find out what people really think about GM.

Information on each strand and its outcome is discussed below.

GM SCIENCE REVIEW[20]

The science review was led by the Government's Chief Scientific Adviser working with the Chief Scientific Adviser to the Secretary of State for the Environment, Food and Rural Affairs, and with independent advice from the Food Standards Agency. The science review was carried out by a 26-member panel comprised of leading scientists from a spectrum of disciplines and perspectives, two lay representatives, a social scientist and a leading scientist with cross membership with the Public Debate Steering Board. It considered peer-reviewed published scientific literature and was

20 http://www.gmsciencedebate.org.uk/

focused on science-based issues identified by the public and the scientific community.

In July 2003 the panel concluded that for current GM crops and GM food:

- the risk to human health is very low;
- these crops are unlikely to invade the countryside and become problematic plants;
- it is unlikely that these crops, if consumed, would be toxic to wildlife;
- there is insufficient information to predict the long-term impact of the herbicide regimes associated with herbicide-tolerant GM crops on wildlife;
- the balance of risks and benefits will vary for each GM crop, therefore case-by case regulation is appropriate.

The panel reconvened to consider comments on its July report and the results of the FSEs, reporting in January 2004 that:-

- none of the new research published since the first Report significantly altered the earlier conclusions;
- the FSEs were of high scientific calibre. The panel found that if GM herbicide tolerant (GMHT) crops are managed as in the FSEs, a significant reduction would be expected in weeds with GMHT beet and spring oilseed rape, whereas the opposite would be found with maize. These effects arise from the herbicides and are not a direct consequence of the GM process. The different findings for different GM crops reinforced the conclusion of the first Science Review that GM crops must be assessed on a case-by-case basis.

ECONOMICS[21]

An evaluation of the costs and benefits of the possible commercial cultivation of GM crops in the UK, published in July 2003, was conducted by the Prime Minister's Strategy Unit (SU). The SU performs long term strategic reviews of major areas of policy, studies of cross-cutting policy issues, strategic audits and joint work with Departments to promote strategic thinking and improve policy-making across Whitehall. It reports directly to the Prime Minister. The study focused on the GM crops that were currently available, as well as possible developments in the next 10-15 years, and developed five scenarios to explore a range of possible futures. The study was informed by experts, the public, science and the best available economic data.

The study concluded that although existing GM crops could offer some advantages to UK farmers, at least in the short-term, any economic benefit is likely to be limited by negative public attitudes and retailer policies. Over the next 10-15 years, the SU considered that there is significant potential for benefits from future developments in GM crop technology as well as potential for impacts on wider science and industry. The key conclusion of the study was that the future of GM crops will depend on the nature of the regulatory system and public attitudes.

21 www.number-10.gov.uk/su/gm/index.htm

GM NATION? THE PUBLIC DEBATE[22]

A public debate, organised by a steering board independent of government, took place in summer 2003. The aim was to promote a programme of debate on GM issues, framed by the public, against the background of the possible cultivation of GM crops in the UK.

- The debate was overseen by a Steering board which comprised of people with different perspectives on GM and people with expertise in public engagement. A number of external contractors were appointed to manage the debate programme and deliver the different strands of the programme. Foundation Discussion workshops -nine workshops of 18-20 participants from different backgrounds/age - groups held in different regional locations.
- Public events - a series of public events organized in three 'tiers' at national/regional, county and local levels. These events included different methods - round-table discussions, expert speaker Q&A, debating a motion – but were informed by stimulus material approved by the steering board. Participants were self-selecting.
- Narrow-but-deep element – series of reconvened discussion groups that involved a selected cross-section of the wider population, who would be exposed to GM issues over a period of two weeks.

Over 37,000 people provided feedback from this range of activities which including more than 600 meetings and visits to the *GM Nation?* website. Key messages emerging from the debate include:

- people are generally uneasy about GM crops;
- there is little support for early commercialisation;
- there is a widespread mistrust of government and multi-national companies;
- there is a broad desire to know more and for further research to be done;
- the debate was welcomed and valued.

IMPACT AND FOLLOW-UP

The Government considered the reports from all three strands of the GM dialogue and published both a detailed response and a Parliamentary statement in March 2004[23]. In these the Government set out its policy on GM crops and said it would:

- assess GM crops on a case-by-case basis, taking a precautionary and evidence-based approach, and making the protection of human health and the environment the top priority
- provide choice for consumers through mandatory labelling of GM food products
- consult on measures to facilitate the co-existence of GM and non-GM crops, and on options to provide compensation to non-GM farmers who suffer a financial loss through no fault of their own

22 www.gmnation.org.uk/docs/GMNation_FinalReport.pdf
23 http://www.defra.gov.uk/corporate/ministers/statements/mb040309.htm

There are currently no GM crops being grown in the UK and no commercial cultivation is expected before 2009 at the earliest. However GM crops have been grown for research and development purposes at a number of sites, for example in the FSEs.

Co-existence

When GM crops are grown commercially measures will need to be applied to ensure that they can coexist with non-GM production. The Department for Environment, Food and Rural Affairs (Defra) consulted on proposed coexistence measures for England between July and October 2006. A summary of responses to the consultation should be available by the end of this year. Defra expects to have measures in place before GM crops are grown commercially.

CHALLENGES IDENTIFIED IN THE PROJECTS

- Generally the UK public is uneasy about GM crops. How will consumer attitudes develop over the next 5-10 years? This is likely to be key to any future success of GM crops.
- Which future developments in GM technology will offer economic benefits?
- Assessment and monitoring of the long-term impact of GM crops on the environment.
- Co-existence of GM crops with non-GM crop production. Particular problems include (1) no legal threshold for the presence of GM crops in organic crops. In practice the organic sector works to the limit of detection of the presence of GM. (2) EU seed purity levels (less than 0.9%) will challenge the seed industry, who work to 1-2% seed purity, while the organic sector would like a level of less than 0.1%.
- Liability – who will pay if there is any environmental damage as a result of GM crops being grown?
- WTO – how will the EU respond to the WTO dispute panel's findings on the implementation of GM crop regulations in Europe.

AUTHOR OF THE REVIEW

Jofey Craig