

REPORT OF A EUROPEAN WORKSHOP
STAKEHOLDER DIALOGUE ON
ENVIRONMENTAL RISKS AND SAFETY OF GM PLANTS

Leiden, The Netherlands, February 28 – March 1, 2001

Schenkelaars Biotechnology Consultancy
on behalf of the European Federation of Biotechnology Task Group on Public Perceptions of Biotechnology
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FOREWORD

Richard Braun, European Federation of Biotechnology Task Group on Public Perceptions of Biotechnology

GM crops were established at a rapid rate on farms in the US: most processed food items on US supermarket shelves contain some of these products. In contrast, in many European countries field trials with GM-crops have led to public controversy about their potential and/or perceived risks and benefits to the environment. The introduction of the first GM-plants to European food and animal feed markets has further fuelled the controversy between stakeholder organisations in the public debate on agricultural biotechnology. Stakeholders comprise biotechnology companies, farmers, seed producers, scientific biosafety advisory bodies, governmental agencies, food processing companies, retailers as well as consumer and environmental non-governmental organisations.

Against this background, the European Federation of Biotechnology (EFB)* Task Group on Public Perceptions of Biotechnology and Schenkelaars Biotechnology Consultancy, a member of the Task Group, conceived and ran a two-day workshop in Leiden, Holland, to promote stakeholder dialogue on the environmental risks and benefits of GM plants. It brought together representatives from different European countries and from different organisations. The workshop led to a constructive exchange of views on how to move forward the present difficult public debate and improve the communication of these findings.

The main objective of the workshop was to facilitate a dialogue between stakeholders: *"How can scientific research into the environmental risks and benefits of GM-crops better answer the stakeholders' concerns, be better used in decision-making and more successfully communicated"*. On the first day several scientific experts as well as several representatives of stakeholder groups presented their perspectives on the central question. On the second day participants started by mapping their different concerns through addressing two questions: *"What scientific research could address these concerns?"* and *"Why is the level of awareness about scientific research that has been done, particularly by the EU as well as national bodies, low and how can it be raised?"* Based on the outcome of the plenary discussions, three clusters of more detailed questions were formulated, which were then addressed by three different working groups:

1. What immediate actions can the Commission (and other relevant bodies) undertake to engage the public in the shaping and the communication of biosafety research?
2. What kind of account of public and specialists' views would most stakeholders find credible for decision-making? How would it be researched and disseminated?
3. How can one construct a research programme on the significance of agricultural systems and world trade, including GM? How can available data be fitted into such an overview?

The outcome of the working group discussions was subsequently subjected to cross-discussion in the final plenary session. The bottom line is that sustainability is a central aim of agriculture and the environmental consequences of GMOs need to be compared with those of traditional crops and techniques in a science based analysis. Monitoring is essential in the use of any farming resource, including GMOs, keeping in mind the multi-functionality of agriculture in European society. The findings need to funnel into an open dialogue with diverse stakeholders and the general public.

In this workshop report you will first find the outcome of the creative part of the workshop, that is a report on the findings, questions and recommendations from the working groups and plenary discussions, which took place on the second day. Elements for these discussions were provided by presentations of several stakeholders on the first day, which you will find in the second part of this report.

As chairman of the EFB Task Group on Public Perceptions of Biotechnology I would like to thank all the participants for the time they were prepared to spend addressing these important issues and for their valuable ideas and practical suggestions.

And finally, I would like to express my gratitude to the European Commission Directorate - General Research for their financial support as well as the Department of Economic Affairs of Leiden. Naturalis and the Dutch national museum of natural history which provided an 'ideal' environment for dialogue on natural and human evolution, for which I am very grateful.

*) The European Federation of Biotechnology (EFB) is an association of scientists from academia, industry, and other circles interested or involved in biotechnology.

A handwritten signature in black ink, appearing to read 'R. Braun'. The letters are cursive and fluid, with a large initial 'R' and a long, sweeping underline.

Prof. Dr. Richard Braun
Chairman of the EFB Task Group on Public Perceptions of Biotechnology

REPORT OF WORKING GROUP DISCUSSIONS AND PLENARY DEBATES

The central question of the “Stakeholder dialogue on the environmental risks and safety of GM plants” was: ***How can scientific research into the environmental risks and safety of GM plants better answer stakeholders’ concerns and be used in decision making?***

After the presentations on the first day of the workshop, on the second day, participants were invited to exchange their views on this central question. During the first brainstorming session many aspects addressed by the presentations were stressed again. These concerned issues such as:

- determination of endpoints for hazard-analysis, for instance by linkage to nature conservation targets
- protocols for pre-release testing
- long-term ecological monitoring programmes
- research for and assessment of alternatives
- need for social – participatory - experiments involving the public into the definition of scientific research priorities and into evaluation of the outcome of scientific research
- stakeholder deliberations on handling scientific uncertainty within a precautionary approach to regulatory decision-making
- (scientific) reflection on communication, language and trust between science and stakeholders

From this first plenary discussion session the following themes were deduced:

- The need for a better understanding of public views and needs. The need for more social science research into this area, so as to better answer questions such as how to evaluate social science research findings in decision-making, and how to set priorities of research and to communicate scientific research results ways that take public concerns into account so as to democratise decision-making processes.
- The need for research on impacts of different agricultural systems and for finding risk assessment protocols that address all the issues. The need to define goals for (sustainable) agriculture.
- The need to debate uncertainty and precaution and the need to analyse the distribution of risks and benefits.

Given these themes, three different working group discussion were convened, each addressing a particular set of questions.

Working Group I

Question: What are the 3-4 immediate actions the Commission (and other relevant bodies) could undertake to engage the public in the shaping and the results of biosafety research?

Given this question, Working Group I discussed a proposal to the Commission (and other relevant bodies) for starting a reiterative Internet-based forum of consultation on (European Commission funded and other) biosafety research and its results. This would be an electronic gateway to public participation, through which issues could broadly be discussed.

A reiterative process should be designed between 1) a ‘representatives forum’, which would arrange themes and issues for debate and deliberation, 2) an ‘open forum’, in which working groups and conferences would take place, and 3) a ‘virtual forum’ or chat-box would be opened for quick responses to queries.

Such a reiterative consultation forum could help to break the “circle of fear” but then it has to be ensured that every stakeholder is involved. It would also facilitate the dissemination of EU biosafety research results and make resources better publicly accessible.

Working Group II

Question: What kind of account of public views would most stakeholders find credible for decision-making? How would it be researched and disseminated?

This set of questions led to discussions within Working Group II along the following lines:

- What do we mean by the public?
- What is the difference between the public and stakeholders?
- What kind of account should be considered, given the influence of consumer power, election power (the public as citizen) or interest group power?

For example, NGOs can voice public views but different opinions are expressed by general public and specific interest groups. With respect to food safety, we are all stakeholders.

There is no single 'European public' and perceptions of safety differ throughout Europe, yet there is a European Commission with a common research programme. Further a variety of world-views, values etc., which are due to different cultures and needs, cannot be designed into one research study. And different stakeholders often have *irreconcilable differences*, based on different expectations (e.g. farmer perspective, consumer perspective, industry perspective) and different research agendas. With respect to gene technology, the first generation of GM crops/food had no consumer benefit. The next generation may have some consumer benefit and this may increase public acceptability. In addition, research needs to have a longer-term vision that cannot be driven only by today's consumer. Thus, there is a need to identify different problem-solving approaches.

Further questions raised by Working Group II included:

- How do we reconcile the difference between what the public says and what they do?
- How should the public views be taken into consideration? How should public concerns feed into decision-making on research?
- How to overcome problems of confidentiality that hampers informed decision-making?

Recommendations for identification of different problem-solving approaches

- Direct the research to address the problems of the public/stakeholders e.g. using telephone polling.
- Use science shops (as in The Netherlands, French-speaking Switzerland) to fuel demand from the public. Currently, it is the retailers who decide what is on the market.
- Use focus groups, lay persons' conferences.
- Use museums, *inter alia* to influence the school curriculum.

Additional recommendations

- Train scientists to be more media-friendly and provide science training for the media.
- Improve communications between scientists and politicians.
- Undertake an *inventory of public participation methodologies* (as a scientific project) and examine the effectiveness of different approaches. This could result in the development of new tools to evaluate the effects of participation.
- Run *focus groups of different people and have different stakeholders interpret the results*. It is likely that different stakeholders interpret the concerns of the focus groups differently.

Working Group III

Question: How would you go about constructing a research programme on the relative impacts of agricultural systems, including GM? Please cover what research is already being done and what should be done? How would you frame the questions and how would you ensure 'public ownership' of the results?

Working Group III thought that generation of data on the impacts of different agricultural systems would provide a context for evaluation of the impacts of GM crops, and it would

make it easier to judge their significance. The group formulated the following considerations for the design a joint stakeholder research process:

1. Define the objective of the research - public participation is needed at this stage. Perhaps form small groups of people from different regions to lay out concerns and hopes. But how to translate 'feelings' into the objectives of a scientific programme? The discussions need the participation of scientists to say what can or cannot be examined from a scientific perspective. It is not necessary to have the debate with everyone, but a good cross-section of the public. The process is as important as the product. Contact between different types of people is likely to be productive in itself. It requires interest groups to come to the table with a worked-out view - but might this be a problem in terms of inflexibility of views?
2. Be clear about the likely use of the results - might it be hard to engage people if it is unclear what results will be? A main concern of some of the participants in the discussion was to avoid falling into the trap of 'comfort science' i.e. experimentation designed to allay concerns but not genuinely scientifically rigorous or useful.
3. Questions that need to be answered to design a research project:
 - What should be the timing of such research, specifically, should commercialisation be stopped in the meantime? Varieties are regularly withdrawn from the market, but are the consequences of GM reversible? If not using GM varieties with commercial consent this would constrain the size of experiments.
 - What are the relevant agricultural systems to compare? Are the distinctions generally understood, given that from a scientific perspective it is hard to handle more than two systems at once? Options are Organic, Extensive/Integrated or Intensive/Conventional Agriculture – the latter may be preferred by many on the grounds that it is most widespread. And is there such a thing as a 'GM system' - do stakeholders consider it as a special system? Some do - others see GM as just one component of general (probably intensive) practice.
 - What is the scope of the research? In the first instance EU would be the preferred scope (but be aware of EU enlargement bringing other kinds of agriculture). On the other hand, currently available crop/trait combinations would anyway limit the area for experiments.
 - Which GM crop/traits combinations should be researched? Focus on those believed to be benign? Or would this draw criticism that it ignores hazards? How do you cover all the ground? Constrained by those crops currently transformed, as only 3 or 4 available are now available? Could oilseed rape, sugar beet or maize as model systems? What will be predictive as possible? By looking at traits conferring selective advantage in nature?
 - Which impacts or goals are at issue? What should be protected? Basic answer is human health and biological diversity, which would also require analysis of the impacts of the use of chemical inputs, waste disposal, energy and fossil fuel use, mineral cycles, water quality and soil quality.
 - Gene flow and hybridisation with wild relatives? Is this actually a concern about consequences of gene flow for biological diversity - or is introgression an impact in itself? Some say yes, if the genes are novel, i.e. transgenes, and that would apply whether the varieties are GM or not.
 - How many years should research take? How far through food chain? From plough to plate?
 - What could be done about any impacts that are suggested by the research?
 - How to establish continuing 'ownership' of research results? Through 'Civic Committees' with members drawn from local political parties, church, trades unions, regulators, (local) NGOs?
 - Develop a vision. What should be to set out what agriculture should be like in 20 years time?

EUROPEAN COMMUNITY SUPPORTED GMO BIOSAFETY RESEARCH

Ioannis Economidis and Charles Kessler, European Commission Research Directorate-General

EC-supported GMO biosafety research started in 1985. By the end of 2000 the EC had supported approximately 80 projects with a contribution of about 70 million Euro. Over 400 laboratories from research, academia and industry have participated in these activities. 6 international symposia on results of biosafety research have been held, the EC has participated in OECD committees and has set up an EC-US Task Force on Biotechnology Research has been set up.

Applications where EC-supported GMO biosafety research has been carried out include environmental bioremediation, crops, biocontrol/pesticides, food and health/veterinary products.

As far as current policy is concerned, the EC's Fifth Framework Programme for Research (FP5) takes a problem-solving approach, having science and technology objectives as well as social, policy and exploitation objectives. GMO biosafety research is specifically addressed by the programme's Quality of Life "Cell Factory" Key Action Area 3.2 "Cell Factory", which anticipates (among other) the following deliverables: "methods and strategies for safe introduction, use, monitoring and tracing of GMOs, and contribution to policy development in this area." The corresponding specific research priorities (Areas 3.2.4 and 3.2.5) for which proposals are sought are:

- Assessment of environmental impact of novel uses of micro-organisms.
- Assessment of gene flow dynamics.
- Ecological impacts of using transgenic plants and animals.
- Development of exploitation systems to reduce any such impact.
- Detection and identification of GMOs.
- Assessment of effects when used for human and animal health, and environment.
- Development of criteria for assessing environmental safety of GMO use.

These research priorities are seen as contributing to a dynamic scheme involving synergy and feedback between biosafety research, regulations and management, which should result in best practices for applying GMOs.

GENETIC MODIFICATION IN THE CONTEXT OF CONVENTIONAL PLANT BREEDING

Philip J Dale, John Innes Centre, United Kingdom

There are discussions about whether genetic modification (GM) is the same as conventional plant breeding. Genetic modification can never be the same, because conventional plant breeding includes a range of different methods. There has been a continuum of methods used in plant breeding, from the kind used by Mendel in the 1800s in his classical genetic experiments, through to modern methods of GM. Over the past 80 years or so, there has been an evolution of breeding methods and it is helpful, when thinking about the pros and cons of GM, to see it in the context of this continuum.

Transfer of genes by pollination

Crops have been domesticated and improved over many thousands of years. Scientific plant breeding began about a century ago and relied principally on moving genes into crops by pollination. This is still the main method of moving genes into crops, even today. If, for example, a breeder wishes to introduce resistance to a disease into a wheat variety, he usually looks for wild wheat lines carrying resistance to that disease. He takes pollen from the wild wheat and transfers it to the cultivated wheat. The progeny, or offspring, from that hybridisation are tested and the plants carrying both the disease resistance and good wheat characteristics are selected and the rest are discarded. In many respects, the skill of plant breeding is in knowing what to discard, as much as what to retain. Because many thousands of breeding lines can result from this kind of hybridisation, it is necessary to discard the majority of them.

Embryo culture moving genes across sexual barriers

It is sometimes difficult to find the appropriate disease resistance (or whatever plant character) in close relatives of the crop, so it is necessary to select more distantly related plants, from different species or genera, to hybridise with the crop. As these plants are sometimes relatives of the crop, they are unable to hybridise. In response to this problem, plant breeders have developed laboratory embryo culture methods to rescue hybrid embryos that would otherwise not survive in nature. The use of embryo culture has been a significant development, because it made possible the transfer of genes across sexual barriers that may have taken thousands of years to evolve.

Inducing mutation in seeds

The next significant development was mutation breeding. In its simplest form this involves exposing a few million seeds to chemicals or radiation, thus inducing random genetic changes. In doing this, the plant breeder has no control over the nature of the genetic change caused: genes can be inactivated (point mutation), segments of chromosomes can be lost (deletion), can change orientation (inversion) or move to new chromosomal locations (translocation). As a result, fundamental and random genetic changes are possible, and frequently common. It has been important, therefore, to develop careful testing of mutagenised plants and, to develop the skills to assess and eliminate the majority of plant lines that have undesirable genetic changes. Only the plants that have desirable changes are retained. Interestingly, much of what we buy in the supermarket, particularly cereals, have had induced mutation somewhere in their plant breeding pedigree.

Mutation in cell cultures and in vitro selection

Another significant development also involves mutation breeding, but cell cultures are used as the material in which to induce mutations instead of seeds. The attraction of this approach is that very large numbers of plant cells can be grown like “vegetable soup” in a culture flask in the laboratory. Mutations can be induced in cell cultures (or allowed to happen spontaneously), in a similar way to those in the seeds described earlier. But the novel feature of this method is that selection for particular plant characters can be carried out separately *in*

in vitro or in the culture vessel. For example, with the introduction of a herbicide into cell cultures it has sometimes been possible to select extremely rare mutations that make cells tolerant to the particular herbicide. The selected cells are then grown independently and plants regenerated from them. In some cases the regenerated plants are tolerant to the herbicide and have been used for the production of a herbicide tolerant crop variety for commercial use in agriculture.

Genetic modification

The most significant development during the last 20 years has been the ability to isolate DNA and genes from any class of organism, and the development of methods to introduce these genes into crop plants. It is currently most usual to insert one to three genes into a crop plant. The position of gene insertion on the chromosomes is random, or close to random, and there is variation in the way in which the introduced genes work. It is usual, therefore, to make one hundred or more transgenic plants, and as with conventional breeding these are tested and the majority discarded. The plant breeder selects only those plants that have the introduced genes working in the desired way.

Concerns about genetic modification

Various concerns have been expressed about GM plant breeding, and three of them that can also be concerns in conventional breeding will be considered here. These are the introduction of toxins, the production of superweeds and the production of novel kinds of plants.

Introduction of toxins

Toxins can also be a serious risk in conventional plant breeding because sometimes it is necessary to hybridise crops with wild relatives that contain toxins. For example, the wild potato has frequently been hybridised with the cultivated potato to introduce disease resistance or other desirable characters. Many wild potatoes, which are relatives of the deadly nightshade plant, contain toxic levels of glycoalkaloids. These wild species are frequently extremely poisonous, so it is vitally important to test the toxin levels of hybrids to eliminate those that have poisonous properties. But people often ask "Aren't poisons from bacteria innately more dangerous than those from other plants?" Deadly nightshade-type poisons, for example, are no more attractive or natural than any other. We need to eliminate toxins from new plant varieties, whatever their origin.

Production of superweeds

Some wild plants with valuable plant characters for improving crop plants are also serious weeds. The wild oat, one of the most serious international weeds, has been used as a source of mildew resistance for transfer into the oat crop. There is the distinct possibility, therefore, that the weediness trait might be transferred into the oat crop, so hybrids need to be tested carefully so that only those plants with desirable characteristics are maintained.

Production of novel kinds of plants

The fact that the transfer of genes into crops from a bacterium, or a completely unrelated organism, is capable of producing novel kinds of crop plants is, of course, one of the main reasons for the attraction of GM plant breeding. It is fair to say that mutation breeding can also produce quite novel products. When billions of cells are exposed to a herbicide, for example, this applies a selection pressure that is rather different from how the herbicide might act in nature. I believe, therefore, that there is a compelling argument therefore to say that mutation breeding and *in vitro* selection can produce quite novel changes. Considering the unpredictability of mutation breeding, it has served agriculture across the world surprisingly well.

One of the special features of GM plant breeding is that it is able to produce novel kinds of plants. At one end of the spectrum, it provides a more precise method of introducing plant genes from sexually compatible species that could be introduced by conventional plant

breeding. At the other end of the spectrum, it will eventually be possible to introduce several genes responsible for new biosynthetic pathways that are likely to be required for the production of certain oils, plastics or pharmaceuticals. Because of this novelty and lack of familiarity to varying degrees, it is important to have an extra tier of safety assessment, and that there is international harmonisation of safety criteria and standards. This safety assessment, both the science and perceptions, will form the basis of several discussions at this meeting.

Conclusions

- There is a continuum of approaches in conventional and GM plant breeding.
- GM provides the potential for greater precision and less unwanted genetic changes.
- GM makes it possible to introduce novel traits, including those controlled by many genes.
- GM is innately neither good nor bad – the challenge is in how we use it.
- Careful safety assessment is essential and procedures need to be harmonised internationally.
- It is illogical to ask detailed safety and environmental impact questions of GM plant varieties and largely ignore the impact of similar plant varieties from conventional breeding.

References for further reading

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GM PLANTS AND BIODIVERSITY IN AGRICULTURAL AND NATURAL SETTINGS

Klaus Ammann, Botanical Garden, University of Bern, Switzerland

Ecologists are in general rather nervous about GM plants. But genetic modification could also provide a way out of present situation, in which conventional breeding has led to a substantial decrease of genetic diversity of our crops plants. In addition, by using protoplast fusion techniques in conventional breeding sexual barriers between plant species and families have also been overcome, although to a more limited degree than possible with genetic modification. In an ecological perspective we should also be pretty nervous about radiation breeding, with some 20'000 experiments, in order to enforce mutation processes and selection directly in the field. Considering also the fact that we do not know exactly what we have done to the genomes and – with the same scale of risk assessment, we should first perform some long term experiments with such radiation traits in the field and in the food industry. But in reality we have not done so - and there are no incidences known, where this way of 'ecologically incorrect' breeding has caused any damage. It is a fact that these traits are now widespread and virtually all wheat products consumed today for instance are based on such traits. This is a plea for a more balanced look at the potential risks of GM food and crops. Millions of Americans eat GM food over many years now and not even a headache has been related to the presence of new transgenes in the crops.

It is more or less the bad luck of the new and elegant molecule based breeding method that we have now marker genes at hand which can tell us with hitherto unheard precision about what happens out in the field. The example of gene flow through hybridization is a typical case: With the new precision of the marker gene detection through molecular methods we start to realize, what really happens in the field. Up to now nobody cared about hybridization of different traits of oilseed rape: Who cared about traits of oilseed rape with an altered oil chemistry which could outcross to normal traits ? The new awareness stems from the high precision of the new molecular detection methods – and to lay people it almost looks as if pollen grains learned to fly with genetic engineering. But the fact is, that in agriculture farmers and professional breeders have learned how to keep the traits clean a long time ago. Still, there is new concern about gene flow – and we will have to take care of it, but we should always keep in mind the baseline.

To assess the hybridisation potential between GM plants to weedy and wild relatives so-called Botanical Files have been developed for The Netherlands and Switzerland. For Switzerland the Botanical Files indicate that (GM) oilseed rape and *B. campestris* do not come together, but (GM) oilseed rape and turnip do, whilst radish does not pose any problems. The Swiss Botanical Files also reveal that *Latuca serriola* is to be considered as an invasive species in Switzerland – it is a close relative of our salad and could easily give away its genes or receive some from cultars. Further, because of the high potential for hybridisation with wild relatives, the Swiss Botanical Files suggest not to release GM traits based on wild and interbreeding grass species in Switzerland. What we learn from this is that we need to assess the risk of unwelcome hybridization case by case and region by region.

On the other hand, GM plants do not necessarily turn into superweeds. The ten-year experiments by Crawley and his team, which have recently been published in Nature (February 2001), have shown that genetically modified herbicide or insect-resistant oilseed rape, maize, beet or potato survive less well in the environment than their conventional counterparts and were extinct within four years.

Further risks of different agricultural systems must be balanced against their benefits. The use of antibiotic resistance marker genes in GM plants is certainly much less risky than applying animal manure full of antibiotic-resistant *E. coli* bacteria as fertiliser in organic farming. In addition, there are several studies demonstrating that the Roundup Ready soybean system does contribute to sustainability in contrast to what some environmental organisations are suggesting. But there is also a very good Swiss study that took 21 years, which indicates that in fields with organic agriculture biomass production and the density of earth worms are much

higher than in conventional fields. As a whole, it can be said that biotech-agriculture and organic farming have both their visionary sides and need to learn from each other.

There has been a lot of controversy about the fate of beneficial or non-target insects in modern agriculture. It is certainly true that pesticides have a considerable impact. As for the transgenic pest-resistant crops the situation is more complex: The example of the Bt crops which have received a transgene from a soil bacterium called *Bacillus thuringiensis* do not only kill the pest insects but also some non-target species. In the laboratory some of those non-target insects suffer considerably, if forced fed with pollen from Bt crops. But it is not easy to adequately interpret laboratory findings with a view to the situation in the field. So, laboratory studies, in which Bt-pollen has been smeared on milkweed leaves in order to force feed larvae of the beautiful and popular monarch butterfly, are not meaningful when field data show that deposition numbers of Bt-pollen grains on milkweed plants are very low. In addition, Novartis (now Syngenta) has semi-quantitatively studied the impacts of Bt-maize versus chemically sprayed maize on 200 beneficial species. These studies demonstrated no statistically significant differences of the populations.

Finally, it is vital to reorganise current flows of scientific data and information on risks and benefits of GMO-based and other approaches. For that purpose Bio-Scope, an international website including an information database <http://www.bio-scope.com/index_e.htm> and also a new Journal 'Environmental biosafety Research', will soon be launched. <<http://www.elsevier.fr/html/detrevue.cfm?code=EV0>>. The author is also running an electronic information network 'Debate', to which everybody can apply through klaus.ammann@ips.unibe.ch.

Bert Uijtewaal, Aventis CropScience, Regulatory Affairs

Commitment to realise the benefits of GM-crops in a safe and sustainable manner

Agricultural food production has been a human activity for centuries, with direct impacts on the environment. A balanced utilisation of space combined with optimal yield and the least possible environmental interference is a necessity.

Recently the cultivation in Europe of genetically engineered agricultural crops has triggered a number of questions from farmers who are going to cultivate these crops, the downstream industry what is going to process the harvested crops and the consumers who are going to consume the end products derived from these crops.

The potential risks involved with intensive agriculture are not dramatically different for GMOs than for traditionally bred crops. The introgression of traits from the crop into the wild flora, the effect of large scale agricultural productions on biodiversity and the occurrence of volunteers in succeeding crops are general concerns. These are linked to the agricultural practice of today, driven by the need to increase the yield per square meter of farmland. On the one hand there is an increasing pressure on the farm community to give up land for urbanisation and nature preservation, while on the other hand, due to population growth, the demands for increasing yields continue. With the introduction of the GM-technology a method is offered for increasing and assuring yield, even with the possible reduction of inputs (e.g. fertilisers / pesticides). This fits perfectly with integrated crop management systems that are the goal of agricultural industry. Best farming practices adapted to the new products show the new GM-derived varieties can offer enhanced production and support long-term sustainable use.

It is Aventis' objective to develop and market products that are safe and can be used in an environmentally sound manner. Product stewardship is a business responsibility that extends beyond requirements mandated by regulatory and compliance issues. This is a permanently evolving system according to the reality of the market. Product stewardship includes initiatives targeted at strengthening communications with customers to assure the safe and sustainable use of GM-crops.

The fate of the product in the environment is evaluated through the monitoring of large-scale field releases. The quality and conformity of the product is ensured through a comprehensive quality assurance programme. This initiative assures that the product meets high standards for purity, stability and quality.

Monitoring, which is a central part of the integrated Stewardship effort, which already starts during the first steps of the event selection and continues during the large-scale releases. Based on the benefit/risk assessment a specific benefit/risk management approach is defined. The monitoring effort should be directed to the question whether this approach should be updated or not and is as such creating a continuum.

Product Stewardship includes the development of good agricultural practices both as a basis of, and in response to, monitoring. Monitoring and the development of guidance documents for farmers thereby become an ongoing interactive and evolutionary process, allowing the gradual, fine-tuned and safe introduction of our products into the environment.

The main objective of the product stewardship plan is to increase understanding of the appropriate management of the GM-products by their users and to improve public awareness and acceptance. Recognising different levels in the discussion, it is important to manage benefits and risks in order to convince the regulatory authorities (Trait/Crop/Event), the farmer (Variety/Seed) and the different entities in the chain (Commodity/Derived products).

SEGREGATION OF GM SEED AND NON-GM SEED

Sofia Ben Tahar, Limagrain Seeds International, France

Organisation of the Chain Quality Assurance System

Limagrain's objectives of the maize Chain Quality Assurance (QA) system are:

- To control the whole Limagrain maize chain from breeding to processing, for GM as well as for non-GM production.
- To give confidence to authorities and customers with a quality assurance (QA) system covering the whole chain.

The maize QA system is based on the following principles:

- Setting up minimal rules to guarantee a non-GM maize chain and a chain with GM maize varieties that have been fully approved by regulatory authorities.
- Leaning on what already exists at several of Limagrain's sites.
- Assuring effective co-ordination between different Limagrain's sites.

The following documents are essential in the maize QA system:

- The Chain Quality Assurance Manual, in which Limagrain's management declares its commitment, and which describes the architecture and functioning of the QA system and refers to the QA system's other documents, and which can also be used as a commercial tool towards Limagrain's customers.
- The Common Quality Plan puts together general rules like documentation control, auditing and training for Limagrain's different divisions and services such as Agro-Production and Agro-Industry Service.
- The Chain Quality Plans, which are specific to a maize variety, an activity and geographical area, and which prescribe the rules to be applied on each, specific site, i.e. breeding, seed production, marketing and sales, grain production, drying and storage, transformation and Research & Development.
- The Sites' Documents, in which the rules of the Chain Quality Plan and the Common Quality Plan are transcribed in conjunction with the specific organisation of a site. The Sites' Documents consist of several operational and registration procedures and are written by the Chain Quality Correspondents and the Operators of each site.

The following actors have essential roles to ensure a good performance of the maize QA system:

- The Management, which defines and sets up the quality assurance policy and warrants its implementation (outside the Group).
- The Quality Assurance Department, which conceives, writes and manages the QA system's documentation, and which co-ordinates, supports, consults, provides training and conducts audits.
- The Chain Quality Correspondents, who define and elaborate the QA system's documentation, prescribe the rules for the organisation of the sites, and write and manage the Sites' Documents.
- The Operators, who participate in writing the Sites' Documents and who practically implement the measures.

The activities of these actors are co-ordinated by a Co-ordination Committee with the following objectives:

- Co-ordination of the actions concerning QA in the maize chain.
- Organisation of internal audits and management reviews.

- Implementation of corrective measures.
- Development of communication support.
- Monitoring of development of molecular tools.
- Provision of support to the crisis management committee.

Management reviews take place regularly, so as to ensure that the integrated Chain QA system remains efficient and coherent with the defined quality policy as well as to ensure the continuous improvement of the QA system and customer satisfaction.

The Biotech Database

The Biotech Database of Limagrain is subdivided into a Technical Database that contains three sections – technical data, references and a forum discussion, and a Commercial Database that contains four sections – biotech information, information on competitors and regulatory information and a forum discussion.

The TechCom consists of representatives of the Quality Assurance Department and the marketing units for seeds and for ingredients and meets to find ways to valorise QA procedures towards Limgrain's customers. To achieve that aim TechCom assesses the campaign's situation, prepares the next commercial campaign, meets customers' expectations by preparing sales brochures and communication tools, and anticipates potential crisis situations in order to be ready to face them.

GMO Detection

Services of the firm Agrogene to Limagrain entail providing technical support and molecular tools to the operators of the different sites through the QA Department and assuring technical surveys on GMO market approval and on the development of GMO detection methods and their ring testing at the international level. The molecular analyses should detect adventitious contamination, so as to guarantee production of non-GM seeds and ingredients. Maize and oilseed rape are the crop species that are being analysed by either qualitative or quantitative PCR and TaqMan technology, for which the 35S CaMV promoter and the nos terminator are the targets in the maize QA system. The protocols are in accordance with French standards.

Limagrain has chosen to work with Agrogene because the firm is reliable, performs both qualitative and quantitative analyses, is specialised in plants, participates in the elaboration of French and European standards for GMO detection methods, has internal R&D, participates in European and international ring tests, own licenses that assure the legality of Limagrain's analyses, owns a civil liability insurance in case of litigation and is a subsidiary of Celera AgGen PE Corp., world-wide leader in GMO detection.

OVERVIEW OF BIOSAFETY RESEARCH ON ECOLOGICAL ASPECTS OF GENETICALLY MODIFIED PLANTS

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The number of field releases of genetically modified plants (GMPs) has followed an exponential trajectory. At the same time, the rate of ecological assessment of these products can hardly be expected to match their rate of release. One reason is the time-intensive nature of ecological experiments. I summarise and assess the current status and future prospects of ecological approaches in plant biosafety research.

First, five appropriate components of biosafety research are explained that include:

1. characteristics of the target plant species and his crossable relatives,
2. phenotypic characteristics of the transgenic plant,
3. covered plant generation time of the examination,
4. number or demography of habitats examined, and
5. range of scientific questions addressed in the study.

Second, six different types of biosafety research are identified based on

1. GMPs examined,
2. scientific methods used, and
3. degree of matching of the above mentioned appropriate components.

It should not be expected that any one of recent studies is able to address all of the appropriate components suggested, but the strengths of 96 representative studies (summarised in 66 groups) as well as their weaknesses is pointed out.

The results of a literature analysis based on the five different components of biosafety research and six different types are summarised in Table 1.

Third, an outlook on the future of biosafety research in the post-commercialization era: gene flow alone should be not regarded as an adverse environmental effect of transgenic plants. Because biosafety research is a time and resource-intensive process, we will have to concentrate on thoughtful and thorough experiments and target the ecologically "riskier" organisms.

Outlook: Environmental risks and benefits

The Biological Diversity Convention (<http://www.biodiv.org/>) in some chapters targets potentially adverse effects of transgenic plants. In conclusion, every introduction of transgenic plants should be weighted carefully against the benefits case-by-case and step-by-step. Productivity increase by crop improvement in combination with sustainable agriculture is the task of the future. Given the speed, with which the development of GM-plants is occurring, the future of ecological research will rest not just on risk assessment based on data collected from the examination of non-GM-plants. We need more valuable data on the ecological performance of a given GM-plant. There should be an expanded experimental evaluation of genetically modified organisms for studying the ecological behaviour of both the crop and wild plant hybrids under field conditions. Transgenic plants are considered more risky if they contain a trait that confers a large fitness advantage in natural situations such as pathogen resistance, herbivore resistance, and abiotic stress tolerance (e.g. salt or freeze resistance). Because biosafety research is a resource-intensive process, we will have to concentrate on appropriate experiments and target the ecologically "riskier" organisms. The types of biosafety studies applied to this future goal can be either non-risky 'model' organisms (e.g. *Arabidopsis*) or the risky organisms themselves in a step-by-step fashion, but first under substantial confinement.

TABLE 1. Types of biosafety research approaches for estimating the ecological effects of genetically modified plants. Appropriate components (a-e) are explained in the text

Type	Study authors	Appropriate component s of biosafety study:				(a)								(b)				(c)	(d)	(e)				
		OR	SB	CO	o.	Mk	HR	VR	IR	FR	CT	BI	(year/s)	Habitats	GF	HP	EA	CO	FI	NT				
A. Without use of GEPs																								
A.1 Herbarium and literature studies																								
	Ammann et al. (1997), Guadagnuolo et al. (1998)	X	X	X	X	-	-	-	-	-	-	-	>100	CH	X	-	-	-	-	-				
	Bartsch et al. (1993)	X	X	X	X	-	-	-	-	-	-	-	>100	DE	X	-	-	-	X	-				
	De Vries et al. (1992)	X	X	X	X	-	-	-	-	-	-	-	>100	NL	X	-	-	-	-	-				
	Ellstrand & Schierenbeck (2000)	X	X	-	X	-	-	-	-	-	-	-	>100	World	X	-	-	-	X	-				
	Elven et al. (1991), Nurminiemi and Rognli (1993)	X	X	X	X	-	-	-	-	-	-	-	>100	NO	X	-	-	-	-	-				
	Kowarik (1993)	-	-	-	X	-	-	-	-	-	-	-	>100	DE	X	-	-	-	X	Spread of woody plants				
	Raybould and Gray (1993)	X	X	X	X	-	-	-	-	-	-	-	>100	UK	X	-	-	-	-	-				
	Sukopp and Sukopp (1993)	X	X	X	X	-	-	-	-	-	-	-	>100	DE	X	-	-	-	-	-				
	Treu and Emberlain (2000)	X	X	X	X	-	-	-	-	-	-	-	> 50	World	X	-	-	-	-	-				
	Williamson (1993)	X	X	X	X	-	-	-	-	-	-	-	>100	Europe	X	-	-	-	-	-				
A.2 Pest management experience studies																								
	Alstad&Andow (1995, 1996), Ives (1996), Siegfried (2000)	-	-	X	X	-	-	-	X	-	-	-	> 50	US	-	-	-	-	-	Pest Resistance Management				
	Glare and O'Callaghan (2000)	-	-	X	X	-	-	-	X	-	-	-	>100	World	-	-	-	-	-	Safety of Bt toxins				
	Hokkanen and Wearing (1995)	X	-	-	-	-	-	-	X	-	-	-	> 50	Europe	-	-	-	-	-	Pest Resistance Management				
	Huang et al. (1999)	-	-	X	X	-	-	-	X	-	-	-	> 2	US	-	-	-	-	-	Pest Resistance Management				
	UCS (1998)	-	-	X	X	-	-	-	X	-	-	-	> 50	US	-	-	-	-	-	Pest Resistance Management				
A.3 Population analysis and plant experiments																								
	Adler et al. 1993	X	-	-	-	-	-	-	-	-	-	-	2	1	-	-	-	-	X	Weed Dormancy				
	Arriola and Ellstrand (1996, 1997)	-	-	-	X	-	X	-	-	-	-	-	3	1	X	X	-	-	X	Resis. Weeds				
	Bartsch & Schmidt/Brand (1997, 1998), Mucher et al (2000)	-	X	-	-	-	-	X	-	-	-	-	3	>5	X	-	X	-	-	Weed Evolution				
	Boudry et al. (1993)	-	X	-	-	-	X	-	-	-	-	-	2	3	X	-	-	-	-	Resis. Weeds				
	Giddings et al. (1997a,b)	-	-	-	X	-	-	-	-	-	-	-	1	1	X	-	-	-	-	-				
	Jrgensen et al. (1996), Landbo and Jrgensen (1997)	X	-	-	X	-	X	-	-	-	-	-	2	1	X	-	-	-	-	Resis. Weeds				
	Klinger et al. (1991, 1992), Klinger and Ellstrand (1994)	-	-	-	X	-	X	-	-	-	-	-	4	2	X	X	-	-	-	Resis. Weeds				
	Linder et al. (1998)	-	-	-	X	-	-	-	-	-	-	-	>10	3	X	-	-	-	-	-				
	Raybould et al. (1998, 2000), Wilkinson et al. (2000)	X	-	-	X	-	-	X	X	X	-	-	5	>5	X	X	X	-	X	Large scale monitoring				
B. With use of GEPs																								
B.1 Indirect crop effect experiments																								
	Donegan et al. (1996)	-	-	-	X	-	-	-	X	-	-	-	1	1	-	-	-	-	-	MO Community				
	Firbank and Forcella (2000)	X	X	-	-	-	X	-	-	-	-	-	3	>3	X	-	-	-	-	Biodiversity impact				
	Hilbeck et al. (1998 a,b)	-	-	X	-	-	-	-	X	-	-	-	1	Laborat.	-	-	-	-	-	Beneficial Insects				
	Losey et al. (1999)	-	-	X	-	-	-	-	X	-	-	-	1	Laborat.	-	-	-	-	-	Non-Target Butterflies				
	Malone et al. (1995), Malone (1998)	-	-	-	X	-	-	-	X	-	-	-	2	Laborat.	-	-	-	-	-	Beneficial Insects				
	Picard-Nizou and Pham-Delegue (1995)	X	-	-	-	-	-	-	-	X	-	-	1	Laborat.	-	-	-	-	-	Beneficial Insects				
	Raps et al. (2001)	-	-	X	-	-	-	-	X	-	-	-	1	Laborat.	-	-	-	-	-	Beneficial Insects				
	Schuler et al. (1998)	X	-	-	-	-	-	-	X	-	-	-	1	Laborat.	-	-	-	-	-	Beneficial Insects				
	Sears and Stanley-Horn (2000)	-	-	X	-	-	-	-	X	-	-	-	1	2	X	-	-	-	-	Non-Target Butterflies				
	Wraight et al. (2000)	-	-	X	-	-	-	-	X	-	-	-	1	1	-	-	-	-	-	Non-Target Butterflies				

TABLE 1. Types of biosafety research approaches for estimating the ecological effects of genetically modified plants (continued)

Type	Study authors	Appropriate components of biosafety study:				(a)							(c)	(d)	(e)					
		OR	SB	CO	o.	Mk	HR	VR	IR	FR	CT	BI	(year/s)	Habitats	GF	HP	EA	CO	FI	NT
B.2 Direct crop performance experiments																				
	Baranger et al. 1995, Chèvre et al. (1997)	X	-	-	-	-	X	-	-	-	-	-	4	1	X	-	-	-	-	-
	Bartsch et al. (1994), Seaglitz et al. (2000)	-	X	-	-	X	X	X	-	-	-	-	1	2	X	-	X	X	-	-
	Bergelson (1994, 1998), Bergelson et al. (1998)	-	-	-	X	X	X	-	-	-	-	-	5	1	X	-	-	-	X	Outcrossing rate
	Bing et al. (1996a,b)	X	-	-	-	-	X	-	-	-	-	-	3	1	X	-	-	-	-	-
	BRIDGE (1991, 1993)	X	X	-	-	X	X	-	-	-	-	-	3	3	X	-	-	X	-	-
	Conner (1994a,b)	-	-	-	X	X	X	-	-	-	-	-	3	1	X	-	-	-	X	Food Toxicity
	Crawley et al. (1993, 2001), Brown (1998)	X	X	-	-	X	X	-	-	-	-	-	10	12	-	-	-	X	X	-
	Devaux et al. (1995)	-	-	-	X	-	-	-	-	-	X	-	1	1	-	-	X	-	X	-
	Dietz-Pfeilstetter and Kirchner (1999)	-	X	-	-	X	X	X	-	-	-	-	3	2	X	-	-	-	-	Gene expression
	Eijlander et al. (1993)	-	-	-	X	X	-	-	-	-	-	-	3	1	X	-	-	-	-	-
	Fredshavn and Poulsen (1995)	X	-	-	-	X	X	-	-	-	-	-	3	3	-	-	-	X	X	-
	Hokanson et al. (1997)	-	-	-	X	X	-	-	-	-	-	-	1	1	X	-	-	-	-	-
	Llewellyn and Fitt (1996)	-	-	-	X	-	-	-	X	-	-	-	1	1	X	-	-	-	-	-
	Madsen (1994)	-	X	-	-	-	-	X	-	-	-	-	3	2	X	-	-	X	X	-
	McPartlan and Dale (1994)	-	-	-	X	X	X	-	-	-	-	-	1	1	X	-	-	-	-	-
	Metz et al. (1997)	X	-	-	-	X	X	-	-	-	-	-	3	1	X	-	-	-	-	-
	Morris et al. (1994)	X	-	-	-	X	-	-	-	-	-	-	1	1	X	-	-	-	-	-
	Parker and Kareiva (1996), USDA (1994a,b)	X	-	-	-	-	-	-	-	-	-	X	2	2	-	-	?	X	X	-
	Paul and Thompson (1995), Thompson et al. (1999)	X	-	-	-	X	-	-	-	-	-	-	5	>10	X	-	-	-	-	-
	Reboud et al. (1999), Champolivier et al. (1999)	X	X	X	-	X	X	-	X	-	-	-	3	3	X	-	X	-	X	Weed Persistence
B.3 Outcrossed hybrid performance experiments																				
	Bartsch et al. (1999, 2000, 2001), Pohl-Orf et al. 2001	-	X	-	-	X	X	X	-	-	-	-	7	4	X	X	X	X	-	Wild beet diversity
	Brown et al. (1996a,b)	X	-	-	-	-	X	-	-	-	-	-	2	1	X	X	-	X	X	-
	Downey (1999)	X	-	-	-	-	X	-	-	-	-	-	4	>10	X	X	X	-	X	Large scale practice
	Fuchs and Gonzalves (1997, 1999)	-	-	-	X	X	-	X	-	-	-	-	5	2	X	X	X	X	X	-
	Linder and Schmitt (1995)	X	-	-	-	-	-	-	-	-	X	-	3	2	X	X	-	-	-	Seed dormancy
	Mikkelsen et al. (1996)	X	-	-	-	-	X	-	-	-	-	-	2	1	X	-	-	-	-	Weed Persistence
	Stewart et al. (1997), Stewart and Neal (1998)	X	-	-	-	-	-	-	X	-	-	-	3	1	X	X	X	-	X	-

Abbreviations: OR = Oilseedrape, SB = sugar beet, CO = corn/maize, o. = other, Mk = Markergene, HR = Herbicide resistance, VR = Virus resistance, IR = Insect resistance, FR = fungus resistance, CT = Cold tolerance, BI = Biochemical ingredient change, CH = Switzerland, NL = The Netherlands, NO = Norway, UK = United Kingdom, DE = Germany, US = United States of America, GF = Gene flow to wild relatives, HP = Hybrid performance of outcrossings, EA = Ecological advantage present in the experiment, CO = Competitiveness measured, FI = Fitness measured, NT = Non-target effects measured

DATA REQUIREMENTS FOR FIELD TRIALS WITH GM PLANTS IN THE NETHERLANDS

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Legal procedures

In The Netherlands field trials with GM plants are forbidden, unless a permit has been obtained from the Minister of Environment, the Competent Authority (CA). An application for a permit must be submitted to the Minister of Environment and must be accompanied by a risk analysis. The CA may seek advice from the Committee on Genetic Modification (COGEM). After having consulted other relevant ministries the CA shall publish the draft decision in the Government Gazette and two national daily newspapers. During a period of four weeks objections to the draft decision can be made (first round of public participation). After this period the CA gives a decision as soon as possible. The decision is sent to the applicant, COGEM and those who brought objections in the first round. The decision is announced again in the Government Gazette and two national daily newspapers. During six weeks all participants of the first round can appeal to the Council of State (second round of public participation). After this period the applicant may use the permit, unless appellants request the Council of State to suspend the permit until a final verdict on the appeal has been reached.

In August 1999 Greenpeace submitted objections against six draft permits:

1. Glyphosate-resistant GM sugar beet
2. Gluphosinate-resistant GM sugar beet
3. Fungi-resistant GM oilseed rape
4. GM oilseed rape with altered carbohydrate metabolism
5. GM oilseed rape with altered architecture
6. Sulfonylurea-resistant GM oilseed rape

In July 2000 the CA published its decision and issued six permits, against which Greenpeace appealed to the Council of State in August 2000. Greenpeace also requested the suspension of the six permits. In October 2000 the Council of State held a hearing on this request. In November 2000 the decision was made to suspend all six permits. The considerations of Council of State were

1. Potential for damage to ecology and to farmers; no detailed data on precise locations for field trials.
2. Legal requirements for risk analysis.
3. Field trials may have irreversible, adverse impacts on environment and permit holder indicated at hearing that the field trials could also be conducted somewhere else (abroad).

It is now not clear when the Council of State will treat the appeal.

Data on host plant

Sugar beet: No detailed data about subspecies, cultivars or lines, and therefore no information about level of ploidy and pseudo-incompatibility. *Comment*: Level of ploidy and pseudo-incompatibility are factors influencing the risk of introgression of transgenes from GM sugar beet plants to cultivated, weedy and wild relatives in the surroundings of the trial locations.

Oilseed rape: No detailed data about subspecies, cultivars or lines and their fertility. *Comment*: These data would be required for a more accurate assessment of the risk of introgression of transgenes from GM oilseed rape plants to weedy and wild relatives in the surroundings of the trial locations.

Data on genetic modification

Sugar beet and oilseed rape: No detailed data on location(s) of genome where vector and T-DNA integrated, number of copies integrated, integration of left- and right borders of T-DNA,

stability of transgene expression, genetic stability of host plants and GM plants. *Comment:* These data are required to assess the risk of changed genetic and phenotypic stability of the GM plant compared to its host plant, as this may to pleiotropic effects. GM sugar beet: undesirable increase of saponine, a potentially toxic compound, and an increased frost tolerance of the GM beet compared to its host. GM oilseed rape: undesirable increases of erucic acid and glucosinates, influencing tolerance to biotic stress compared to its host, and increase of potential for survival and invasiveness through altered composition of carbohydrates and fatty acids of GM oilseed rape seeds compared to those of the host. GM oilseed rape: data on the location(s) of the insertion(s) into the genome is relevant, as for plants of the Brassica species, this location is a relevant factor in the risk of introgression of transgenes from GM oilseed rape plants to weedy and wild relatives in the surroundings of the trial locations.

Data on GM plant

GM sugar beet: Reference to 37 permits for field trials with several GM sugar beet plants in The Netherlands, France, Belgium, UK and Chile. Except intended effects no differences compared to host have been observed. No methodology of observation and no empirical data resulting from observations were provided. The DNA introduced is present stable in the GM sugar beet plants. No (statistical) data on Mendelian inheritance and possible deviations provided. No data on genome stability of GM sugar beet plant compared to that of host plant. No empirical data on (increased) potential for survival and invasiveness of GM sugar beet compared to that of host plant (in the absence of selection pressure by glufosinate or glyphosate). *Comment:* In July 1999 the Minister of Environment in Parliament indicated that from that moment on in The Netherlands data would be required as if Directive 90/220 had already been revised in line with the European ministerial proposal of July 1999.

Risk analysis of GP1020, GP1080, EPSPS, BAR and PAT

GP1020, GP1080 and EPSPS confer resistance or tolerance against glyphosate. Details about the donor-organisms are confidential. BAR and PAT confer resistance against glufosinate. Selection markers: hygromycin-R and (prokaryotic) kanR, ampR, tetR and spc/stre (plus 'origin of replication' Ori Col E1). All these transgenes do not confer GM sugar beet plants a selective advantage in the environment, so their potential for survival and invasiveness would not be enhanced compared to host plants. This analysis has also been based on (not further specified) information from earlier field trials with GM soy, GM cotton and GM sugar beet containing one of the transgenes. In case of (animal) consumption trials these transgenes would have no toxic or allergenic effects. *Comment:* Field experiments with glufosinate-resistant GM oilseed rape suggest that without selection pressure this GM crop had no increased potential for survival and invasiveness compared to that of its conventional counterpart. But such experiments have not been conducted with the GM crops applied. And it is difficult to predict invasiveness. Only in the case of EPSPS (protein) and PAT (protein) data on potential toxic and allergenic effects are available from other cases and literature. No data were provided on the potential toxicity of metabolites of the herbicides that will be applied in growing the GM crop. This information is relevant to assess the risk of (animal) consumption trials.

Risk analysis of GM sugar beet plants

Outcrossing from GM sugar beet to cultivated, weed and sea beet may in principle occur. Therefore the field trials should have an isolation distance of 1.000 meters as foreseen in beet seed production. *Comment:* Isolation distances in seed production are to minimise incrossing and therefore allow contamination of three percent in the case of sugar beet seed. Some authors suggest that an isolation distance of at least 3.200 meters would be needed in sugar beet seed production. The Dutch Botanical Files suggest a local, small ecological effect on Dutch wild flora from releases of GM (sugar) beet plants, i.e. potential for introgression and establishment of transgene(s) into gene pool of *Beta*. Monitoring is limited to monthly 'visual' observations. 10 scaled-up field trials with glufosinate-resistant GM sugar beet take place in the same regions as 10 scale-up field trials with glyphosate-resistant GM sugar beet. Due to

case-by-case approach, no attention for potential synergy between these field trials leading to multiple herbicide-resistant volunteers and weedy beets.

Risk analysis of FUR1, FUR2, CAHY1, CAHY2 and PHYA

Fur1 and fur2 confer resistance to biotic stress like certain fungal diseases. Indirectly this would contribute to improved feed quality. Data on donor-organism of fur1 and fur2 are kept confidential. Outcrossing of fur1 and fur2 from GM oilseed rape to weedy and wild relatives would confer only a limited selective advantage, as distribution of fungal diseases is not determining the distribution of *Brassica napus* in The Netherlands. CaHy1 and CaHy2 have, through altering the carbohydrate metabolism, specific (confidential) effects as well as impacts on feed quality and on tolerance to cold and drought. Donor-organisms and vector are kept confidential. Data of donor-organisms of tissue-specific promoters Pseed and Pgreen are also kept confidential. High levels of Phytochrome A lead to dwarf growth and retardation of shadow avoidance. This would make GM oilseed rape more competitive on the field. Outcrossing of PhyA to weedy and wild relatives would however make recipient plants less fit. Selection marker: hygromycineR. It is not possible to conduct a full analysis of the impacts of fur1, fur2, CaHy1, CaHy2 and PhyA on the fitness of GM oilseed rape as well as of potential effects from outcrossing. The field trials have the objective of obtaining more information on fitness effects. But permits require containment so as to prevent outcrossing. *Comment:* Many key data are kept confidential and ill-defined usage of concept of 'fitness'. Monitoring limited to monthly 'visual' observations. No empirical data on (increased) potential for survival and invasiveness of GM oilseed rape compared to that of the host. No empirical data to confirm whether distribution of fungal diseases does not limit distribution of *B. napus* in The Netherlands.

Risk analysis of GM oilseed rape

Outcrossing of transgenes fur1, fur2, CaHy1, CaHy2 and PhyA from GM oilseed rape to cultivated, weedy and wild relatives is possible in principle. An isolation distance of 400 metres is therefore required, that is twofold the isolation distance required for the (pre)basis oilseed rape seed production. Removal of related plants in the isolation zone after flowering of GM oilseed rape is required, before the flowers of these related plants have stopped flowering. *Comment:* The Dutch Botanical Files suggest a local, small ecological effect on Dutch wild flora from releases of GM oilseed rape plants, i.e. potential for introgression and establishment of transgene(s) into gene pool of *Brassica*. In particular, as fur1, fur2, CaHy1 and CaHy2 may confer a (limited) selective advantage to recipient related plants. Isolation distance in seed production are to minimise incrossing and therefore allow contamination of a two percent in the case of (pre)basis oilseed rape seed. Regional transgene flow resulting from (scaled-up) GM oilseed rape trials may occur over distances of hundreds to thousands of metres. Criterion of 'flower that stopped flowering' cannot be enforced.

Conclusions

Incomplete data sets. In some cases key data relevant for risk analysis are kept confidential. Incomplete risk analysis by applicant and competent authority. Various areas of scientific ignorance and uncertainty have been identified. Potential for introgression and establishment of transgenes in weedy and wild flora, i.e. *transgenetic* contamination of gene pools of *Beta*, respectively *Brassica* cannot be excluded (despite required physical containment measures). Against this background invocation of precautionary principle should lead to destruction of the six permits by Council of State.

REVIEW OF STUDIES ON Bt-PLANTS FOR GREENPEACE AND IDENTIFICATION OF POTENTIAL IMPROVEMENTS OF THEIR ECOLOGICAL ASSESSMENT

Matthias Meier, EcoStrat GmbH, Switzerland

Introduction

The EcoStrat study "Review of non-target organisms and Bt-plants" was commissioned by Greenpeace International in April 2000 and can be downloaded from:

http://www.greenpeaceusa.org/media/press_releases/gmo-report-complete.pdf

Objectives of the study were to review and analyse studies dealing with the ecological safety testing of transgenic Bt-plants and their side effects on non-target organisms. The basis was a compilation of studies put together by Novartis (now Syngenta) plus additional studies dealing with the same issues.

The analysis of the studies identified scientific flaws concerning:

- Experimental method and design.
- Statistics.
- Results.
- Conclusions.

In its comments on each study EcoStrat has justified the identified deficits with science based argumentation. The analysis comprised in total 5 unpublished lab studies for regulatory purposes, 9 published lab studies (some sponsored by industry, some cited for regulatory purposes), and 14 field studies (8 clearly published).

Comments on regulatory studies

- All testing methods were conducted under the 'pesticide paradigm' that has only limited merit to test for ecological implications of transgenic plants.

The test designs used in the 5 regulatory studies were adopted from standardized laboratory test protocols for the ecotoxicological risk assessment of pesticides as they are described in the OECD guidelines for the testing of chemicals. However, because there are fundamental differences between synthetic insecticides and Bt-toxin expressed in transgenic plants these test protocols are insufficient for assessing ecological effects of transgenic insecticidal plants on non-target organisms.

Synthetic insecticides on the one hand have an immediate mode of action and because their half-life period is rather short (few days to few weeks depending on the substance) target and non-target organisms are exposed for only a limited period of time. Recovery of pests and natural enemies is possible.

Insecticidal Bt-toxin expressed in transgenic plants on the other hand acts quite differently:

The toxin is expressed in almost every part of the plant and it is also expressed during the entire life of the plant. Thus, temporal and spatial distribution of the Bt-toxin is extended leading to a different mode of exposure and different routes of exposure. Therefore, the range of potentially affected non-target organisms is also extended.

- Only one chronic, long-term test (also the only one where adverse effects were observed).

Modern synthetic insecticides induce death within seconds or minutes. Therefore, the emphasis in the ecotoxicological safety testing relies on short-term lethal effects. In the case of Bt-toxin the mode of action is different. Even in highly susceptible insects (e.g. European corn borer) Bt induces death after one to two days after ingestion. In less susceptible insects adverse effects are to be expected after long-time exposure only. Therefore, acute toxicity tests are of minor relevance for the ecological safety testing of Bt-toxin

- No multi-trophic testing, only bi-trophic trials using lab-produced Bt-protein or highly processed leaf-protein powder.

Since Bt-toxin expressed in transgenic plants is present and enters into the food chain throughout the entire crop season sublethal and lethal effects on different trophic levels are very likely to occur. Therefore, multi-trophic interactions should be considered in the test design.

- Suitability of all feeding methods used needs to be demonstrated.

In none of the regulatory studies it was verified whether the test organisms had taken up any Bt-toxin. Looking at the experimental set-up of some studies an uptake seems rather unlikely. For example in one study water fleas were put into water mixed with pollen from Bt-corn and non Bt-corn in the control treatment. Water fleas' natural food source consists of algae, bacteria and detritus. All these food groups are of a size of 1 to 5 μm . However, corn pollen has a size of over a 100 μm . Therefore, it is very unlikely that the water fleas in the study ingested any Bt-toxin at all.

Comments on published laboratory studies

Most studies had serious methodological or statistical problems:

- Pollen fed to natural enemy species that does not feed on pollen.

In one study, pollen from transgenic Bt-plants was fed to larvae of the green lacewing. However, green lacewing larvae are predaceous and not known to feed on pollen. The inappropriateness of pollen as food for green lacewing larvae is also reflected in the high control mortality of 51%.

- Coated meal moth eggs given to piercing-sucking predator that only sucks out egg content.

In another study testing for effects on green lacewing larvae, meal moth eggs were dipped into a solution of Bt-toxin coating the eggs with a layer of Bt-toxin on their outer surface. Green lacewing larvae were provided with these eggs as food. However, green lacewing larvae have forceps-like mouthparts. With these mouthparts they pierce into their prey items and suck out the content. When sucking out meal moth eggs coated with Bt-toxin on the outside green lacewing larvae probably do not ingest any Bt-toxin.

- Least sensitive adult stages of natural enemies used.

In some studies tests were carried out using adult stages of natural enemies. However, in order to exclude adverse effects on non-target organisms, tests with natural enemies should always use the most sensitive stage, which usually is the 1st larval stage.

- Only few studies were truly replicated.

In order to verify obtained results, experiments have to be replicated over time at least two better three or four times.

Comments on field studies

- Except for 2 studies, all were carried out for one field season (only acute, intra-seasonal effects detectable).

From field studies carried out for one field season, only limited conclusions can be drawn regarding long-term effects. However, effects of transgenic insecticidal plants on the population level are very likely to manifest itself after several generations. Therefore, field studies should be carried out for several field seasons.

- In 5 studies sampling frequencies for direct visual sampling were 3-4 times per season; in all other 5-10 times.

In order to carry out an analysis of the population dynamics of pests and predators in crops sampling frequencies have to be as high as possible. It is not possible to explore reliably a prey-predator dynamics with only 4 samples per season.

- Except for 2 studies no trophic relationships were investigated but 'menu-plan inventories' were established.

As in laboratory studies, the investigation of multi-trophic relationships will reveal possible negative effects of insecticidal transgenic plants on non-target organisms. Natural enemies and pest species should be analysed jointly for their seasonal population dynamics. Further, the differentiation of life stages is important for the ecological assessment since often only larval stages of natural enemies are predaceous.

- Taxonomic identification levels of these 'menu-plan inventories' were crude

By only listing order or family names of the insects identified in most of the field studies, important ecological information is missed and limits the conclusions regarding risk assessment. For example the order Hymenoptera consists of honey bees, wild bee and bumble bee species. Because of the importance of bees for pollination detailed information is desirable. Insect orders of Diptera or Coleoptera contain both, pests and natural enemies. Detailed information beyond the order level is necessary because of the importance of natural enemies in these orders for biocontrol.

Conclusions from the analysis of the studies

- Data basis for ecological safety testing of transgenic Bt-plants is unsatisfactorily small and with regard to the methods applied often of limited value.
- No long-term and rigorous field trials have been conducted other than the ultimate experiment of 'commercial production' in the US.
- No comprehensive ecological monitoring of 'commercial production' experiment has been undertaken so far.
- Because of the different test designs the different studies are hardly comparable.
- Synthesis and a structural evaluation (e.g. risk analysis) are impossible.

Improvements

- Standard scientific-technical protocols and guidelines allowing the pre-release testing of transgenic plants to ensure their environmental safety and sustainable use. Internationally valid, authoritative, detailed and transparent protocols and guidelines are required.

The global working group "Transgenic Organisms in Integrated Pest Management and Biological Control" (a working group under the umbrella of the "International Organisation of Biological Control (IOBC)") has realized the lack of standard protocols and is about to develop detailed guidelines for the international biosafety testing of transgenic plants (see: Hilbeck et al. Concept Note. In: IOBC Newsletter No. 2. Hilbeck A. & M. S. Meier (eds.). In press.)

- Monitoring programmes have to be developed before large-scale release. Requirements include monitoring of plant characterisation, of biodiversity and non-target impacts, of pest resistance management, of gene flow and consequences, and of indirect effects on human health arising from altered environmental conditions (altered pesticide use, changes land use, etc.).

Standard guidelines as well as monitoring programmes have to be developed in a case-by-case approach to each transgenic cultivar and have to be adjusted consecutively to the newest scientific knowledge.

Perspectives from an environmental organisation

David Azoulay, Friends of the Earth (FoE) France

Introduction

How did France go in two or three years times from being the number one country in terms of number of experimentation and the first European country to give commercial release and marketing consent to being the leading country in the institutional battle for the moratorium? An answer to this question will show what have been the French citizens' concerns about GMOs (citizens, not just environmentalists....). What are the methods used by the promoters of GMOs. And why did they fail?

France was considered as the key country for the acceptance of GMOs by the biotech industry, probably because it is the biggest agriculture country in Western Europe and a big maize grower. The first authorisation was given on January 23rd 1997 to a Novartis Bt maize (Bt 176). As soon as this authorisation was granted, organisations such as FoE, Greenpeace, Ecoropa, Confédération Paysanne (a farmers' group) took legal actions to challenge this authorisation. These actions and their repercussions were made possible by a combination of factors. First, at that time no real debate over GM technology had really started in France. But public concerns on the issue were growing due to (quote of industry representative), "Irrationality of the public and the public relations or marketing strategies of NGOs". This of course does not mention the will of the industry to impose GM technology with as little transparency as possible. Second, the French consumer is quite sensitive about his food, since like other European consumers, French consumers had already burnt his fingers with BSE and contaminated blood. Both were affairs where scientist and politician minimised the risks before facing a huge health scandal a couple of years later. So the very famous "loss of confidence" in experts was already there, and hearing the same scientist and politician saying "Don't worry", "Trust us" and "We know what is good for you" did not help. Especially since the year before, some 150 scientist published a report asking for more studies before any authorisation is granted. The "consensus among scientists" presented by industry funded scientists was not an argument anymore and it made them sound very arrogant.

The European legislation provided that in order to obtain authorisation, a new GMO must have been through a complete evaluation and control of all the new characteristics transferred to the GMO through genetic manipulation. But there was urgency for biotech industries to gain marketing consent without having to do all these tests. Maybe not because they were afraid of the results (that would be even more cynical since it would presume that they knew all about environment, health and social risks attached to the technology) but because the economic objectives were such that delaying further more the marketing of their imperfect GMO would definitely jeopardise profits. A maize variety is only viable on the market for 2 to 5 years; if you have to test it for two or three years before you can market it, your main objective (profit) is not guaranteed anymore (supposing that the results of the experiment allow you to obtain the authorisation). Further, they maintained that none of these testing were compulsory in the US, so they thought they could do the same in Europe, even though the provisions of law were different. So they presented incomplete dossiers. And, because of the composition of the national committee in charge of studying and giving an advice on these authorisation consent consisted of scientists mostly working themselves on biotechnology research programs partly funded by industry, they obtained consent for marketing.

So FoE had growing concerns. More and more public groups were asking for a public debate. It should be stressed that their positions were probably not as radical as they became afterwards. Most organisations were not campaigning against GMO with some exceptions but for the opening of a debate. Hurry of the industry to market their product and arrogance of both industry and industry-funded scientist, who felt they had no time for such a thing as public debate, and profits were waiting. All these combined factors paved the way for the legal action against the authorisation that was given. And the plaintiff gained access to administrative documents proving that none of the risks had been correctly assessed. When

they were made public, it was impossible for the French government, as it would have been for any European government, not to change its position.

The evolution could have been less radical, but many citizens groups became more and more active after this and the debate spread. Citizen mobilisation was the key to this evolution. It is interesting to see how the audience of information rings and publications expanded from specialists only, such as the campaigner, the scientist, etc., to a much broader audience in a couple of years. The citizens actually invited themselves to the debate and made it a public issue. An anthropologist M. Mead from the beginning of the century has said: "Never doubt that a group of thoughtful and committed citizens can change the world. Indeed it is the only thing that ever has".

It is clear that this evolution did not occur in a day. Civil society's pressure grew, and at the same time, independent researchers started to make some points in particular concerning the transfer of genes from GMOs to wild relatives. These points made the French government ready for a change, especially since farmers started to ask for a better monitoring of GMOs. This led to the turning point announced in July 1998 by France's own national moratorium on GM plants with wild relatives, i.e. oilseed rape and beet.

In June 1999, when the European Council of Environment Ministers announced the *de facto* moratorium, France was a key country also because it had some very strong arguments about traceability, labelling, and liability, which were directly inspired by the argumentation of civil society. Such an evolution is not as simple or easy as what it might seem from the outside. If the position now held by France reflects what has always been the environment minister's concern, there must have been dissent among the French government, notably with the other competent authority for GMO regulation, the agriculture minister. What civil society, including some but not all farmers groups, was reversing the balance of powers within the government.

Concerns of FoE

GMOs that have actually been commercialised contain imperfect insertions. We do not know where and how many, and we don't know anything about the interactions of the different genes between themselves. Lack of information and research on the health risks attached to new products. Until now there has been no full nutritional and toxicology evaluation of eating ten years GMOs. Risks of antibiotic resistant marker genes have not been evaluated, or if evaluated, not taken into account.

Environmental risks: Threat to biodiversity, gene transfer to wild relatives with problems it may cause (multi-resistance to herbicides, creation of stronger resisting insects and pests, etc. few. And social risks: increased dependancy of farmers towards a small number of transnational firms, destruction of agricultural and social structures of small farming communities in the south.

Transparency

So far, FoE France has focused on transparency and freedom of information and choice for the consumer. What has been done, why, and what were the results? The French agricultural ministry in charge of disclosing the information about testing has really unwillingly fulfilled this obligation. Further, FoE France was found out that there was very many different authorities supposed to be aware of the exact situation of GMO experimental dissemination. But local authorities did often not know about experimental releases, which were carried out on their territory. Some experimental releases that were listed in the town hall had not advertised by the CGB, the French committee in charge of authorising and monitoring GMO releases. Further, in a few rare cases, where information was available, it only concerned the region, where an experiment would take place, which is not of great help for farmers. There was no way of knowing in what town or on what exact part of the land had these releases taken place.

The argument was that it was not 'safe' to disclose this information. The problem is that there was a legal obligation of disclosing this information, and in terms of safety, the neighbouring farmers (organic or not) needed to know what kind of experiment was carried out in their neighbouring field. So FoE decided to invest a lot of time to find and disclose this information and published a map on its web site, connected to a database, in which the entire experimental release sites town by town with the type GMO tested, could be found. It took FoE approximately a whole year with the help of a lot of local groups since FoE had to go to court in many cases to overturn the ministry of agriculture's refusal. One of the problems was fear for destruction of those experimental sites. But no FoE group in Europe, in France or anywhere else participates in these kinds of actions. FoE did not publish the information to allow supporters of this type of action, but to make sure that legitimate transparency was ensured and that provisions of law were obeyed also by the state (this is the definition of a state of law). This action had good repercussions and obliged the state and local authorities to show a little more respect to the public and to be a little more transparent with the information. But once again, finding out that the information about what was supposed to be very carefully monitored was not transparent at all and rather chaotic. There was no single authority in France capable of listing site by site every experiment that was going on. This did not help the public to gain confidence.

Experimental releases and research

How much money has been dedicated to research by the European Commission, and how irrational the consumer, who does not see all that is done to address his concerns? But you only find what you're looking for. And considering the titles of various research programmes funded by the Commission, it does not seem that this kind of research actually addresses concerns of stakeholders like long term nutritional and toxicological impacts and long-term environmental risks. Hopefully the revised 90/220 directive will improve this situation since under the new directive, risk assessment includes cumulative long-term effects on health and the environment including biological diversity and effects on non-agricultural ecosystems. In addition, the revised directive requires direct, indirect, delayed and immediate adverse effects on the environment and human health to be taken into account.

Another issue is the independence of the research that is being carried out. A major problem as identified by FoE has also been put to words by a publication from INRA, the French national institute for research on agronomy, which can not be suspected of being very pro NGO. In a paper published in 1998, INRA saw a serious emerging problem: "The independence of experts is at stake in an area requiring vigilance. In plant biotechnology, competence is largely in the hands of the industry actors; among researchers in public institutions it is rare to find one who does not work in partnership with industry." Gilles Eric Seralini, an independent molecular biologist and member of CGB have made a similar statement. "Most of the scientific members of the committee advising on releases and marketing consent are themselves involved in programmes partly funded by the industry. This is exactly how you find authorisation granted after a sole week of reviewing a dossier containing a one week test on two rats and one cow".

Part of the answer would be a greater independence of CGB, which could fund programmes not designed to prove that GMOs are safe but to assess potential long-term consequences of the use of such technology. But this is not a demand for the opposite of what the Commission is now funding, a study designed to prove that GMOs are unsafe. More objective and more independent research is needed. If you want to raise the awareness and implication of different stakeholders about research, just address their concerns.

Concerning the experimental release process, FoE has the opinion that it should be better monitored. Also to make sure that the products of these experimental releases are not commercialised afterwards as has been the case in the Netherland with Avebe's GM potato ending up in animal feed. Also to avoid a situation such as where FoE discovered some "phantom experimental releases" in France. And to avoid such nonsense as announced by the British government to extend the buffer zone for experiments with GM oilseed rape up to a 100 meters, when it has been proven that contamination can occur on distances over 4 kilometres as shown by Advanta's contaminated oilseed rape from Canada. FoE would also

like to point at the Italian government, which has recommended that all experiments should take place in greenhouse conditions in order to harmonise conditions.

Liability

During summer 2000 in several European countries including France, some conventional oilseed rape, maize and soy seeds appeared to be contaminated with GMOs. The decision of the state was to tear up the oilseed rape, and to let the maize and soy in the fields. Now what were the justifications of this? There was no legal basis to make anyone liable for this contamination. If the government ordered the ripping off the fields, who would pay for the damage suffered by farmers? The seed distributor? The seed producer? The contaminating seed producer? The state? The farmers themselves ? It was agreed that Advanta would suffer the cost of what had been ripped up. But it was done in a sort of good-will attitude. The company said: "We do not consider we are responsible for what happened, neither can we be held liable, but in order not appear as the bad guy again, we will pay for the damage." The same questions led the government not to order the destruction of maize fields.

Some may argue that there can be no damage caused by a transgenic crop. But this is not valid. Outcrossing, which has led to seed contamination and food contamination (Starlink maize accident!), did show that damages might occur, even though we do not know for sure what they can be. We also know that the pressure from the industry prevented any legal text to be adopted (or even presented) by the European institutions. But, let's face the facts, how do you plan to raise trust among citizens and consumers if the producer of the product affirms that by no means shall be held liable in case of damage. If the producer does not trust his own product enough to accept responsibility for it, why should other stakeholders accept this responsibility? Would you accept to buy a car from a constructor telling you that whatever defects the car might have, he is not responsible? Insurance companies should also join this stakeholder dialogue, also because insurance companies have great experience in risk evaluation. It is therefore not surprising that so far they have refused to insure the application of GM crops. Insurance companies can not be considered as philanthropic institutions. If they refuse to insure an activity, it is just because they know, just as FoE knows, that we don't know enough about the possible consequences of this new technology to take the risk.

GENETICALLY MODIFIED ORGANISMS – NO CHOICE

Margarida Silva, Quercus, Portugal

Introduction

Quercus is the largest environmental organisation in Portugal. It also takes part in an anti-GMO network consisting of environmental and organic agriculture groups and consumer associations.

Why have consumers a right to worry that they have no true choice when it comes to eating GM food within current technical and legal frameworks? Since environmental and human health impacts have not been proved or disproved, this leaves many consumers facing complex personal choices. An overarching issue seems to be irreducible uncertainty associated with the use of GMOs, although one point seems clear: What exactly happens in the environment will determine what exactly we will be eating from our plates.

On any scale the numbers are staggering. In the year 2000 total global acreage cultivated with GM crops reached 44 million hectares, whereas in 1996 this acreage was just below 2 million hectares. There must be some implications given these numbers.

Four different kinds of consumers

How does each kind of consumer exercise his or her freedom to choose non-GM food? Roughly, four groups of consumers can be distinguished. The first group consists of 'accepting consumers'. They believe GMOs are okay and hold benefits to the individual and society, or they simply do not care what they eat. These consumers are the happiest group. In fact they feel no need to choose non-GM food and they are not concerned whether there is any choice available or not.

The second group consists of 'unaware consumers', who have never heard of GMOs or lack enough information to act. These people will never have any choice, simply because nobody took the time to tell them that they can choose, or explain the issues at stake. Maybe they do not even have the basic scientific background that would allow them to grasp the issues. They are an easy prey and never bother anyone. According to the Eurobarometer, 75% of the Portuguese people have never discussed modern biotechnology with anyone.

The third group consists of 'interested consumers'. They feel concerned and wish to avoid GM food for health, environmental or other reasons. They read labels and look for alternatives. They will start by choosing GM-free brands, or even organic food. But they usually end up looking beyond labels, realising that GM foods can never be truly avoided. There are three different reasons why the interested consumer will feel this way. First, because certified GM-free alternatives do not exist for every plant or animal product and are not available in every store, restaurant or country they happen to visit. Second, because mistakes happen just like in the StarLink maize case; tomorrow it will be something else and we will eat it before we know it and biotech companies seem to offer little hope of being able to do more than simply mopping up the milk after the spill. Third, because genetic pollution occurs. It is here to stay. We have seen conventional seed stock that became contaminated due to cross-pollination from fields located miles apart. We have heard of transgenes popping up unexpected because of mistakes by breeders. And we have also seen from literature that horizontal gene transfer can move GM traits pretty much anywhere, from plants to microbes, bees or chicken – and all these things occurred in just the last couple of years. None of these three points bodes well for clear and consistent consumer choice.

The fourth group consists of 'activist consumers'. These are people, who are willing to help public pressure movements in order to guarantee the availability of GM-free food. Many will bring a background in agriculture, trade and development issues to the debate on GMOs. They may spend an important chunk of their time fighting GM food. And they end up very

concerned, when they discover additional glass ceiling at more fundamental levels related to GMOs:

- Communities wishing to avoid genetic pollution are not entitled to establish GM-free zones inside the European Union. This has become quite clear in the case of Austria and Italy, among others.
- Compliance with labelling regulations, which are generally not monitored in Portugal. The agriculture ministry has been unwilling or unable to publish any information whatsoever on how the labelling regulations have been enforced, although Quercus has repeatedly requested such information.
- Experimental releases of GMOs are not independently assessed. In Portugal no single experimental release was subject to governmental monitoring of genetic pollution – or for anything else.
- Ministries also tend to get cold feet when it comes to public access to information. In Portugal the agriculture minister is still preparing a response to a fact-finding letter from Quercus sent 15 months ago.
- Governmental advisory bodies do not seem to be more successful in getting the agriculture ministry's attention, particular if these bodies advocate a long moratorium and profound reforms. A long awaited report by the Portuguese National Council for the Environment and Sustainable Development drew a deafening silence from all six responsible ministries.

Against the background of these four different kinds of consumers, the 'accepting consumers' by choosing not to exercise their right to choose are the only group that is not side stepped by the biotech industry. And European politicians are now discussing levels of contamination, accident percentages, acceptable thresholds and exemption lists. But these are mostly administrative decisions, based more on economic feasibility than consumer desirability.

So now we find ourselves negotiating fractions of choice but lost track of what true choice should mean from a consumer point of view. The concept of 'zero contamination' somehow slipped through the cracks along the way. What we now have are numerous food products that are GM-free from a legal point of view but not from a biological or chemical standpoint. Does this sound confusing? That is because it is confusing.

Conclusions

Although highly sophisticated, biotechnology is still in its infancy in its use of genetics and in its understanding of complex ecosystem connections or health implications. Its contribution to some societal problems could however be extremely positive, and such research should not be shelved. But how to balance risks, especially unknown risks, and possible benefits, is of course the million-dollar question.

In order to proceed a problem-based approach is needed. This means that for each problem to be faced all possible approaches (be they technological, cultural, economic and political) should be lined up. Subsequently itemisation should take place of their known risks and benefits, history of safe use, economic, biological and social costs, whether or they solve more than one problem at once, and whether they promote self-sufficiency and local control. On that basis, to the best of our ability, a weighed hierarchy with different solutions would be created. Then efforts should be focussed only on the top two or three more desirable approaches in terms of guaranteed long-term benefits to society. This kind of evaluation is something what everybody does in his or her personal life to a certain degree.

It would also get us beyond mere labelling and traceability arguments to an expansion of the precautionary principle. When better solutions are available, genetic modification of food should have no role. This would eliminate the risks of GM altogether. On the other hand, food biotechnology should be heavily funded if it is to hold this most positive outlook. In this smaller number of cases, genetic pollution and any known and unknown risks would be closely and patiently monitored, and obviously minimised to the extend possible.

GM PLANTS AND FOOD: PERSPECTIVES FROM A FARMERS ORGANISATION

David Carmichael, National Farmers Union, United Kingdom

Major developments in agriculture took place in the 20th century in respect of plant breeding, the control of weeds, pests and diseases and improved mechanisation. With the advent of the 21st century, attention has focussed on crop biotechnology, which has become a highly controversial subject. To the farming industry the most powerful argument for the adoption of GM technology is based around the economics of production. Nevertheless the concept that GM technology is inherently dangerous, carrying with it risks associated with release of genes into the environment, is widely held.

In the early 1990's the European Community instituted a comprehensive system for the assessment and control of genetically modified organisms (GMOs). Under Directive 90/220/EEC no product comprising or containing GMO's can be placed on the market until it has been shown that measures have been taken to avoid adverse effects on human health and the environment. In addition any GM product to be used in food had to be approved under the EU Novel Foods Regulations.

Recently Directive 90/220/EEC has been extensively revised. The NFU, the major farming trade association in the UK, now wishes to see its early adoption by the European Parliament followed enactment in the UK. In addition the NFU is calling for an EEC Directive and its UK counterpart to require the labelling of the constituents of animal feedstuffs, this to include the source of each of the constituents. It is not regarded as sufficient to record simply the percentage of protein, fat and minerals, the source must also be recorded on the label. Although it is accepted that the use of antibiotic marker genes poses minimal risk in response to consumer concerns the NFU is seeking the immediate phase out of such marker genes.

Finally there is a strong call for significant levels of funding to be made available to develop biotechnological innovations which will be able to be used to produce GM minor crops. While biotechnological techniques for disease and pest control are already developed for major crops such as maize and soya, little attention has been paid to horticultural and other minor crops. Similarly there is a critical need for the use of biotechnological techniques for the development of non-food or 'alternative' crops. Such crops would include oilseed crops for the production of industrial alcohols and ingredients as well as fibre crops for the production of lightweight boards and possibly clothing. Little attention has been paid to date to the use of GM technologies for the production of fuel crops such as Miscanthus and short-term coppice.

The attitude of the consumer to GM technology in the UK has been largely based on information fed to it by activist groups and a sceptical media. In the period 1998 – 2000 the potential introduction of GM crops and food into the UK precipitated acute political and scientific controversy. Indeed in February 1999 modern biotechnology was subject to more intense and acrimonious debate in the British media than at any time in the preceding 25 years.

To understand the origins of the heightened consumer concerns over GM technology and GM foods it is necessary to look back to 1996 when the BSE crisis in the UK sensitised public concern to question food safety. This was raised still further when it was revealed that unsegregated mixtures of modified and unmodified soya were being imported into the UK from North America. The removal of choice from the consumer over whether or not to purchase foodstuffs containing GM ingredients activated a number of environmental organisations and consumer groups. Over the succeeding two years this lobby gained significant momentum.

By the end of 1998 media interest in GM foods had risen markedly. Several newspapers adopted a campaigning stance, led principally by the Daily Mail and Daily Express, with several other tabloid newspapers moving in the same direction. This high profile campaigning debate was maintained throughout the first half of 1999 and has been followed by, what I perceive as, a slow decline in media interest.

It is difficult in the absence of any recent definitive studies on consumer attitudes to determine accurately present public opinion and level of concern. A survey of readers' letters to a leading UK farming journal indicated only 5 letters out of a total of 167 in a twelve-week period addressing the subject of GM technologies in agriculture. In the same period this journal ran a total of four articles equally balanced on each side of the debate.

As a signatory to the Rio Convention the UK Government has adopted the Precautionary Principle. Broadly stated this principle may be expressed as: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically".

In the UK the Precautionary Principle is central to guiding the development of government policy and has clearly influenced the present position with regard to the introduction of GM crops. In early 1998, English Nature and the other statutory nature conservation agencies called for a moratorium on the introduction of GM crops into commercial agriculture. Although it was generally accepted these crops posed no risk to human or animal health there was a question about the impact of the new herbicide regimes on the abundance and diversity of farmland wildlife. Therefore influenced by the public debate in accord with the guidelines established by the Precautionary Principle the Government sought, together with the Statutory Environmental Agencies and Biotechnology Industry to establish the environmental safety, or otherwise, of GM herbicide tolerant crops in agriculture. A series of field scale trials was set up to address the specific question of the effect of these crops on farmland wildlife when grown in a commercial setting. The crops involved, oilseed rape, maize and beet, were all on the verge of entering commercial agriculture in the UK, but under a voluntary agreement with industry, these crops would not be grown, other than in the evaluations, until the evaluation programme is completed in autumn 2002.

The industry side of this agreement was taken forward by a cross-industry association termed SCIMAC – Supply Chain Initiative for Modified Crops. The membership of this group comprises representatives from the plant breeders, biotechnology companies, agricultural merchants and farmers. Their role extends to identifying trial sites, provision of seeds and inputs, management advice and product disposal. SCIMAC has no role in the scientific programme associated with the trials or in the evaluation of the results, that is the remit solely of a Scientific Steering Committee established by the Government.

Although accepted by the Statutory Nature Conservation agencies and the Biotechnology Industry the Farm Scale Evaluations have not been accepted by some pressure groups. The view of the farming unions is that these trials form an essential part of the evaluation process and must be completed before any decision is made on the permissibility of future commercial production of GM crops.

Looking to the future, if it can be demonstrated that the use of GM herbicide tolerant crops in agriculture will pose no significant threat to farmland wildlife and diversity, that is, the environment in which I farm, then it is essential that farmers are able to adopt this new technology. Without this we will not be able to achieve the economics of production that will enable us to compete on world markets. It is not an exaggeration to say that agriculture has reached a crucial threshold.

PERSPECTIVES FROM A NATIONAL BIOSAFETY COMMITTEE

Willem Brandenburg, Committee on Genetic Modification, The Netherlands

Introduction

In The Netherlands applications for field trials with GM plants are sent to BGGO, a technical-administrative body handling the application procedure. The Ministry of Environment is the competent authority regarding environmental biosafety regulations on contained use, releases into the environment and market releases. It may seek scientific advice on an application from the Committee Genetic Modification (GOGEM).

In the case of the food safety assessment of GM foods it is possible to develop international protocols and guidelines. This is however not possible for the environmental risk assessment of GMOs.

Regulatory principles

The environmental risk assessment of GMOs is based on the precautionary principle in a case-by-case and step-by-step fashion, whereas the food safety assessment of GM foods is based on the concept of 'substantial equivalence'.

Making comparisons and extrapolations and using analogies and generalisations are applied in the environmental risk assessment of GMOs, supported by data sets on the environment, the gene and the gene product from biosafety research, such as in the format of Botanical Files, Gene Files (and Food Files). Botanical Files have been developed for The Netherlands and Switzerland. At the moment a preliminary start has been made to develop European Botanical Files.

Within COGEM there is often a real struggle to decide if the evidence available allows comparisons to be made or analogies to be used. But zero tolerance can never be achieved.

New regulatory developments

The revised Directive 90/220 foresees that the precautionary principle should be applied more strictly. Further pre-release and post-release monitoring procedures are foreseen as well as stricter duties for national environmental inspection services.

There is also an informal need for a cost/benefit analysis and for stakeholder dialogue.

The dialogue

Regulatory bodies and stakeholders have to be involved in the design and formulation of regulations.

It is worthwhile looking at the framework of relevant international and national legislation before entering the dialogue.

SCIENTIFIC UNCERTAINTY, PRECAUTION AND DECISION-MAKING

Julie Hill, Green Alliance & the UK Agriculture and Environmental Biotechnology Commission, United Kingdom

The Green Alliance is an UK-based NGO working to ensure that the environment is at the heart of all decision-making. The UK Agriculture and Environment Commission provides the UK Government with a strategic view of the impact of biotechnology on agriculture and environment and covers England, Scotland, Wales and Northern Ireland.

The central question of the workshop is: 'How can scientific research into environmental risks and safety of GM plants better answer stakeholders concerns and be used in decision-making'. My answer is that this could be addressed:

1. By acknowledging and communicating uncertainty.
2. By ensuring public engagement in research agendas.
3. By making transparent the links between research and policy.
4. By promoting public ownership of decisions.

Recent social science research undertaken in the UK (1, 2) shows that uncertainty is a key public pre-occupation, but most information providers feel uncomfortable with communicating uncertainty. It is now generally acknowledged that the significance of uncertainty and precaution can only be determined by debate. Overviews of research results should therefore set out what is not known, as well as what is known. Further, the significance of uncertainties needs to be widely communicated and debated, and there is a need to reach beyond the usual 'stakeholder' groups.

In the EU there is at present minimal engagement for stakeholders, and zero for the public. So, there is little understanding of how the scientific research agenda is set, its relationship to policy and its costs. This is made worse by general lack of transparency. The public may ask the following questions:

- Who decides what research is important? Whose priorities does it reflect?
- What are the assumptions behind research projects?
- How are researchers selected? How is quality ensured? How is 'independence' ensured?
- What is done with the results? Are they publicly available? Is there a clear link to policy?
- How is research followed-up?

So How to move towards public engagement in research agendas?

One way would be to develop a research forum; a 'multi-stakeholder' body that includes public representatives. Such a forum could provide an annual review of research priorities for public and private institutions. For EU institutions, presenting to this forum would drive transparency, ensure an 'overview' is taken and assumptions laid out.

How to move towards public ownership of decisions?

Social science research (3) shows that the public expects 'justification' of GM products, and examination of alternatives to GM. Scientific research can help by properly documenting benefits and identifying alternatives. GM has focused attention on existing agricultural techniques, so the debate should become more about agriculture than GM. This indicates a

need for research into relative impacts of different systems. There is also a pressing need for 'baseline' data on the state of the environment in order to assess what has changed as a result of introducing GM or any other new agricultural technology.

However, no amount of research will answer the question 'Does it matter?' Research should inform, not drive debate. Ownership of decisions ultimately comes from trust in decision-makers – but a key part of this is 'are they asking the right questions?'

References

(1) Wising Up - The public and new technologies. Robin Grove-White, Phil Macnaghten, Brian Wynne. November 2000 Available from The Centre for the Study of Environmental Change, Lancaster University, LA1 4YN, UK. e-mail: csec@lancaster.ac.uk

(2) Steps into Uncertainty - Handling Risk and Uncertainty in environmental policy-making - Green Alliance/Green Alliance special briefing no.6 June 2000

(3) The Public Consultation on Developments in the Biosciences - written by MORI, commissioned by the Office of Science and Technology (Part of UK Department of Trade and Industry) May 1999.

DEVELOPMENT OF NEW AND SUSTAINED FORMS OF DIALOGUE BETWEEN RESEARCHERS AND SOCIAL OPERATORS

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Quality control of knowledge production and sharing process and extending the decision-making process

High stakes decisions must often be taken with some urgency, or else they will occur by default. Examples of such decisions are in areas such as greenhouse gas emission policies, releases of GMOs, life engineering such as cloning, and nuclear reactor waste storage and disposal. Expert evaluation, such as risk assessment, science-based safety standards, is however insufficient for public and private decision-making on issues involving high uncertainties and irreversibilities. An explanation of this insufficiency is not the irrationality of the members of society, but rather the inherent properties of the situations. These properties are:

- Irreducible uncertainties, including complex system unpredictability and real yet unquantifiable risks of health and environmental damage or of loss of economic opportunities.
- Plurality of social values and hence divergent concerns and justification criteria.
- High decision stakes, including commercial and military interest, risks of social disruption, possible severe irreversible impacts on health of populations and long risk/impact time-horizons.

So, what do we do when facts are uncertain, values in dispute, stakes high and decisions urgent? Where value plurality is irreducible, high quality consultation and negotiation processes, based on knowledge sharing, provide the best possible assurance of satisfactory outcomes for society. This approach is characterised by a change of emphasis from (technical) quality of inputs for a decision problem to the quality of the process itself. This approach achieves its goals along the following axes:

- *Credibility* of economic, scientific and technical inputs to decision-making.
- Socially, economically and technically *robust* choices.
- Wide social *legitimacy*.
- *Scientific quality assurance* in a context of complexity, high systems uncertainties and social indeterminacy.

Against this background extended processes of knowledge-sharing, deliberation and negotiation need to be developed that are adapted to the full diversity of social actors involved. The process design is critical and stakeholders typically extend across:

- Government agencies and regulatory bodies.
- Concerned citizens and the wider public.
- The scientific community, industrial and commercial interests.
- NGOs and 'public interest' activist groups.

Hence, tools for communication and consultation procedures will (need to be) developed that provide for:

- Identification and development of elements of common problem definition and common language for clear communication.
- Sharing of the reasons and justifications brought by the different social groups to the deliberation process.
- Skill development of the participants in new deliberative processes.
- Understanding of the assumptions underlying expert evaluation techniques, of the terms in which these techniques can contribute to reasoned decisions and limitations to their application.
- High status to participation by professionals and lay people in the consultation processes.
- Search for novel and compromise solutions based on respect of divergent criteria and the need for coexistence.

**Stakeholder dialogue on the environmental risks and safety of GM-plants,
February 28 & March 1, Naturalis, Leiden, The Netherlands**

AGENDA

Central question of the workshop:

How can scientific research into the environmental risks and safety of GM plants better answer stakeholders' concerns and be used in decision making?

DAY I

Morning Session

Moderator: Richard Braun, EFB Task Group

**GM-plants, environmental risks and safety, regulations, and biosafety research:
state of affairs**

- 10.30 – 10.40 Introduction to workshop:
Richard Braun, EFB Task Group
- 10.40 – 10.50 Introduction to EC-supported GM plant biosafety research:
Ioannis Economidis, European Commission Research DG
- 10.50 – 11.30 GM plants in the context of conventionally bred plants:
Philip Dale, John Innes Centre Plant Research, United Kingdom.
- 11.30 – 12.00 GM plants and biodiversity in agricultural and natural settings:
Klaus Ammann, Botanical Garden, University of Bern, Switzerland.
- 12.00 – 12.30 Risk assessment and Aventis' stewardship of GM-plants:
Bert Uijtewaal, Aventis, Belgium.
- 12.30 – 13.15 Lunch

Afternoon Session

Moderator: David Bennett, EFB Task Group

**GM-plants, environmental risks and safety, regulations, and biosafety research:
state of affairs**

- 13.15 – 13.45 Overview of biosafety research on ecological aspects of GM plants:
Detlef Bartsch, Technical University Aachen, Germany
- 13.45 – 14.15 Data requirements for permits for field trials with GM plants in the
Netherlands: case study of appeal by Greenpeace at Council of State Piet
Schenkelaars, biotechnology consultant, The Netherlands.
- 14.15 – 14.45 Review of studies on Bt-plants for Greenpeace and identification of
potential improvements of their ecological risk assessment:
Matthias Meier, EcoStrat, Switzerland.
- 14.45 – 15.15 Coffee / tea

Stakeholders concerns about environmental risks and safety of GM plants:

Precaution, consumer choice & stakeholder engagement:

**What scientific research could address these concerns? Why is the level of awareness
about scientific research that has been done low and how can it be raised?**

- 15.15 - 15.45 Perspectives from an environmental NGO
David Azoulay, Amis de la Terre, France

- 15.45 - 16.15 Perspectives from a consumer NGO
Margarida Carvalho e Silva, Quercus, Portugal
- 16.15 – 16.45 Perspectives from a national biosafety committee
Willem Brandenburg, Committee on Genetic Modification, The Netherlands.
- 16.45 – 17.15 Perspectives from a farmers organisation:
David Carmichael, National Farmers Union, United Kingdom.
- 17.15 – 17.45 Discussion
- 18.00 – 19.30 Reception together with Bio Business drink of Bio Sciencepark:
Address by Mrs Melanie Schultz van Hagen, Councillor of Economic Affairs, City of Leiden.
- 19.30 – 21.00 Dinner

DAY 2
Morning Session

Moderator: Francoise Bieri, EFB Task Group

**Stakeholders concerns about environmental risks and safety of GM plants:
Precaution, consumer choice & stakeholder engagement:
What scientific research could address these concerns? Why is the level of awareness
about scientific research that has been done low and how can it be raised?**

- 09.00 – 09.30 Scientific uncertainty, precautionary principle and decision making:
Julie Hill, The Green Alliance, United Kingdom.
- 09.30 – 10.00 Segregation of GM seed and non-GM seed:
Sofia Ben Tahar, Limagrain, France.
- 10.00 – 10.30 Coffee / tea
- 10.30 – 11.00 Development of new and sustained forms of dialogue between
researchers and social operators:
Silvio Funtowicz, Institute for Systems, Informatics and Safety –
EC Joint Research Centre, Italy

**Mapping by participants of stakeholders' concerns, scientific research and
engagement that could address these concerns.**

- 11.00 – 12.00 First Round
- 12.00 – 13.00 Lunch

Afternoon session

Moderator: Julie Hill, EFB Task Group

- 13.00 - 14.15 Second Round
- 14.15 - 14.45 Coffee / tea
- 14.45 – 16.00 'Bullet point ' recommendations, including dissenting views and
remarks, for engaging stakeholders and scientists in research that would
better answer stakeholders concerns and be used in decision
making.

PARTICIPANTS OF EUROPEAN WORKSHOP STAKEHOLDER DIALOGUE ON THE ENVIRONMENTAL RISKS AND SAFETY OF GM PLANTS

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BACKGROUND DOCUMENTATION

References sent to participants before workshop

1. Handling scientific uncertainty in European environmental decision-making, Report of a Green Alliance seminar, 17 -18 April 2000, London.
2. European policy-making: Science and governance in the European Union: a contribution to the debate, Silvio Funtowowicz et al., Science and Public Policy, October 2000.
3. Communication from the Commission on the Precautionary Principle, Brussels, 02.02.200, COM (2000)1.
4. Risk Assessment in a rapidly evolving field: the case of genetically modified plants (GMP), Scientific Opinion of the Scientific Steering Committee, expressed on 26/27 October 2000.
5. The ecological risks of genetically engineered organisms: an introduction to the problem, Piet Schenkelaars (Friends of the Earth Europe, 1993).
6. Public Perceptions of Agricultural Biotechnology in Europe, draft summary of main results, Brian Wyne et al., April 2000.