Proceedings of the International Workshop on Transgenic potatoes for the benefit of resource-poor farmers in developing countries

Manchester, United Kingdom
5 – 9 June 2000

The International Potato Center (CIP) seeks to reduce poverty and achieve food security on a sustained basis in developing countries through scientific research and related activities on potato, sweetpotato and other root and tuber crops, and on the improved management of natural resources in the Andes and other mountain areas.

CIP is a Future Harvest Center and receives its principal funding from 58 governments, private foundations and international and regional organizations known as the Consultative Group on International Agricultural Research (CGIAR). Future Harvest builds awareness and support for food and environmental research for a world with less poverty, a healthier human family, well-nourished children and a better environment. Future Harvest supports research, promotes partnerships and sponsors projects that bring the results of research to rural communities, farmers and families in Africa, Latin America and Asia.
Phthorimaea operculella, the potato tuber moth, damages potato leaves and tubers (left and bottom), but transgenic plants (right and center) are resistant to the pest. Photos courtesy of A. Lagnaoui and V. Cañedo (CIP)
Proceedings of the
International Workshop on

Transgenic potatoes
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Workshop on Transgenic potatoes for the benefit of resource-poor farmers in developing countries: Introduction and outcomes

Wanda Collins, International Potato Center
John Witcombe, DFID Plant Sciences Research Program
Jill Lenne¹ and Simon Eden-Green, DFID Crop Protection Program

Publicly funded research to develop transgenic potatoes for the benefit of resource-poor farmers in developing countries is substantial. It will continue to grow as the potential of the technology to promote both production and utilization of potatoes is realized. Transgenic potatoes are being produced as a public good to help poor farmers overcome constraints that have proven to be difficult to solve by other means. However, constraints to the uptake of these new potatoes need to be considered and resolved at this early and promising stage of development if the benefits of the technology are to be maximized in the future.

To promote the development, uptake and utilization of transgenic potatoes to meet the needs of the poor in developing countries, the International Potato Center (CIP) and the Plant Sciences Research and the Crop Protection Programs of the United Kingdom Department for International Development (DFID) organized and sponsored a workshop for invited participants to address the topic of Transgenic potatoes for the benefit of resource-poor farmers in developing countries. This five-day workshop, held in June 2000 in Manchester, UK, was considered by the DFID Programs and CIP as a critical step in the future development and use of transgenics to meet developing country needs.

Participants were invited from 11 developing countries. Each of those countries works with, or is interested in, transgenic potatoes to address their potato production and/or quality constraints. Other participants included scientists from Europe, the USA and CIP, as well as senior-level program managers from DFID, CIP and the Food and Agriculture Organization of the United Nations (FAO). The goal of

¹ Current position: Deputy Director General for Research, ICRISAT, Patancheru, India
the conference was to build agreement and support for the appropriate use of transgenic potatoes in sustainable agriculture for the benefit of poor farmers in developing countries. The approach throughout the workshop was to focus on issues of specific relevance to the uptake of transgenic potatoes.

During the workshop, the participants reviewed current work and experiences in each participating country in order to more precisely define barriers, constraints, opportunities and incentives. These experiences are reflected in the country profiles submitted by the developing country participants. The workshop also provided participants with a valuable opportunity to use their collective experiences to outline an action plan for the steps needed to promote continued development and uptake of transgenic potatoes (see Box 1).

One of the future actions suggested by the participants was the creation of a potato biotechnology network, which would link the participants of this workshop in future activities for the benefit of all of them. That suggestion has been implemented with the creation of PotatoGENE (Potato Genetic Engineering Network) by the International Potato Center. PotatoGENE will provide useful information to researchers, users, policymakers and the general public. A website for PotatoGENE will be operational soon.

A further output of the workshop was the agreement by participants on the traits that are most urgently needed, for which transgenic potatoes could provide a solution in developing countries. The traits, and the number of developing countries listing them as important, are:

- Late blight resistance (9)
- Bacterial wilt resistance (6)
- Potato tuber moth resistance (6)
- Viruses (PVY and potato leaf roll virus) (5)
- Quality (2)
- Nematodes (1)

This information should provide guidance to future investments in transgenic approaches, and also serve as a basis for developing collaborative projects among participants and approaching donors for funding.

The workshop was successful in bringing participants from both developing and developed countries together to share experiences and discuss the future of transgenic potatoes for meeting the needs of the world’s poor. It is critical to sustain the interest and enthusiasm generated by this workshop by seeking additional opportunities for the participants to build on this initial effort.
Box 1. Suggestions for future action

**Strategies for addressing public concern**
- Build capacity for media relations and spokesmanship
- Provide Access to information for specified users
- Conduct workshops with advocacy groups demonstrating and teaching constraints and the beneficial solutions offered by the technology
- Develop and provide information on benefits
- Develop and provide information on risks and existing risk analyses
- Raise public awareness of regulatory work on risks
- Raise public awareness of safety issues
- Develop a website with lists of background information
- Provide a resource of audited positive information sources
- Form National Interest Groups to address relevant issues

**Seed system issues and intellectual property rights**

**Intellectual property rights**
- Identify relevant existing core technologies for potato improvement
- Develop a joint strategy for acquisition of core technologies for freedom to operate for resource-poor farmers
- Provide information on core technologies and their IPR status through a “Potato Biotechnology Network” (perhaps hosted by CIP)
- Identify national contact on IPR issues
- Develop training activities on implications and impact of IPR issues on small scale farmers.
- Develop a brochure on “The steps for technology transfer and IPR implications”

**Seed systems**
- Strengthen formal seed sector to enable seed labeling;
- Develop physical and descriptive markers as needed by formal/informal systems
- Provide advice and support for community based seed systems for production technologies and crop management of transgenics
- Conduct market or farmer participatory research (MPR or FPR) for acceptable/feasible phenotypic labeling in tuber or plant
- Characterize local production / management practices for transgenics
- Provide technical support to national regulatory systems

**Gene Flow, Effects on Non-Target Organisms and Biosafety Issues**
- Build capacity in developing countries to deal with issues related to gene flow and potential effects on non-target organisms through regional courses, emphasizing biosafety issues, risk assessment
- Undertake research activities underpinning biosafety decision/regulations for regulatory bodies, including assessment of gene flow and transgene fitness in centers and non-centers of biodiversity (with reference to FAO model)
- Develop simple method to assess effect of transgenics on soil function
- Interact with IOBC working group for possible best practice definition and experiments

**Health and Food Safety**
- Promote development and inclusion of information at gene construct and plant/gene interaction levels in the development by national governments of minimum standards to ensure transgenics do not differ in safety from non-transgenics
- Collect data and information regarding toxic effects;
- Promote action to define what testing is actually needed for specific GMOs
- Determine where specific national standards exist, and encourage sharing standards between countries
- Build capacity for addressing health and food safety issues including knowledge, facilities and maintenance, ongoing short- and long-term training, and aiming for self-sufficiency
- Establish regional or sub-regional groups to examine issues
- Identify sectors/stakeholders and encourage participatory approaches to health and food safety issues
Argentina

Marcelo Huarte

Introduction

Production and use
The total potato production area is 100,000 ha. There are various cropping seasons: winter (5%); spring (27%); summer (47%); and autumn (21%). The yield is highest for the summer crop (25 tons/ha) and lowest for the autumn crop (15 tons/ha). Until recently the main market was fresh potato with an annual consumption of 50 kg per capita. Because of the different cropping seasons, freshly harvested potatoes are available throughout the year. The processing industry is developing fast. The use of cold stores is mainly by the seed and the processing industries.

The main production area for the summer crop is southeast of Buenos Aires. A wide rotation scheme (about 6 years) with pasture, wheat and maize as predecessors to the potato crop is used. Potatoes are irrigated and mainly produced on large farms (110 ha). Often in these large potato fields, a number of rows are sown with corn and straw that are later used to cover potato clamps (above ground potato storage piles). In other areas where potatoes are grown during the other seasons, soils with low organic matter are frequent and the rotation scheme has been too narrow.

Varieties and seed
The main variety grown is Spunta. Other varieties are Huincul, Pampeana, Frital and Ballenera. The french fries industry uses Kennebec and Russet Burbank. The country has developed its own seed industry. Regarding seed quality, the first emphasis was on virus diseases, but other quality characteristics, such as physiological age and soil seed-borne diseases, have received more attention in recent years.

The pre-basic seed comes from laboratories that perform in-vitro multiplication. The pre-basic seed from the laboratories can, in certain cases, be multiplied in the field for a limited number of

1 Instituto Nacional de Tecnología Agropecuaria, Balcarce, Argentina
generations because the infection pressure of PVY is relatively high. There are specialized laboratories that test seed samples for viruses. The ELISA (enzyme-linked immunosorbent assay) test is used on sprouted tubers previously treated with Rindite® to break dormancy. Only about 10% of the seed used is certified, but farmers send non-certified seed samples to the laboratories for virus testing. Therefore, all the seed planted has passed some post-control test besides field inspections.

Certified seed is grown in the summer season in various places in the country, but non-formal seed comes from other production seasons. The seed is stored in refrigerated stores and in clamps. Seed physiological problems are related to seed storage methods and adjustment to seed production seasons.

Major constraints to the production and utilization of potatoes that can be addressed best by transgenics

The major constraints are viruses (PLRV, PVY and PVX), late blight, *Alternaria, Fusarium* dry rot, *Verticillum* dry rot, grubs, quality factors (dry matter and reducing sugars, texture of final products) and herbicide resistance.

National research organizations with the capacity to develop GMOs

- INTA (Instituto Nacional de Tecnología Agropecuaria) Castelar, CICV (Centro de Investigaciones en Ciencias Veterinarias)
- INGEBI (Instituto de Genética y Biología Molecular, Buenos Aires)

Institutions working with potato GMOs

- CICV
- INGEBI

Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of perceived importance are

**Food safety**
- Toxins
- Allergens

**Effects on non-target organisms**

**Gene flow**
- To related wild species
- To related cultivated species
- To other potatoes of the same species

**Gene transfer of constructs to other pests**
- Viruses, disease organisms, nematodes
- Weeds
Control of variety purity/identification
Seed systems for production and distribution
Stability of transgenes

Major policy concerns for deployment and uptake of GMOs

Food safety and acceptance
There is no major public awareness about this issue although the regulatory office SENASA (Servicio Nacional de Sanidad Agroalimentaria) has intervened in some aspects concerning soybean releases and the Secretary of Agriculture is concerned about the possible rejection of Argentine exports of transgenic corn and soybeans by the European Community countries.

Biosafety
Biosafety is included in the present regulations emerging from CONABIA (Comisión Nacional de Biotecnología Agropecuaria), the regulatory commission on GMOs. The main legal body for this aspect is Resolution 289/97, modifying Resolution 837/93. This regulation from the Secretary of Agriculture has taken into account other regulatory actions from the UN (Project for the Environment), USA [EPA (Environmental Protection Agency) and APHIS (Animal and Plant Health Inspection Service)] and Canada [EC (European Community) and OCDE (Organización de Comercio)].

Intellectual property rights
Intellectual property rights issues are considered in the present regulation of patents. There is some revision underway related to Plant Breeders’ Rights and GMOs to try to incorporate some recognition to the original breeder of the GM variety, and there are private agreements regarding this issue.

Monitoring and testing for transgenes
Although there is some regulation on the testing of GMOs and the actions to be taken after the test, there is no major official monitoring of transgenes of released varieties. Some isolated efforts from research groups are made, but there are no standard procedures.

Status of transgenic potatoes release

Release to farmers
No transgenic potatoes have been released to farmers for commercial production.

Controlled research trials
Controlled research trials have been carried out using transgenic potatoes with virus resistance (PLRV, PVY and PVX) and insect resistance (Bt). The inventors are INTA Castelar, CICV, INGEBI and Monsanto.

The transgenic plants with resistance to PLRV, PVX and PVY from INTA and INGEBI evolved from coat protein mediated resistance using replicase transformants. Biosafety considerations regarding the transfer of viral sequences by recombination in the field with wild virus have been raised elsewhere. For this reason, INTA and INGEBI are exploiting the characterization and cloning of resistance genes naturally present in Solanum. These genes could be introduced into commercial varieties, replacing the use of foreign pathogen sequences. INTA and INGEBI have transformed the varieties Spunta, Kennebec and Huinkul.

The resistance to insects used by Monsanto is based on the Bt toxin. No information is available on the type of transformation they used for virus resistance. Monsanto has worked with varieties useful for the local french fries processing companies: Russet Burbank and Shepody. All trials have been
conducted at the INTA Balcarce Experimental Station. Recently, Biosidus, a private company with a high innovative profile, is representing INTA and INGEBI and running trials in other regions of the country.

**Other GMO crops**
Large proportions of Argentine’s soybeans are transgenic (70% of the total area planted with soybeans), and there is commercially grown corn. Currently, testing of GMO’s is underway for a number of crops (Table 1).

**Biosafety regulations**

The CONABIA (biosafety committee) was created under the Resolution 124/91 of the Secretary of Agriculture. Biosafety regulations have been formulated by the Resolution 289/97 and the Modifying Resolution 837/93.

**Strategy components for the successful release of transgenic potatoes**

From the standpoint of the grower, a successful transgenic variety should resemble the original variety in all its characters, with the obvious exception of the transformed character(s). This has not been fully achieved with Spunta and other local varieties.

The strategy of release should be strongly based on the certification system, implementing the use of proper identification tools (i.e. molecular markers) if they are not in place. Transgenic resistance to viruses must not interfere with the local diagnosis system based on ELISA. Many of the original coat protein mediated resistance clones showed a positive reaction in ELISA, although the virus was not present. Commercial strategies should involve few growers at the start to enhance the monitoring and access possible biosafety risks. However, this is a matter for the commercial policy of each company.

**Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenic plants**

- Lack of risks to native germplasm and to non-target organisms (gene flow)
- Argentina is a secondary center of origin of potatoes and its pests; therefore, the risk of undesired gene flow should be minimized
- Use of natural genes from the same species
- Lack of risks to human consumption
- Absence of reporter genes in the constructs (especially antibiotics)
Table 1. Surface (ha) planted with GMO’S under special conditions in 1997/98

<table>
<thead>
<tr>
<th>Crop</th>
<th>Modification</th>
<th>Surface (ha)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotton</td>
<td>Herbicide</td>
<td>95,540</td>
</tr>
<tr>
<td></td>
<td>Bt</td>
<td>49,800</td>
</tr>
<tr>
<td></td>
<td>Herbicide + Bt</td>
<td>69,480</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>214,820</td>
</tr>
<tr>
<td>Sunflower</td>
<td>Bt</td>
<td>250</td>
</tr>
<tr>
<td></td>
<td>Diseases</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>330</td>
</tr>
<tr>
<td>Corn</td>
<td>Herbicide</td>
<td>2,631,958</td>
</tr>
<tr>
<td></td>
<td>Bt</td>
<td>3,731,093</td>
</tr>
<tr>
<td></td>
<td>Herbicide + Bt</td>
<td>157,774</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>6,520,825</td>
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<tr>
<td>Potatoes</td>
<td>Virus</td>
<td>920</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>920</td>
</tr>
<tr>
<td>Soybeans</td>
<td>Herbicide</td>
<td>111,966</td>
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<tr>
<td></td>
<td>Quality</td>
<td>270</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>112,236</td>
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<tr>
<td>Wheat</td>
<td>Herbicide</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>20</td>
</tr>
<tr>
<td>Grand total</td>
<td></td>
<td>6,849,151</td>
</tr>
</tbody>
</table>

1Source: CONABIA, M Pequeño A.
Bolivia

Javier Franco¹, Antonio Gandarillas¹, Roberto Gallo² and Beatriz Zapata³

Introduction

Bolivia is located in the central part of South America. The Andean Mountains cross its occidental area. The andean region includes different agricultural and ecological zones ranging from the altiplano to inter-Andean and mesothermic valleys. The wide biodiversity found there is an extremely valuable resource whose potential for food security is inestimable. Over two million people inhabit the rural areas of the Bolivian Andes, producing approximately 60% of the food consumed in the country. A high percentage of farmers are poor and only grow for home use.

Different factors, such as the lack of access to adequate technologies and market opportunities, cause productivity to be one of the lowest in the continent. Farming in the Andes involves a series of interrelated actors and complex processes making up productive chains, going beyond what takes place in individual farmers’ fields.

Major constraints to the production and utilization of potatoes that can be addressed best by transgenics

Many peasant families in the Andes depend on potato as their staple food and as an important source of income. It is also an important food resource for many of the poor city dwellers. In the Andes and the mesothermic valleys of Bolivia, where most of the country’s 130,000 ha potatoes are grown, production levels are low, averaging 6 tons/ha. Several biotic and abiotic limiting factors (insects, nematodes, fungal and bacterial diseases, frost and drought) contribute to this low national average yield, and some of them could be addressed best by transgenics.

The most important nematode species attacking the potato crop in the Andean regions of Bolivia are Globodera spp. and Nacobus aberrans. N. aberrans is more widely distributed and causes more severe damage than Globodera spp. The direct yield losses caused by N. aberrans and Globodera spp. can reach 88 and 58%, respectively. It is also important to consider that farmers are incorporating more wilderness areas to obtain better potato yields in nematode–free soils. These areas are only marginally suitable for agriculture and are rich sources of biodiversity, which eventually could be degraded.

The most important insects pests are the potato tuber moth (PTM) Phthorimaea operculella and Symmetrischema tangolias and the andean potato weevil complex (APW) Premnotypes latithorax, Rhigopsidius tucumanus and Phyrdenus muriceus. Potato tuber losses by PTM species during the storage period can reach 50 and 100%, respectively. The losses in tuber quality for the three APW species have been estimated as 100, 80 and 20%, respectively. Among the fungal and bacterial diseases, rhizoctoniasis (Rhizoctonia solani), wart (Synchitrium endobioticum) and bacterial wilt (Ralstonia solanacearum) cause direct yield and other economic losses by affecting the quality of the tubers produced for consumption or seed. Bacterial wilt can cause losses up to 100%, and infested soils can not be used for potato production for several years.

¹ Fundación PROINPA, Cochabamba, Bolivia
² National Seed Program, La Paz, Bolivia
³ Ministerio de Desarrollo Sostenible y Planificación, La Paz, Bolivia
Frost and drought are abiotic problems in certain Andean regions that can cause yield losses from 40 to 100%, depending on the crop period and the frequency, intensity and severity of the event.

National research organizations with the capacity to develop GMOs

- Fundacion PROINPA, Cochabamba
- Centro de Biología Molecular de la Universidad Mayor de San Andrés, La Paz
- Instituto de Genética de la Universidad Mayor de San Andrés, La Paz

Institutions working with potato GMOs

PROINPA is planning screenhouse evaluations in November 2000.

Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of perceived importance are

Gene flow
Bolivia shares with other Andean countries the privilege of being the center of origin and diversity of wild and cultivated potato species.

Effects on non-target organisms
This aspect is under study in Leeds University, UK. After the evaluation of transgenic potatoes for their resistance to nematodes in Bolivia, similar studies will be carried out locally with native and common non-target soil microorganisms.

Seed systems for production and distribution
There is a formal seed production and certification system, but this only covers 5% of the seed demand. This represents a constraint for the deployment of transgenic potatoes. Self-produced seed and/or seed tubers purchased in local/regional markets conform the informal system. Consequently the quality of the seed tubers is often poor due to the presence of several pests.

Food safety
Transgenic potatoes must be approved by the Health Ministry before their deployment.

Gene transfer to of constructs to other pests
There are no local laboratory capabilities to undertake this major technical concern, but the possibility of setting up appropriate laboratories to carry out this type of evaluations is under consideration.

Control of variety purity/identification
As native potato cultivar(s) will be transformed, plant or tuber phenotypic markers will be incorporated to distinguish them from non-transformed plants.

Stability of transgenes
The stability of transgenes is under study at Leeds University, UK.
Major policy concerns for the deployment and uptake of GMOs

Food safety and acceptance
Strong and aggressive international concern by environmentalist groups is an important factor.

Biosafety
There is local concern because Bolivia is a center of origin and diversity of potatoes. It is very important to strengthen national capabilities concerning the biosafety of transgenic potatoes. This implies the development and establishment of several mechanisms for measuring and monitoring risks to biological diversity.

Intellectual property rights
There would be no problem with intellectual property rights because native transformed potato cultivars would not be under any transnational patent (Atkinson, 1998).

Monitoring and testing for transgenes
This is related to seed systems and control of variety purity, but local laboratory capabilities are required.

Status of transgenic potatoes release

Release to farmers
No transgenic potatoes have been released to farmers for commercial production.

Controlled research trials
A greenhouse evaluation will be carried out in November 2000. Thereafter, if the transformed lines prove to be resistant, the following year field microplot evaluations will be conducted. The transgenic potatoes have resistance to *Globodera* spp. and *Nacobus aberrans*. Howard J Atkinson from Leeds University, UK, is the inventor.

After obtaining approval from the National Biosafety Committee, Desiree transformed tubers will be evaluated under containment conditions (screenhouse) and in field microplots at Toralapa Experimental Station (Cochabamba, Bolivia) for their resistance to the potato parasitic nematodes *Globodera* spp. and *N. aberrans*. The field trial with these Desiree transformed tubers will follow very strict regulations established by the PROINPA Local Biosafety Committee and be supervised by inspectors from the Potato Seed Producers Unit (SEPA) nominated by the National Biosafety Committee to avoid any possible effect in the surrounding ecosystem. The regulations to be followed are

1. Desiree plants under Toralapa conditions (3450 meters above sea level) do not normally produce flowers, but should this occur the flowers will be removed to avoid any risk of gene flow to other potato plants.
2. Waycha potato plants will be planted next to transformed Desiree plants to check any possible gene contamination by pollen dispersal.
3. The experimental field will be isolated from other potato crops by at least 30 meters.
4. Volunteer potato plants will be eliminated in the 30 meters surrounding the potato-free area.
5. A barley crop will surround the potato-free area.
6. The field trial will be harvested by hand and any residual plant tissue will be destroyed by incineration.
7. No potato crop will be planted in the experimental plot for a 3-year period after this field trial. Other crops such as barley, oats and beans will be planted, and any potato plant found growing there during this period will be treated with a herbicide or pulled out and incinerated.
Genetic stability of transformed potato plants will be monitored under controlled conditions. Timely inspections of the experimental field will be carried out three weeks after planting to confirm isolation procedures; when 50% of the Waycha potato plants are flowering; and at harvesting to assure elimination of residual plant tissues.

Other GMO crops
Soybean tolerant to herbicide and Bt transformed cotton by Monsanto are grown commercially.

Biosafety regulations
There is a National Biosafety Committee (CNB) created by SD 24676, and its members include representatives from the Vice-Ministries of Natural Resources and Environment, Agriculture, Industry, Foreign Affairs and Health. Other members are from the Bolivian university system. The CNB is responsible for all matters related to the biosafety of GMO. The Bolivian biosafety regulations were approved by SD 324676 on 21 June 1997, according to the Biological Diversity Agreement signed in Rio de Janeiro in 1992 and confirmed by Law 1580 on 25 July 1994.

Components of a strategy for the successful release of transgenic potatoes

- Approval by National Biosafety Committee to conduct greenhouse and/or field trials according to the characteristics of the constructs and risk evaluations (environment, biodiversity and consumption).
- Public awareness of transformed potato plants, indicating advantages (improved yields, nematode control, no need to incorporate new agricultural lands, etc.) and disadvantages (probable risks?).
- Controlled release to a few farmers organized in farmer schools to show them the advantages of transformed potato plants within an integrated nematode management program.
- A strong formal seed production system to expand the use of nematode resistant potatoes.

Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenic plants

- Public awareness

Literature cited

China

Zhang Yongfei¹

Introduction

China is the largest potato producer in the world. According to the 1998 Yearbook of Chinese Agricultural Statistics, more than 4 million ha are planted with potatoes, with an average yield of 14.18 tons/ha. Realizing the great potential of potato, both for food safety and as a cash crop for resource-poor farmers in the remote areas, the government has been emphasizing the distribution and production of virus-free based quality potato seed and the promotion of potato processing. Relevant research to improve potato quality (both conventional and GM breeding) is encouraged. During the past 15 years, genetic engineering has been used diversely by Chinese scientists for virus resistance, fungi resistance and tuber quality improvement. This profile aims to give a brief introduction on the utilization of GM crops in China with reference to potato.

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

The major constraints are viruses, late blight, insects, frost, reduced sugar content, starch characteristics and protein content.

National research organizations with the capacity to develop GMOs

- Academia Sinica
- CAAS (China Academy of Agricultural Sciences)
- Universities

Institutions working with potato GMOs

- Biology Department, Peking University
- Genetics Institute, Academia Sinica
- Biotech Center, CAAS

Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of perceived importance are

Gene transfer of constructs to other pests

Effects on non-target organisms

¹ Yunnan Normal University, Kunming, Yunan Province, China
Food safety
Stability of transgenes
Gene flow to related cultivated species
Seed systems for production and distribution
Control of variety purity/identification

Major policy concerns for deployment and uptake of GMOs

Food safety and acceptance
Biosafety
Intellectual property rights

Status of transgenic potatoes release

Release to farmers
Transgenic potatoes with PLRV/Y-R and late blight resistance traits have been released to farmers for commercial production. The inventor is Peking University.

Controlled research trials
Transgenic potatoes with the casein gene invented by Fudan University, Plant Institute of Academia Sinica have been tested in controlled research trials.

Other GMO crops
Other GMO crops are Bt cotton, cDNA reverse DNA sequence tomato, and amylase GM paddy rice.

Biosafety regulations

There is biosafety committee and biosafety regulations are in place.

Components of a strategy for the successful release of transgenic potatoes

Multiple resistances: The limited release of the transgenic virus-resistant potato into commercial production is not satisfactory because these plants have little resistance to late blight.

Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenic plants

- Increase of productivity
- Improvement of quality
- Biosafety
Colombia

Orlando Acosta

Introduction

Colombia, a country in the Andes where the potato originated, is located in the northwest of South America. The total area under potato cultivation is about 160,000 ha, producing an average of 2,850,000 tons/year. Potato yields per hectare have remained between 18–20 tons during the last decade (Niederhauser, 1993; Lujan et al, 1991; Acosta et al, 1994; Porras, 2000, personal communication).

The potato growers represent 90,000 families, more than 80% are poor farmers working small plots of land. The Colombian Federation of Potato Growers (Fedepapa) was launched in 1975 with the aim of improving potato production and marketing in Colombia (Herrera, 1992).

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

The major limiting factors, biotic and abiotic, to potato production that can be addressed by transgenic technology are pests, disease, frost, drought and high humidity. All these factors affect potato yields in cultivated areas in different proportions.

A systematic program was started in 1948 to improve potato crops (Gómez, 1990; Estrada, 1989), and to date more than 26 potato cultivars have been produced by the Colombian Institute for Agriculture and Livestock (ICA) breeding program (Gómez, 1990; Lujan and Arevalo, 1992). During the last two decades, many growers have been supplied with thousands of tons of certified basic seed of Colombian Purace, Pastusa, Monserrate and Capiro cultivars. However, even these improved crops are constantly under the threat from many insects, nematodes, fungi, bacteria, viruses and viroids, which, individually or in combination, can cause severe damage or disease.

Insects

*Tecia solanivora* (“polilla Guatemalteca”) is the most devastating insect, producing serious damage to Colombian potatoes (Del Valle, 1997). This tuber-attacking insect is already spread throughout the country. *Premnotypes vorax* (white worm) affects tubers in cultivated potato crops at more than 2,900 meters above sea level, while several species of “chizas”, including *Ancognata escarabaideae*, cause damage in tubers growing in the region of Antioquia and on the Savannah of Bogotá. These three insects are responsible for losses ranging from 10 to 50%. However, some promising potato clones resistant to insect attack have been recently reported (Estrada, 2000).

Viruses

In surveys of some Colombian potato producing areas, PVX, PVY, PLRV and PVS have often been found (Acosta et al, 1994). Most of the commercially important Colombian potatoes are, to a greater or lesser extent, susceptible to PVX, PVY and PLRV. Losses caused mainly by co-infections with these viruses have been estimated to reach 65% in particular cultivars (Acosta et al, 1994). Yield losses caused by PVX, PVY and PLRV can differ according to the altitude of the area where the potatoes were grown (Sanchez et al, 1991). The average losses caused by potato viruses can be higher than 20%.

1 National University of Colombia, Bogotá, Colombia.
Fungi
Late blight caused by *Phytophthora infestans* is the most important fungus disease in Colombia, being distributed throughout the whole country. Fungicide and insecticide costs account for more than 9% of total potato production cost (Anon, 1993).

Frost
The losses caused by frost (-3° to -6°C) account for up to 30% of annual production (Estrada, 1987). Frost affects potato crops mainly in January and February and occasionally in July.

Drought
This abiotic limiting factor reduced yields during 1977 by more than 10%.

High humidity
Flooding in potato growing areas has produced yield losses from 10 to 15%. The quality of tubers designated for processing is seriously affected by humidity, leading to decreased dry matter content. During 1998 and 1999, the processing industry rejected about 20% of tubers affected by this limiting factor.

National research organizations with the capacity to develop GMOs

The common use of techniques such as tissue culture, rapid propagation and virus indexing methods is aiding the introduction of genetic engineering techniques. The following national institutions are involved in developing GMOs:

- **IBUN** (Biotechnology Institute, National University of Colombia) has reported the production and characterization of transgenic tobacco plants resistant to the PPT herbicide (Chaparro et al, 1995; Moreno et al, 1998). IBUN has also produced transgenic potato plants (Franco-Lara, 1995; Franco-Lara, 1998; Franco-Lara and Barker, 1999). IBUN also regularly gives training in transgenic technology (Acosta and Webster, 1996).

- **CORPOICA** (Colombian Institute for Agriculture and Livestock Corporation) is dedicated to engineering banana plants having durable resistance to CMV.

- **CENICAFE** (National Coffee Research Center) is testing coffee plants transformed by the chitinase gene under greenhouse conditions. The purpose of these experiments is to protect coffee plants from insect attack.

- **CIB** (Biological Research Corporation) has recently obtained a Bt transgenic potato.

- **Plant Biotechnology Unit of Javeriana University** is trying to confer resistance to potyvirus infection in *Passiflora edulis* and *P. mollisima* (Colciencias, 1998).

Institutions working with potato GMOs

IBUN, in co-operation with SCRI (Scottish Crop Research Institute, UK), has produced transgenic potato (*Solanum phureja* cv. Egg yolk) plants expressing the PLRV coat protein (CP) gene. The pSCR107 foreign gene construct, containing the selectable marker gene *nptII*, was used. The transformants were selected with kanamicin. Greenhouse trials are being conducted to test PLRV resistance in the transformed lines.

CIB is involved in testing *CryI A(b)* gene expression in transformed potato (*Solanum tuberosum* cv. Diacol Capiro) plants. These plants were transformed with the foreign gene construct pKC2301 and also selected with kanamicin.
Major technical concerns for deployment and uptake of GMOs

Gene flow
Because Colombia is at the center of potato origin, several technical concerns have been raised by the National Biosafety Committee about the deployment and uptake of transgenic potatoes. These concerns include gene flow to related wild species such as *Solanum andreanum* and *Solanum estradai*, to related cultivated species (*Solanum tuberosum*) and to potatoes of the same species (at least 112 accessions).

Food safety
According to food safety guideline standards for allergens and toxins, evaluation of tubers from Bt potatoes for toxicity and allergenicity is required. In Colombia, tubers from non-transgenic potatoes have tested positive to PLRV CP in up to 20% of the crop in particular areas.

Effects on non-target organisms
The effect of Bt potatoes against non-targeted insect soil populations and against other wild species must be evaluated.

Gene transfer to of constructs to other pests
The well-documented detection of recombination between host RNA and an infecting virus genome has given rise to new concerns about the release of virus resistant transgenic potato because recombination could generate viruses having properties different from the infecting strain.

Control of variety purity/identification
ICA is in charge of the evaluation of new varieties. However, ICA needs additional investment to build up greater capacity for carrying out the evaluation of the uniformity and stability of the transgenic varieties.

Major policy concerns for deployment and uptake of GMOs

National policy concerns about the deployment and uptake of GMOs were recently raised, mainly during and after the International Biosafety Conference held in 1999 in Cartagena, Colombia. Ill-informed journalists linked to Greenpeace initiated a campaign against the introduction of transgenic products. Thus, many consumers now perceive GMOs as being risky. The public perception of GMOs is exaggerating the actual risk involved. However, former Colombian president Alfonso López Michelsen is encouraging the private production sector to adopt transgenic crops as a contribution to the reactivation of the economy in this sector.

Food safety and acceptance
Given that the concept of GMOs is just starting to be understood, it is necessary that food safety be ensured. Public perception and acceptance of these issues might be addressed mainly by public education, scientific capacity and systematic dialogue.

Biosafety
The major policy concerns regarding biosafety include the need to preserve the genetic resources from possible impacts of GMOs, and the need to address the public perception of GMOs as being potentially hazardous.

Intellectual property rights
IPR issues concerning transgenic potato crops will involve negotiation with the developers of transgenic technology. The transgenic potato technology used to date has been under the umbrella of research purposes.
Monitoring and testing of transgenes
The monitoring and testing of the transgenes will be the responsibility of the National Biosafety Committee in agreement with the developer of the potato transgenic technology.

Status of transgenic potatoes release

Release to farmers
No transgenic potato has been released to farmers for commercial production.

Controlled research trials
No transgenic potatoes are being tested in controlled field trials.

Other GMO crops
There are no GMO crops in the field.

Biosafety regulations

There is a resolution issued by ICA, in which, according to the faculties conferred to it by law, the object and scope of the regulations regarding the introduction, production, release and marketing of GMOs are defined. The resolution also contains several definitions about biosafety, risk-assessment, and release into the environment, among others. The procedures for submitting requests, infractions and sanctions are included.

ICA considers, among other things, that: (1) GMOs contribute significantly to the production of food and raw materials, but may in their turn constitute a real or potential threat to agriculture, livestock production and agro-ecosystem sustainability; and (2) It is necessary to preserve Colombia’s genetic resources from the possible effects that the GMOs could have on their sustainable conservation.

The ICA board of directors has created the National Biosafety (Technical) Committee (CNT) for the introduction, production, release and marketing of GMOs. The CNT is composed of 11 members belonging to the private production sector, ICA’s biosafety and genetic resources unit, the Ministry of Agriculture, Ministry of Health, Ministry of the Environment, the National University of Colombia and the National Association of Farmers. This committee advises ICA about biosafety regulations and policy.

Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenic plants

Several issues have been raised in this context — including the labeling of engineered foods, public perception, ecological risks, possible transgene spread from potato, restriction to traditional varieties, monopolies from seed supermarkets and the limitations to transgenic technology development. Within the latter are low public and private investment in biotechnology research, poor relationships between research centers and the productive sector, low capacity in high technology management, marketing and commercialization, no venture capitals for investment in new biotechnological enterprises and low investments in high level training (Colciencias, 1999).
Literature cited


Introduction

It is not known exactly when the potato was introduced into Cuba. The first written reference appeared in 1778. In 1993 the 10 ton/ha average yield was greatly surpassed for the first time in the history of this crop in Cuba. This increase has been maintained, and potato yields are presently over the world average. The cultivated area of potato is about 16000 ha. Weather conditions are a great constraint for potato cultivation in Cuba because cold fronts are necessary for obtaining good tubers. The fungal diseases *Alternaria solani* and *Phytophthora infestans* make compulsory 10 or 12 fungicide applications in a crop cycle. The virus PLRV, the insect *Thrips palmi* and the acarus *Poliphagotarsonemus latus* are also important because they cause crop losses.

Transgenic potatoes resistant to fungi, insect or virus could be important for the better use of chemicals and for higher yields. Tolerance to herbicides is a trait of interest for modifying the potato because of the high use of this technology. The development of the processing and industrialization of potato requires varieties with low levels of reducing sugar and a high content of solids. This could be possible from modified potatoes. The development of transgenic potatoes is part of the National Program of Potato whose main objective is to satisfy the needs of the Cuban people.

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

The major constraints are fungal diseases caused by *Alternaria solani* and *Phytophthora infestans*, tolerance to herbicides and modification of potato for the industry.

National research organizations with the capacity to develop GMOs

- Genetic Engineering and Biotechnology Center, Havana, Camaguey and Sancti Spiritus
- Center of Plant Biotechnology, province of Ciego de Avila
- Institute of Plant Biotechnology, Villa Clara

Institutions working with potato GMOs

- Genetic Engineering and Biotechnology Center

Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of their perceived importance are

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1 Centro Nacional de Seguridad Biological, La Habana, Cuba
Food safety
There is concern regarding the existence of allergens and toxins. This is the major technical concern for the deployment and uptake of GMOs in Cuba.

Effects on non-target organisms
This is other major technical concern — for example, the effects on micro-organisms of the soil, because they are not completely known. This is considered very carefully when analyzing risks.

Gene transfer
The antibiotic resistance is a concern. Work is being done to eliminate it. There are some species of Solanum that constitute weeds. This is not a concern because of the non-flowering characteristic of potato plants in Cuba.

Stability of transgenes
Field trials are done at least 3 years before releasing the potatoes.

Seed systems for production and distribution
These activities are in the hands of state bodies

Control of variety purity/ identification
Every year the government regulates the seeds to be sold and bought.

Gene flow
Cuba is not the origin of any cultivated species so this is not a concern. Cuba is a center of domesticated species. The only cultivated solanaceae is Solanum tuberosum. Potato plants generally do not blossom in Cuba. Reproduction is not by seeds, but by asexual reproduction.

Major policy concerns for deployment and uptake of GMOs

Food safety and acceptance/Biosafety
Biosafety comprises both food safety and the monitoring and testing for transgenes. It also includes planification of public education regarding GMOs.

Intellectual property rights
They are considered through the rights of the person who obtains the GMO.

Status of transgenic potatoes release

Release to farmers
No transgenic potatoes have been released to farmers.

Controlled research trials
Transgenic potatoes with resistance to late blight have been released for controlled research trials. The inventor is the Genetic Engineering and Biotechnology Center. The test was carried out in experimental center for the genetic enhancement with unmarked areas, limited access and trained personnel.

Other GMO crops
Other crops such as papaya, sweet potato, and sugar cane have been released for testing in controlled research trials.
Biosafety regulations

The National Center for Biological Safety was created in 1996. The Ministry of Science, Technology and Environment has adopted the Decree Law 190 for Biological Safety, the Resolution 42/99 for the classification of biological agents and the Resolution 8/00 for facilities.

Components for a strategy for the successful release of transgenic potatoes

The assessments were made in research centers with trained personnel and strong biosafety regulations. The genetic enhancement is considered part of the national seed system. I consider it necessary to strengthen the links among the state bodies in charge of all the process.

Major issues affecting successful government approval, uptake, deployment and acceptance of potato transgenic plants

- Proof of the safety of the product for man and animals.
- Proof of the low level of risk to the environment.
- Preparation of the public for the acceptance of the transgenic plants.
India

Prakash S Naik¹, D Pattanayak¹ and S K Chakrabarti¹

Introduction

Biotechnological research in India is mainly confined to the various research institutes under the Indian Council of Agricultural Research, Council of Scientific and Industrial Research, universities and few private sector companies. Biotechnological advances in Indian agriculture have so far been mostly limited to the development and utilization of tissue culture methods for crop improvement and multiplication. The most successful activity in this area has been the micropropagation of elite planting material. The development of high tech products through recombinant DNA technology is still at the experimental and evaluation stage in the country. However, with the availability of a reasonably good infrastructure in more than a dozen laboratories and the trained manpower spread over the major research organizations, the country is well positioned to exploit genetic transformation technology for crop improvement. Specific goal-oriented genetic transformation projects on nationally important crops, such as rice, mustard, cotton, potato, etc., have been initiated in the country. Potato (Solanum tuberosum) is the most important non-cereal world food crop and is next to rice, wheat and maize in terms of total production. Presently, in India the potato production area is about 1,136 million ha, producing nearly 19,237 million tons with an average yield of 16.9 tons/ha. India ranks fifth in area and production globally. Potato produces more dry matter, protein and calories per unit land and time than that of any other major food crops. The high productivity, nutritional quality and amenability to genetic manipulation make potato a choice crop for developing transgenic plants on diverse parameters. In developed countries potato has already been identified as the target crop species for improvement by genetic engineering. A recent survey of biotechnology related projects in the European Union revealed that the most represented crops in descending order were potato, oilseed rape, wheat, maize and barley. In India the traits that are being improved in potato through genetic engineering are tolerance to insect pests, resistance to late blight and improvement in nutritional quality.

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

Production

Late blight, bacterial wilt, viruses, the potato tuber moth and sensitivity to high temperatures are the major production constraints best addressed by transgenic potatoes. Tolerance to higher temperatures would enable the extension of potato cultivation into the warmer regions of the country.

Utilization

The alteration of the carbohydrate metabolism for the industrial production of cyclodextrin, fructan, and quality starch would overcome certain utilization constraints. The production of vaccines for major livestock diseases such as Rinderpest and Foot and Mouth Disease of cattle, and New Castle disease of poultry are new utilization possibilities.

¹ Central Potato Research Institute, Shimla, India
There are several research organizations in India that have the expertise and capability to develop GMOs. Some of the important organizations are listed below:

- CCMB (Center for Cellular and Molecular Biology), Hyderabad
- NRCPB (National Research Center on Plant Biotechnology), Indian Agricultural Research Institute, New Delhi
- NCPGR (National Center for Plant Genome Research), Jawaharlal Nehru University, New Delhi
- University of Delhi, Delhi
- IISc (Indian Institute of Sciences), Bangalore
- Bose Institute, Calcutta
- NBRI (National Botanical Research Institute), Lucknow
- MKU (Madurai Kamraj University), Madurai
- BARC (Bhabha Atomic Research Center), Trombay, Bombay
- NII (National Institute of Immunology), New Delhi
- IMTECH (Institute of Microbial Technology), Chandigarh
- TNAU (Tamil Nadu Agricultural University), Coimbatore
- ICAR (Indian Council of Agricultural Research), many constituent institutes, including CPRI (Central Potato Research Institute), Shimla

Institutions working with potato GMOs

The mandate crops and biotechnological aspects are different for each of the above research organizations. The Central Potato Research Institute (CPRI), Shimla, is the only research organization in India that is exclusively working on potato. This institute, in collaboration with the National Research Center on Plant Biotechnology (NRCPB) and National Center for Plant Genome Research (NCPGR), has developed and is developing transgenic potatoes possessing:

- Resistance/tolerance to late blight
- Resistance/tolerance to potato tuber moth
- Superior nutritional (protein) qualities

Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of their perceived importance are

Food safety

Food safety guidelines for allergens and toxins are under:

- Allergenicity evaluation of genetically transformed products
  - In vivo assays
    - Passive cutaneous anaphylaxis (PCA) test
    - Pransnitz-Kustner (PK) test
  - In vitro assays
    - Radio-allergosorbent (RAST)/RAST inhibition test
    - Enzyme linked immunosorbent assay (ELISA)
- Toxicity evaluation of transgenic seeds
  - Acute oral toxicity test in rat [Adoption: Organization of European Cooperation and Development (OECD) 401]
- Sub-chronic (90 days) oral toxicity test in rat (Adoption: OECD 408)
- Primary skin irritation test in rabbit (Adoption: OECD 404)
- Irritation to mucous membrane test in female rabbit (Adoption: OECD 405)
- Skin sensitization test in guinea pigs (Adoption: OECD 406)
- Sub-chronic (90 days) oral toxicity test in goats

Toxicity evaluation of transgenic vegetables
- Acute oral toxicity test in rat (Adoption: OECD 401)
- Sub-chronic (90 days) oral toxicity test in rat (Adoption: OECD 408)
- Primary skin irritation test in rabbit (Adoption: OECD 404)
- Irritation to mucous membrane test in female rabbit (Adoption: OECD 405)

Toxicity evaluation of transgenic leaves
- Sub-chronic (90 days) oral toxicity of leaves in male rabbit (Adoption: OECD 408)

Stability of transgenes
This is an important aspect, particularly for the transgenic varieties possessing resistance to insects and/or diseases. The breakdown of resistances in these varieties due to the evolution of new complex pathogenic races or the development of resistance in casual organisms needs to be monitored regularly. Gene pyramiding is an attractive option for incorporating durable resistances.

Effects on non-target organisms
The following information needs to be provided prior to the deployment of GMOs.
- Effect on non-target insects, birds, fish and animals, including mammals and wild life of extensive exposure to transgenics.
- Plans for protecting human and animal health from undesirable effects.

Gene flow
- To related wild species.
- To related cultivated species.
- To other potatoes of the same species.

When seeking non-regulated status for transgenic plants under the Environment (Protection) Act 1986, the following information on gene flow is essential:
- Taxonomy, genetics, pollination pattern, etc.
- Description of the relatives and near relatives of the transgenic plant in the ecosystem.
- Methods of pollen dispersal in target plants and in its relatives.
- Gene transfer to non-transgenic lines, including near relatives, and percentage of transfer under specific field conditions.
- Out-crossing potential including pollen transfer to cultivated genotypes and wild species, and its implications.
- Implication of transfer of genetic information to species to which it can interbreed.

Gene transfer to other pests
- Weeds
- Viruses, disease organisms, nematodes

The description of the transgenic insert and information on its ability to establish itself in other hosts (weeds, viruses, nematodes, etc.) must be provided.

Control of variety purity/identification
This would be taken care of by the seed-producing agency(ies).

Seed systems for production and distribution
- Once a transgenic variety is approved for commercial cultivation by the Review Committee for Genetic Manipulation (RCGM) [based on the report of the Monitoring-cum-Evaluation Committee
Transgenic potatoes for the benefit of resource poor farmers in developing countries. 

The Genetic Engineering Approval Committee (GEAC), production and distribution of its seed should not be difficult. I presume that the guidelines would be the same as that for seed production in traditional varieties (Legislation on Seeds, Seed Act, 1966).

Deployment of GMOs with Terminator Gene Technology that prevent small holder farmers from holding and replanting seeds may lead to the selective elimination of resource poor farmers in developing countries.

Major policy concerns for deployment and uptake of GMOs

Food safety and acceptence
Prior to the acceptance of transgenic food, proof of food safety, as determined by the various tests listed in the previous section under “Food Safety” is essential.

Biosafety
The major policy concerns for biosafety are the potential of GMOs to become weeds, gene flow from GMOs to other organisms, the impact of GMOs on biodiversity and the capacity of pest and pathogens to adapt to the cultivation of GMOs.

Intellectual property rights
A major IPR concern is the broad nature of the patents for products, processes and crops already awarded to several private sector companies in industrialized countries. The application of IPR to agriculture needs rethinking because technological development in agriculture, particularly in developing countries, is primarily driven by public investment and the developed products are considered “public goods”. In the words of Ismail Serageldin, a “scientific apartheid” is likely to emerge due to the growing gap between developed and developing countries in the generation of scientific knowledge in biotechnology. Therefore, public-private partnerships are needed to meet the challenges in 21st century.

Monitoring and testing for transgenes
The Review Committee on Genetic Manipulation (RCGM) of the Department of Biotechnology (DBT) regularly brings out guidelines specifying procedures respecting activities involving GMOs to ensure environmental safety. For rigorous monitoring and evaluation of transgenics a Monitoring-cum-Evaluation Committee (MEC) consisting of experts drawn from user Ministries has been incorporated in the Revised Biosafety Guidelines, 1998. Field testing of transgenics is done under strict supervision by MEC. After thorough investigations on biosafety aspects, MEC submits its recommendations to RCGM. The latter recommends environmentally safe and economically viable transgenics to the Genetic Engineering Approval Committee (GEAC) for consideration for release into the environment.

Status of transgenic potatoes release

Release to farmers
No transgenic potatoes have been released to farmers for commercial production.

Controlled research trials
The Ama1 gene cloned from Amaranthus hypochondriacus that produces Ama1 protein rich in all amino acids, including lysine, tryptophan and sulfur-containing amino acids, has been introduced into the dihaploid potato line A-16 at the NCPGR. The effectiveness of this gene in improving nutritional quality has been tested under controlled research trials. The research group at the NCPGR is led by Dr. Asis Datta who is also Vice-Chancellor of the Jawaharlal Nehru University, New Delhi, and Chairman of RCGM.
In collaboration with the NRCPB and NCPGR, CPRI is using three traits in controlled research trials. These traits are:

- Synthetic Cry1Ab for the control of potato tuber moth.
- Ama1 gene cloned from Amaranthus hypochondriacus.
- Tobacco osmotin gene for control of late blight.

At CPRI, controlled research trials have been conducted with cry1Ab transgenic lines of Indian potato cultivars and an application has been presented to seek permission from the RCGM for open field trials in hot spot areas. The transgenic lines developed using the other two genes are under testing. Dr. PS Naik, Sr. Scientist, leads the research group at the CPRI.

**Specific release or test requirements**
The important requirements for Cry1Ab would be food safety, effect on non-target organisms, efficacy and economic viability. The requirements for Tobacco osmotin are the same as those for the Cry1Ab gene. Because the gene Ama1 has been isolated from an edible plant, it is likely to be safer than others. However, the protocol laid down by RCGM needs to be followed.

**Other GMO crops**
The GMO crops in advanced stages of testing are rice, mustard, tomato, brinjal, cauliflower and cabbage.

The first genetically engineered variety, released last week for commercial cultivation, is Bt cotton developed by Monsanto and Maharashtra Hybrid Corporation.

**Biosafety regulations**

Biosafety regulations and biosafety committees at various levels, starting from the nodal point (i.e. research organization) to the final release in environment are in place.

**Components of a strategy for the successful release of transgenic potatoes**

Transgenic potatoes have not been released in India for commercial cultivation.

**Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenic plants**

The following facts about potato in India makes the crop more amenable for biosafety regulations:

- Potato is not native to India and hence there are no wild species of this crop in this country.
- More than 80% of potatoes are grown on the sub-tropical plains of the country under short day conditions where most of the potato genotypes do not flower.
- Potato harvesting is followed by severe summer weather, which does not permit the survival of volunteer plants.
- Over-cooking of foodstuffs is a normal practice in India.
- Evaluation of potato GMOs and their final release into the environment must be strictly in accordance with the biosafety norms laid down by the government of India.
- The GMOs in question should have a convincing edge over the existing potato varieties and the alternate technologies available in India.
- Public awareness: In view of the anti-GMOs campaign launched by NGOs, it is essential to educate consumers and farmers about the technology and to make it more transparent and acceptable.
Kenya

Charles Lung’aho

Introduction

The potato (Solanum tuberosum) has been cultivated in Kenya since the end of the nineteenth century (Durr and Lorenyl, 1980) and is the second most important food crop after maize. It is a staple food for many rural and urban families and is increasingly becoming important as a cash crop for urban markets. Production has traditionally been concentrated in the highlands (1500-3000 meters above sea level) primarily due to favorable ecological conditions. However, due to diminishing land sizes and a high population growth rate, cultivation has recently expanded to the less productive marginal areas. Production is mainly carried out in scattered patches of intensive, small-scale agriculture (McArthur Crissman, 1989). Production inputs, particularly fungicides and fertilizers, are utilized at rates, which are well below the economic optimum. Current production is estimated at 840,000 tons per year in two growing seasons. The area cropped to potato ranges between 90,000 — 100,000 ha per year with average yields of less than 10 tons/ha.

Among the more than sixty varieties grown in the country, only a few are widely distributed. Distinct seasonal patterns of supply and demand and the dominant role of the inter-regional trader characterize the marketing of potatoes in Kenya. The inter-regional trader purchases potatoes directly from the field and forms the main link between producing areas and urban markets. Ware potatoes are mainly sold at harvest, with storage for future sale seldom practiced. Consumption is growing in urban areas and in traditional zones of production. However, it is low in non-producing rural areas. Processing for chips, mainly from fresh potatoes, has expanded in recent times. Crisps are still cooked and packaged in small-scale operations with variable packaging and product quality. The basic problem facing potato growers in Kenya today is low yields, which are the result of high losses due to diseases and the lack of adequate quantities of healthy planting material.

Major constraints to the production and utilization of potatoes that can be addressed best by transgenics

Late blight and bacterial wilt are the main diseases. Bacterial wilt is both a cause and a symptom of the problems in all stages of the seed production system. Potato tuber moth is a serious pest in the non-traditional production sites. Potato leaf roll virus is the major cause of seed degeneration. Frequent droughts are an important constraint.

National research organizations with the capacity to develop GMOs

- Kenya Agricultural Research Institute (KARI)
- Moi University

KARI is working on transgenic sweetpotato. Moi University is working on Sorghum and simsim transformation.

1 Kenya Agricultural Research Institute, Limuru, Kenya
Institutions working with potato GMOs

No institution is working on transgenic potatoes at present.

Major technical concerns for deployment and uptake of GMOs

Kenya is one of the few countries in Sub-saharan Africa with functional biosafety guidelines in place. These have been employed in enhancing the development and deployment of the virus resistant sweetpotato for Africa, promoting the biotransformation laboratory developments and ensuring that both technical and national policy concerns are addressed.

The National Biosafety Committee raised several technical concerns regarding the deployment and uptake of transgenic sweetpotatoes. Similar concerns are likely to be raised if transgenic potatoes are introduced in Kenya. These, in order of their perceived importance, include:

Gene flow
- Cross-hybridization of genetically enhanced potato with wild relatives.
- Can the introduced genes prejudice the beneficial functions of the potato or related organisms in the environment?
- What is the ability of the transgenic potato to reproduce spontaneously, and does the modification change the plant’s phenotype?

Food safety
- Can the genetically enhanced potato cause disease or ill health to humans, plants and animals?
- What is the likelihood that the introduced gene could cause and increase in toxicity for animals and humans?

Effects on non-target organisms
- Can the construct transfer to other natural pests, such as weevils, virus, nematodes?
- What is the effect of the transgenic potatoes on the wild and agricultural biota in the habitat?
- The possible/potential development of resistance to virus coat protein in natural pests, such as bacteria, fungi, weevils, etc.

Gene transfer of constructs to other pests
- Can trans-encapsulation with incoming virus occur and what are the effects?
- The ability of the construct to transfer to other hosts e.g., aphids, potato tuber moth, nemathods, and what is the result?

Seed systems for production and distribution
- KARI is presently the sole producer of pre-basic seed potatoes through its Foundation Seed Unit. The production consists of several steps during which an initial disease-free source of planting material is multiplied in a tissue culture laboratory, screenhouses/glasshouses and open fields.
- Farmer multipliers, following established certification standards within a formal set-up, would do subsequent multiplications. A vibrant informal sector that accounts for over 90% of the seed potatoes also exists.

Control of variety purity and identification
- The administrative process of evaluation and release of new varieties is conducted under the auspices of KEPHIS (Kenya Plant Health Inspectorate Service). The performance data of the transgenic potato plants would have to be submitted to the specialist variety committee, which compares them to existing varieties.
National Performance Trials (NPTs) are conducted for at least three seasons in different agro-ecological zones. The distinctness, uniformity and stability trials (DUS) are carried out by KEPHIS. They are designed to assure the stability of varietal characteristics over several generations and to assist in compiling the technical information for official listings.

Subject to good results from NPTs and DUS trials, the specialist variety release committee forwards a recommendation for release to the National Variety Release Committee.

Stability of transgenes

- The stability of introduced genetic material in the potato lines.

Major policy concerns

In addition to the above technical issues, national policy concerns on the deployment and the uptake of transgenic sweetpotato in Kenya were raised. It is expected that such issues will be raised in case transgenic potatoes are introduced in the country. Such issues include:

Food safety and acceptance

Given the level of understanding of GMOs in the country, the food crisis situation in Africa and the level of hunger, starvation and malnutrition, the debate on food labeling and acceptance of GMOs has not been a major issue in Kenya. Safety for humans and animals for such foods (like any other food/fee product) must be ensured. The main opposition may lie at the personal moral acceptance, but this can be addressed by open dialogue and balanced information.

Biosafety

The development and uptake of all genetically modified organisms in Kenya are governed by and must meet the national biosafety requirements. The development and implementation of this structure in Kenya has been painstakingly slow, understandably so because this was the first case.

Intellectual property rights

Issues of intellectual property rights regarding the deployment and transfer of transgenic potatoes in Kenya will have to be negotiated with the developer of the transgene, perhaps through ISAAA (International service for the Acquisition of Agri-Biotech) – Afri-Centre. A royalty-free License Agreement to operate transgenic potato technology in Kenya would be in order.

Monitoring and testing of transgenes

- The laboratory, greenhouses and on-station evaluation of the transgenic potato is expected to remain the responsibility of KARI and the developer of the transgenic potato. In the case of sweetpotato the responsibility was KARI’s and Monsanto’s.
- The monitoring and assessment of the evaluation process would be the responsibility of KARI’s Biosafety Committee, KEPHIS and the National Biosafety Committee (NBC), the first on behalf of the Institute, and the latter two for the government.

Status of the release of transgenic potatoes

Release to farmers

No transgenic potatoes have been released to farmers for commercial purposes.

Controlled research trials

There have been no controlled research trials with transgenic potatoes.
Other GMO crops
No other transgenic crops have been released to farmers for commercial production.

Biosafety regulations

Kenya has developed and is implementing a national biosafety structure. This is comprised of National Biosafety Regulations and Guidelines for Biosafety and Biotechnology of 1998 and a National Biosafety Committee (NBC) composed of people from different organizations and levels in Kenya. Currently the structure is operated under the umbrella of the National Council for Science and Technology in the Ministry of Education, and efforts are underway to find better homage for the structure and legalize it through an Act of Parliament.

Components for a strategy for the successful release of transgenic potatoes

In approving the release for testing of transgenic sweetpotatoes, Kenya has applied the following strategy:

- Confirming at laboratory level gene integration and expression, using laboratory based techniques such as PCR.
- Greenhouse virus challenge and the establishment of protection, using techniques such as tissue printing.
- On-station virus challenge and agronomic studies at KARI centers for at least 4 seasons.
- Following a review of the data from on-station studies and further NBC approval, trials to move to on-farm evaluation with farmer involvement to establish protection, agronomic performance, consumer valuation and acceptance, concomitantly with the following:
  - Food safety assessment, including toxicity evaluations and substantial equivalence
  - Bulking and distribution will have to take into account partners in technology up-scaling, product performance and dissemination, farmer management training, product uptake pathways, and marketing and socio-economics issues.
  - Regional distribution and dissemination will have to consider regional biosafety structures/ harmonization, regional technology sub-letting agreements and technology transfer and adoption

It is expected that a similar approach would be followed in the case of transgenic potatoes.

Major issues affecting the successful government approval, uptake and development of potato transgenic plants

- Non-restrictive intellectual property rights access of technology for farmers
- Presence of adequate biosafety capacity for reviewing and monitoring product performance
- Proof of the successful environmental performance of the transgenic potatoes
- Food safety issues adequately addressed
- Establishment of uptake pathways for adoption and use of products

Literature cited


Mexico

Ariel Alvarez-Morales¹ and Rafael Rivera¹

Introduction

During the period 1988 to March 2000, Mexico has approved 150 proposals for field trials for 18 different transgenic crops. The most widely tested crops have been maize, tomato, cotton, soybean and squash. The most commonly tested traits are insect resistance, herbicide tolerance, delayed ripening and virus resistance. In terms of commercialization, only the FLAVR SAVR tomato of CALGENE and ZENECA have been totally deregulated and thus can be grown and sold in Mexico without any restriction. Bt-potato and rapeseed modified for its oil content can be imported and consumed because the Secretary of Health has approved them. However, neither are allowed to be freely grown in Mexico. Bt-cotton is also being grown in large extensions. This crop is being closely followed by independent scientists to assess the effectiveness of the strategies employed to avoid or delay insect resistance, such as the use of non-transgenic refugia. Until November 1999 the evaluation of proposals to conduct field trials or pre-commercial releases of GMOs was carried out by what was then known as the National Biosafety Committee for Agriculture (CNBA). Since the beginning of 2000, a new biosafety structure has been set up. The new regulatory body is an intersecretarial commission, which includes the following State Secretaries: Education, Commerce, Human Health, Agriculture, Environment, and Science and Technology. They conform what is known as the intersecretarial Commission of Biosafety and Genetically Modified Organisms (CIBIOGEM). CIBIOGEM has an advisory body, the Consultative Council for Biosafety, which is formed by a group of independent scientists covering a wide range of disciplines that are related to the possible release and use of transgenic organisms as food, feed or for industrial purposes. Under the new regulatory structure, Mexico will revise, update and implement homogenous legislation that will address the needs and concerns of the public, research groups and industry, taking also into account the new international agreements such as the Cartagena Protocol.

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

Viral and fungal infections are the major constraints best addressed by transgenics.

National research organizations with the capacity to develop GMOs

- CINVESTAV IPN–Irapuato
- The Autonomous University of Aguascalientes
- INIFAP
- National Autonomous University

Only CINVESTAV and the Autonomous University of Aguascalientes are presently working with GMOs.
Institutions working with potato GMOs

CINVESTAV IPN– Irapuato is working with transgenic potatoes.

Major technical concerns for the deployment and uptake of GMOs

The major technical concerns in order of perceived importance are

Food safety
Toxins: Increased levels of alkaloids

Effects on non-target organisms

Seed systems for production and distribution

Control of variety purity/identification

Property rights

Major policy concerns for deployment and uptake of GMOs

Food safety and acceptance
There is no formal food policy for GMOs at present.

Biosafety
Biosafety is not a policy concern at this time.

Intellectual property rights
Intellectual property rights are not presently an issue.

Monitoring and testing for transgenes
This is not a policy concern at the moment.

Status of transgenic potatoes release

Release to farmers
No transgenic potatoes have been released to farmers for commercial production.

Controlled research trials
Transgenic potatoes with virus resistance have been tested in controlled research trials. The inventor is Cinvestav-IPN. The following information was required:

- Detailed information regarding the genetic modification
- Detailed information of the reproductive biology of the potato
- Detailed information concerning distribution of wild relatives present in Mexico
- Detailed information regarding introgression between cultivated and commercial potatoes
- Information regarding any known instances of wild or commercial potatoes becoming weeds
- Levels of viral infection among non-cultivated and cultivated potatoes

Developing country profiles
Other GMO crops
Other GMO crops such as maize, tomato, cotton, soybean and squash have been tested in Mexico.

Biosafety regulations

There is a biosafety committee and biosafety regulations are in place.

Components of a strategy for the successful release of transgenic potatoes

The testing has been carried out together with the national agricultural research organizations.

Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenic plants

- Demonstration of the safety of the product as food and that the GMO is equivalent to the non-transformed potato
- Appropriate channels for distribution are needed
- Agricultural practices usually do not include buying potato seed, especially among low-income farmers
Nepal

Namita Maskay¹

Introduction

Potato (Solanum tuberosum L.) is one of the most important food crops in Nepal. It is a staple food for the people living in the highlands and a side dish for the people living at lower elevations. It occupies the fifth position in area and fourth in total production compared with the main staple crops of rice, maize, wheat and millet. Out of the total area planted with potato about 20% is in the high hills and mountains, 50% is in the mid-hills and 30% is in terai (southern plain).

In the Fiscal Year 1998/99, 110,000 ha were planted with potato with production of 1,091,000 tons and a productivity of 9.2 tons/ha. The productivity of this crop is very low compared with neighboring countries. One of the main reasons for this low productivity is the lack of good quality seed potatoes of varieties that are high yielding and disease resistant. Bacterial wilt of potato caused by Ralstonia solanaceaeum is one of the most destructive diseases of potato in the hills of Nepal. Yield losses have been reported from 5–100% in both field and storage conditions. This disease is difficult to manage due to the wide host range and soil and tuber-borne nature of the pathogen, and the non-availability of resistant varieties. Similarly, potato tuber moth (Phthorimaea operculella) is one of the most damaging pests of potato under both field and storage conditions. It may damage more than 50% in the field and up to 100% in storage. Due to these reasons transgenic potatoes resistant to potato tuber moth and bacterial wilt could be beneficial for the country, especially for the farmers.

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

There are serious problems with the bacterial wilt disease (causal organism Ralstonia solanaceaeum) in the field and in storage throughout the country. During storage huge losses of potatoes take place due to the potato tuber moth (Phthorimaea operculella). Therefore, potato tuber moth and bacterial wilt resistant transgenics are needed.

National research organizations with the capacity to develop GMOs

Presently, there are no organizations with the capacity to develop GMOs.

Institutions working with potato GMOs

There are none.

¹ Kathmandu, Nepal
Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of their perceived importance are

Gene flow
- To related wild species
- To related cultivated species

Gene transfer to of constructs to other pests
- Viruses, disease organisms, nematodes
- Weeds

Control of variety purity/identification

Effects on non-target organisms

Major policy concerns for deployment and uptake of GMOs

Food safety and acceptance
GMOs will probably be accepted if the effect against the major constraint is significant, and the product is completely safe for human health.

Biosafety
No biosafety regulations are in place at present.

Intellectual property rights
Not applicable at present.

Monitoring and testing for transgenes
This should be conducted in containment for research purposes.

Status of transgenic potatoes release

Release to farmers/Controlled research trials
No transgenic potatoes have been released for testing or for commercial purposes.

Other GMO crops
No other GMOs have been released for testing or commercial purposes.

Biosafety regulations

There is no biosafety committee, nor are there biosafety regulations in place.
Major issues for the successful government approval, uptake, deployment and acceptance of potato transgenic plants

- The Nepal Agricultural Research Council (NARC) insists that whoever imports transgenic materials should notify NARC so that records can be maintained.
- The Nepal Agricultural Research Council seeks support to develop biosafety regulations.
South Africa

Dave Berger

Introduction

Potato is second to maize in importance as a carbohydrate source for the people of South Africa. Currently, about 1.8 million tons of potato are produced per year with an estimated farm gate value of US$ 410 million. Most of the production is consumed locally (~30 kg/capita). Due to the diverse geographical regions in the country, fresh potatoes are available throughout the year. The potato industry is well organized with a seed certification scheme administered by Potatoes South Africa. There are about 10,000 ha of seed potato production, which supplies producers of table (ware) potatoes (50,000 ha), 60% of which are sold in seventeen fresh produce markets throughout the country. About 20% are processed (an expanding industry). In addition, there is an important informal sector of resource-poor farmers producing potatoes under dryland, low input conditions. This is mainly in the provinces of KwaZulu-Natal, Eastern Cape, Western Cape and the Northern Province. In line with the government’s policy of encouraging SMMEs (Small, Medium and Micro Enterprises), the Agricultural Research Council is working together with the Provincial Departments of Agriculture and NGOs to assist these farmers.

Major constraints to production and utilization of potatoes that can be addressed best by transgenics

The traits needed are resistance to late blight (Phytophthora infestans), potato tuber moth (Phthorimaea operculella), common scab (Streptomyces scabies), TSWV, PLRV, PVY and bacterial wilt (Ralstonia solanacearum).

National research organizations with the capacity to develop GMOs

- Agricultural Research Council (ARC-Roodeplaat, ARC-Infruitec)
- Council for Scientific Research (CSIR-Bio/Chemtek)
- University of Pretoria (Forestry and Agricultural Biotechnology Institute)
- University of Cape Town (Microbiology and Biochemistry Departments)
- University of Stellenbosch (Plant Biotechnology Institute, WineBiotech, Department of Genetics)
- University of Natal (Botany Department, Pietermaritzburg)

Institutions working with potato GMOs

- ARC-Roodeplaat

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1 ARC-Roodeplaat, Pretoria, South Africa
Major technical concerns for deployment and uptake of GMOs

The major technical concerns in order of their perceived importance are

**Intellectual property rights**
The lack of effective/novel transgenes that are free from intellectual property rights constraints.

**Marker genes**
The lack of methods for marker gene-free transformation or removal of marker genes after selection.

**Effects on non-target organisms**
No data on resistance management strategies (Bt gene) in South African environment.

**Gene flow**
Little data on the outcrossing of South African cultivars to related wild species or potatoes.

**Stability of transgenes**
Data are needed.

**Seed production systems**
Plant pathology problems in long term could appear due to farmers planting disease resistant transgenic potatoes outside the seed certification scheme.

**Gene transfer to pests**
The problem of marker genes.

**Food safety**
Novel Bt or Bacterial R gene have not been tested yet for allergenicity/toxicity. Research organizations lack strong IPR portfolio’s for IPR trading.

**Control of variety purity/identification**

Major policy concerns for deployment and uptake of GMOs

**Policy concerns**

**Food safety and acceptance**
- Public opinion follows world trend.
- Products benefit farmer, not consumer.
- No GMO food labeling regulations in place (Department of Health).
- Who pays for extremely costly toxicity/allergenicity tests?

**Biosafety**
- Resistance management (Bt).
- Trans boundary movement of GM potatoes in Africa.

**Intellectual property rights**
- Intellectual property rights situation unclear for several methodologies of GM potatoes.
- Lack of “freedom to operate” – inhibits commercialization.
- Funders unwilling to support research where “freedom to operate” unclear.
- Patenting of intellectual property rights by multinationals in South Africa with no intention to commercialize defensive patents.
Multinationals require unrealistic licensing agreements.
Clarity whether transgenic can be registered as new variety (Plant Breeders Rights).

**Monitoring and testing for transgenes**
- No mechanism for monitoring resistance management on farms.
- No kits/standards for detection of GM material on farm or in processed potato products.

**Socio-economic concerns**
- Research limited by high cost of developing GM potatoes locally.
- Dual economy – large scale farmers vs. developing farmers.
- Premium paid for GM seed – could exclude small farmers.
- Trade barriers on export of GM potatoes or derived potato products.
- Technology agreements with farmers.

**Status of transgenic potatoes release**

**Release to farmers**
No transgenic potatoes have been released to farmers for commercial production.

**Controlled research trials**
Transgenic potatoes with the PLRV coat protein (1997) and the Bt (cry1C) (2000) have been tested in controlled research trials. The inventors of the PLRV coat protein gene and the Bt (cry1C) are ARC and Vitality Technologies Ltd., Israel, respectively.

**Other GMO crops**
Several crops have been field tested from 1989 to the present. Commercial releases are Bt maize (160,000 ha) and Bt cotton (18,000 ha).

**Biosafety regulations**
There is a biosafety committee. During 1989–1999 biosafety evaluations were carried out by the South African Committee on Genetic Experimentation (SAGENE). In 1997 the GMO Law was passed. At present the GMO law structures are in place and operational.

**Strategy components for the successful release of transgenic potatoes**
Requirements for field tests:
- Good partnership between research institution (e.g. ARC-Roodeplaat), potato industry (growers, commodity organization), private sector (private tissue culture labs, processors, seed growers).
- Reliable research labs to develop products.
- Good review system for trials.
- Well organized potato industry and seed certification scheme.

**Major issues for the successful government approval, uptake, deployment and acceptance of potato transgenic plants**
- Positive public opinion.
- Good product – obvious benefit to farmer/consumer.
- Correct cultivar (adapted to South African conditions).
- IPR agreements concluded.
- Full risk assessment available on food safety (toxicity and allergenicity) and environmental issues (outcrossing, resistance management, affect on non-target organisms).
- GMO law and structures proven to work.
- Clear government policy on GM food labeling and detection limits.
- Affordable GM potatoes (not too high premium).
- Creative mechanisms to make GM potatoes available to both large-scale and small-scale farmers. These must be in line with SA government’s policy of building economy by stimulation of SMME’s rather than food subsidies.
- Well organized potato industry and seed certification scheme.
- Resolution of trade barriers in Europe (which block import of secondary products derived from GM potatoes).
- Future - GM potato varieties for processing industry.
Uganda

Theresa Sengooba¹

Introduction

In Uganda potato (*Solanum tuberosum L.*) the fifth important food crop, following bananas, cassava, maize and sweet potato. The crop was introduced around 1900 (Akimanzi, 1982) and gradually spread throughout the highlands of southwestern Uganda and around the slopes of Mount Elgon. Potatoes are widely cultivated in these highlands, mainly between 1500 to 2500 meters above sea level (masl). Some varieties adapted to lower altitudes have been introduced and are spreading in these areas. However, the quality tends to be lower than that of potatoes produced at higher altitudes. The crop is grown both for home consumption and for sale to local urban markets. Potato cultivation has expanded from 7000 ha in 1966 (Mukiibi, 1972) to 56,000 ha in 1998 (FAO, 1999). The national per capita consumption is 19.1 kg, but reaches 100 kg in southwestern Uganda (Ewell, 1991). Farmers’ yields rarely exceed 10 kg/ha (Adipala, 1999), although the potential yield is much higher. Researchers have recorded more than 25 kg/ha on experimental stations, and from some farmers fields, especially those around Kalengyere Research Station, where potato research is based (Hakiza et al, 1997).

The causes of low yields include several biotic factors in combination with poor soil fertility management. The major biotic constraints are late blight (*Phytophthora infestans*), bacterial wilt (*Ralstonia solanacearum*) and viruses (PLRV, PVX and PVY). Limited availability of improved seed is another major frustration in potato cultivation (Low, 1997; Kakuhenzire, 1996).

Major constraints to production and utilization that can be addressed best by transgenics

Late blight is a major problem for potato cultivation that could be tackled though the use of transgenics. Presently, the main control strategy is breeding and selection for resistant genotypes. Fungicides are applied by about 45% of the farmers who spray on an average of 2 to 3 times a season. The fungicides are improperly used at times, making potato production both expensive and hazardous. If late blight is not controlled, tuber yield losses can reach 90%, depending on the variety and the weather conditions.

Bacterial wilt is estimated to cause an average of 30% yield losses and 100% crop damage has been recorded in some farmers’ fields (Alacho and Akimanzi, 1993). The disease is particularly devastating at lower altitudes. Conventional breeding and other integrated pest management strategies have not provided satisfactory and durable levels of control. If there were opportunities for a better control of bacteria wilt through use of transgenics, Uganda would be justified to explore such a technology.

Value-adding traits could also present an opportunity for resource poor potato growers and consumers — for example, traits conferring nutritional values, enhancing health or improving the contribution of potato to a cropping system. Transgenics could be considered for such traits, depending on the value, profitability and cost of investment.

¹ Namulonge Agricultural and Animal Production Institute, Kampala, Uganda
National research organizations with the capacity to develop GMOs

- National Agricultural Research Organization (NARO)
- Makerere University

None of these organizations are working with GMOs, but they are developing the capacity in terms of laboratory facilities and human resource development in the various areas of biotechnology, including gene mapping, transformation and regeneration. A private laboratory, Med Biotech, is also active. These institutions are linked to research abroad through collaborative projects that may yield transgenics crops of bananas, cassava and coffee.

Institutions working with potato GMOs

No institutions are working with potato GMOs.

Major technical concerns for deployment and uptake of GMOs

Considering the global trend in agricultural research and development and the liberalized trade, GMOs may enter the country with or without government involvement. For this reason, Uganda prefers to join the debate on GMOs and prepare for a safe use of this technology, where and when necessary. Some technical concerns must be addressed concerning the uptake of GMOs. These may vary, depending on the crop and trait involved.

Gene flow

In the case of potato, the effect of the transgenic plants on the genetic diversity of cultivated genotypes, and the possible genetic disruption or contamination of related species should be well understood. The interactions of GMOs, by environment and by ecosystem, are not known and should be studied on a trait basis to guarantee the safety of non-target organisms. There is a general suspicion that a gene construct could transfer to other non-target organisms, making them harmful to man or causing unfavorable disruption to the environment. There is also a general concern over the stability of transgenes, basically due to lack of information and experience. There is inadequate capacity to track gene flow to other flora or fauna. The behavior of GMOs over time is not predictable. Persley (2000) states that the full understanding of the benefits and risks associated with new GMOs may take several decades.

Food safety and acceptance

There are food safety standards and regulations, but due to poverty-related factors, they are not adequately enforced. In the case of GMOs, safety must be assured. The product must be free of allergens, toxins or any other chemical that might harm consumers. If precautions for using GMOs exist, people with low income would be the most vulnerable. Hence, it is the responsibility of the researchers who produce the GMOs to make them safe for resource-poor consumers.

Seed systems for production and distribution

Potatoes are grown from home-saved seeds or those produced and distributed through informal seed systems. Transgenic potatoes must fit into, or supplement this seed system if they are to be adopted and sustained. The general fear is that GMOs may disrupt the informal seed systems, increasing seed costs and causing dependency on seed producers.

Others

The Uganda Biosafety Framework requires that the impacts and risks posed to humans and the environment by the GMO be evaluated to identify any hazards before a release is carried out. The necessary laboratory and field facilities should be developed, and scientists trained in handling transgenics during evaluation and selection, and in monitoring the efficiency of risk management.
Policy concerns about GMOs

Food safety and acceptance
The safety and quality of consumable products is a major issue. The Food and Drug Act handles standards for food and drugs but does not cover biosafety concerns regarding GMO foods and drugs, and the labeling of foodstuffs, feeds or pharmaceutical products for the consumer, so that informed decisions concerning their use can be made. The present biosafety regulations recommend that transgenic materials (foodstuffs, feeds or pharmaceutical products) be labeled by law. In the case of potatoes grown by poor farmers, such a law may be difficult to enforce, but could be applied up to a certain stage within the seed production system. The primary responsibility for GMO safety will lie in the hands of researchers and the regulatory system.

While scientists appreciate that some potato production and utilization constraints could be addressed through the use of transgenics, GMO crops have not always been well accepted in developed countries where the technology largely originates. There are a few ‘environmentalists’ in Uganda who may be against GMOs. A negative attitude towards GMOs could also come from external sources. It is, therefore, important to enlighten the people of Uganda that GMOs may be beneficial to them, regardless of their acceptability elsewhere.

Biosafety
Currently the National Biosafety Committee derives its legal status from the Uganda National Council for Science and Technology (UNCST) statute. The law, which established the Council, empowers it to formulate policies and strategies for Science and Technology in all fields including biotechnology and biosafety. Although this legal instrument and others that cover agricultural research and environmental protection provide a framework for handling GMOs in Uganda, there are plans to strengthen the NBC legally through its own legislation.

Intellectual property rights
The issues of intellectual property rights have been addressed through the Plant Variety Protection Act, which has been formulated and is to be processed through Parliament in the near future. This act will protect a transgenic variety, but not the gene as an entity.

Status of transgenic crops

Release to farmers
No transgenic potatoes have been released to farmers for commercial purposes.

Controlled research trials
No transgenic potatoes have been released for controlled research trials.

Other GMOs
No transgenic crops have been released for controlled research trials or commercial production.

Biosafety regulations

There is a National Biosafety Committee (NBC) and biosafety guidelines have been formulated. Uganda has developed a ‘Biosafety Framework’ (Nyiira et al., 2000) with the assistance of the United Nations Environment Program. This framework provides guidelines for the safe introduction, evaluation and release of transgenic crops in the country. The objectives of the biosafety guidelines are to
Ensure and guarantee public and environmental safety with regard to accident prevention, containment and waste disposal when GMOs are utilized in research and development, as well as in industrial production processes.

Determine measures for risk assessment, evaluation and reduction in all operations involving GMOs or any other processes of biotechnology, including, but not limited to, the prescription of appropriate conditions for the use of biotechnology and its product.

Promote opportunities for the application and exploitation of innovative biotechnology products for the general well being of humanity.

Administrative procedures for biotechnology and biosafety have been laid out. One of the functions of the NBC is to approve and monitor the deliberate release of genetically engineered organisms. The NBC is the administrative arm of the National Council for Science and advises on matters concerning biotechnology and biosafety. The NBC has 19 members with representatives from

- Uganda National Council for Science and Technology (UNCST),
- Ministries involved in biotechnology and environmental issues,
- Universities and institutions in private sector involved in biotechnology research.

The committee maintains links with biotechnology institutions through institutional biosafety committees.

**Major issues affecting the successful government approval, uptake, deployment and acceptance of potato transgenics**

Although Uganda has developed biosafety regulations and the NBC is in place, scientists would still be skeptical about the handling or the approval for the introduction of GMOs into the country. Several major issues are still to be addressed for the successful government approval, uptake, deployment and acceptance of transgenic potato or that of any other plant, including:

- Public awareness of GMOs: Targeting politicians, senior administrators and scientists is required. These people need to know the potentials of transgenic potatoes, why and when it is necessary to resort to such technology to solve potato production constraints. The advantages of deploying GMOs instead of conventionally produced genotypes have to be well articulated.

- Technical information on GMOs, including the scope of their safety and the expected and possible interactions with the environment, should be given to all scientifically minded people. A critical mass of technical people in the country should be conversant with GMOs, in terms of research and development.

- Well developed capacity for risk assessment and monitoring is required to backstop the national competent authority that will take charge of biosafety regulations. The scientists involved need to know how the technology may fail and what to do if this happens. The effects of the introduced genes, gene markers or any gene carriers have to be well understood by the technical people.

- Training in the handling GMOs in selection and evaluation is required to ensure proper advancement and the disposal of the chosen and the rejected materials, respectively.

- Participation of local scientists in preparing and implementing projects that will produce GMOs for use in Uganda would be useful. Roles and functions should be defined at project formulation stage. The production of GMOs locally and in the local environment may make the technology less feared.

- Success stories with transgenics in countries more advanced in this technology would increase support and stimulate positive attitudes for undecided minds. Negative experiences with GMOs should also be known, so that precautions are taken where necessary.
The pathway for GMO to farmers has to be established to ensure the transfer and application of this technology under the poor farmers’ conditions. This will involve on-farm trials and demonstrations to introduce the technology to clients. An appropriate seed system will be required to ensure availability of the technology to farmers.

**Conclusion**

Although use of transgenic potatoes may not totally eliminate potato production constraints, it has a potential to reduce some problems substantially and to contribute to increased productivity and profit gains from the crop. Some opportunities to enhance the value of the crop may also be exploited. The concerns about transgenic potatoes in Uganda today originate from the general lack of technical knowledge, experience and public awareness about the technology. There is a need to address policy, legal, administrative, technical and public awareness issues before transgenic potatoes or GMOs of any other crop can be successfully evaluated and utilized. The technology development and transfer aspects will also need attention to enable resource poor farmers and consumers access to the products.

**References**


### Aggregated country profile information

<table>
<thead>
<tr>
<th>Country</th>
<th>Traits Needed</th>
<th>Institutes Working With Potato GMOs</th>
<th>Technical Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuba</td>
<td>Resistance to: late blight. Tolerance to: viruses. PTM. PLRV. drought.</td>
<td>CPRI in collaboration with NRCBP and NCPGR</td>
<td>gene transfer to other pests. variety. purity/identification.</td>
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<tr>
<td>India</td>
<td>Resistance to: late blight. tolerance to: bacteria. wilt. PTM. PTM. PLRV.</td>
<td>None</td>
<td>gene flow. effects on non-target organisms.</td>
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<tr>
<td>Mexico</td>
<td>Resistance to: viruses. fungi.</td>
<td>None</td>
<td>no IPR-free effective/ novel transgenes.</td>
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<tr>
<td>Nepal</td>
<td>Resistance to:</td>
<td>None</td>
<td>no marker gene-free trans-formation.</td>
</tr>
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<td>South Africa</td>
<td>Resistance to: late blight. PTM. common scab. TSVV. PLRV. PIVV. BW.</td>
<td>ARC, Roodeplaat</td>
<td>effects on non-target organisms. capacity to access risks is lacking.</td>
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<td>Uganda</td>
<td>Resistance to: late blight. A. solani. Tolerance to: herbicides.</td>
<td>None</td>
<td>very little is known about GMOs and capacity to access risks is lacking.</td>
</tr>
<tr>
<td>Country</td>
<td>Argentina</td>
<td>Bolivia</td>
<td>China</td>
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<td><strong>Policy Concerns</strong></td>
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<td></td>
<td>public awareness</td>
<td>standard procedures to monitor transgenes</td>
<td>public acceptance capacity for risk assessment and transgene monitoring</td>
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<td><strong>GMO Potatoes Released</strong></td>
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<tr>
<td></td>
<td>controlled research trials: PLRV, PVY, PVX, Bt</td>
<td>no</td>
<td>to farmers for production: PLRV/Y, LB</td>
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<tr>
<td><strong>Biosafety Committee</strong></td>
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The effect of transgenic potatoes on non-target organisms

Sue Cowgill

Introduction

Several transgenic traits are currently available in potato, including plants with resistance to pests and diseases. In most cases the plants have been modified to express genes from bacteria or higher plants. For example, the expression of genes from *Bacillus thuringiensis* confers resistance to *Phthorimaea opercullela* (Gleave et al, 1998) and *Epitrix cucumeris* (Stewart et al, 1999). In these cases, the plants produce novel proteins not normally encountered by the non-target associates of potato. Other transgenic traits may involve the production of higher levels of naturally occurring proteins, or the expression of protein in plant parts where it would not normally occur. In all of these cases, it is important to assess the risks posed by such changes.

Ecological risk has been defined as the likelihood that release of a novel material will cause adverse effects such as mortality or reductions in populations of non-target organisms, due to acute, chronic or reproductive effects or disruption of community or ecosystem function (Jepson et al, 1994). The current paper presents a set of criteria for the selection of appropriate non-target organisms and suggests a framework for determining the level of testing required.

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1 Centre for Plant Sciences, Leeds Institute for Plant Biotechnology and Agriculture, University of Leeds, Leeds, United Kingdom
Identification of potential test species

The characteristics of the transgenic plant and the biology of potential non-target species are both important in identifying test species for risk assessment. Each transgene-promoter combination should be considered separately. This is because different transgenic proteins have different modes of action, and the pattern of expression of proteins will vary according to the promoter gene used.

The community of non-target organisms that may be exposed to transgenic proteins can be defined by carrying out surveys of the invertebrates associated with potato crops in a particular agro-ecological region. Using survey results, it should be possible to define a list of non-targets. These can be subdivided into the following four broad categories based on feeding behavior/ecological function: herbivores, natural enemies, pollinators and organisms associated with soil function. The final category includes the soil microflora and various invertebrate groups, which are classified as micro, meso or macro fauna according to their size. The ability to detect and monitor changes in the dynamics of soil organisms is important because transgenic disease resistance often involves the transformation of plants with genes that code for anti-microbial proteins.

A subset of test species can be selected from the categories described above on the basis of several simple criteria such as: relevance, ease of maintenance and handling and sensitivity.

Relevance within the agro-ecosystem
Ideally, the test species should be associated with potato in a wide range of locations and be relatively immobile and abundant. Herbivores and pollinators that feed exclusively on potato should be selected for study in preference to more polyphagous species. Test species with short generation times might also be preferred to facilitate the study of the cumulative effects of exposure to transgenic proteins over several generations.

Ease of maintenance and handling
Laboratory studies often require the use of individuals of a known age. Therefore, it is useful if the test species can be cultured in the laboratory to ensure its availability as well as its homogeneity in terms of age. This increases ease of handling, which ensures that standard test procedures can be developed and experiments can be carried out by different laboratories.

Sensitivity
Studies of the impact of pesticides on natural enemies have shown that different species of predators and parasitoid differ in their susceptibility to insecticides (Hassan, 1998). Similarly, younger instars of some Lepidoptera are more susceptible to Bt than older instars of the same species (Rausell et al, 2000). Where such information is available, the sensitive species or life stage should be selected so that the study represents the “worst case scenario”.

Examples of studies of the effects of transgenic plants on non-target organisms

Herbivores
There is currently little information about the impact of pest-resistant potatoes on non-target herbivores. The feeding ecology and phenology of herbivores is important in determining the exposure of the insect to the transgenic proteins. In studies of the non-target effects of nematode-resistant potatoes in UK, the leafhopper *Eupteryx aurata* was selected as a test organism (Cowgill, unpublished). Although this insect is not a major pest for potato and occurs on several non-crop plants, during August – September large numbers of nymphs do occur on potatoes. The 1st and 2nd instar nymphs are relatively immobile and feed close to the site where they emerge. Therefore, potato is the only host for this generation of the insect. Because both nymphs and adults feed on mesophyll cell contents, they were considered at risk from exposure to the protease inhibitor expressed with the plants (a cysteine protease inhibitor under control of the CaMV35S promoter).
Natural enemies

In the case of natural enemies, the feeding behavior of their host and the expression patterns in the plant will be important in determining whether or not a predator or parasitoid is exposed to the transgenic protein. Researchers working with pests of other crops, such as maize, have shown that herbivorous species can sequester Bt toxins. The survival of natural enemies, such as the green lacewing, is reduced when they consume such prey (Hilbeck et al, 1999; Hilbeck et al, 1998). The composition of the digestive enzymes of the predatory stink bug Perillus bioculatus changes after it has consumed Colorado beetle larvae reared on transgenic plants expressing proteinase inhibitors (Bouchard et al, 2000). It is not known if these changes alter the fitness of P. bioculatus.

The consumption of aphids from transgenic plants expressing snowdrop lectin (GNA) resulted in adult coccinellids with reduced fertility and longevity compared to those who were fed aphids from control plants (Birch et al, 1999). Therefore, GNA may ensure that aphids consuming it are suboptimal food for coccinellid larvae rather than having a significant direct toxic or adverse effects on predator development (Down et al, 2000). However, the development of coccinellid Hippodamia convergens was not adversely affected when it fed on aphids from transgenic potatoes expressing Bt toxin (Dogan et al, 1996).

Aphid honeydew can be an important food resource for coccinellids and may present another potential route of exposure to the toxin. GNA has been detected in the honeydew of aphids fed on transgenic tobacco plants in which the rice sucrose synthase promoter provided phloem specific expression of the transgene (Shi et al, 1994). There is currently no information about the presence or consequence of other plant-derived novel proteins in aphid honeydew. The stability of novel proteins in honeydew under field conditions is also not known. The adults of several natural enemies also feed on pollen and nectar, which may present other routes of exposure to transgenic proteins.

Pollinators

Potato plants produce little or no nectar (Free, 1970), and consequently they are of little importance to nectar-feeding insects. They do produce pollen, however, and the commonly used CaMV35S promoter gene directly expression of transgenes to the pollen grains of certain plants, such as tobacco (but not in Arabidopsis thaliana) (Wilkinson et al, 1997). In potato, pollen is released from poricidal anthers by vibratile pollinating bees including Bombus spp (Buchmann et al, 1977). This mechanism may limit the number of insect species that utilize potato pollen as a resource. Insect visitors that have been recorded on Solanum flowers include the bees Leioproctus spp. Anthophora incerta and the syrphid Scaeva melanostoma (Johns and Keen, 1986). These are clearly the insects for which the risk of GM potato pollen should be assessed.

There are several studies of the effect of ingestion of protease inhibitors (PI) on the honeybee, Apis mellifera (Burgess et al, 1996; Girard et al, 1998) and on the bumblebee, Bombus terrestris (Malone et al, 2000). Results show that high doses of PI are required to produce adverse effects on adult bees. Therefore, it is possible that no further tests with plants expressing these proteins are required for bees.

Soil organisms

Soil microflora are critical in determining the functioning of agro-ecosystems (Wardle et al, 1999) and are also involved in processes such as soil carbon mineralization, litter decomposition, nutrient mineralization, nitrification/denitrification, and contaminant biodegradation. Determining the rates of these processes, particularly denitrification (Siciliano and Roy, 1999) has been proposed as a method for estimating the effects of toxicants on microbial communities. After one particular process is selected for study, it is also necessary to define the type and magnitude of any change that constitutes a significantly adverse effect. Reduced nitrification is often proposed as an endpoint. However, farmers often apply chemicals to inhibit nitrification because nitrate is less readily retained by terrestrial systems than ammonia (Efroymson and Suter, 1999). Clearly, the magnitude of any observed change is important. An adverse effect can be defined as a change that exceeds the natural range of process rates at the location of concern (Efroymson and Suter, 1999). This takes into account the natural, rapid changes in microbial populations and functions that occur independently of the presence of toxicants or transgenic proteins with fluctuations in temperature, moisture, pH and many other factors (Domsch
An alternative approach to the study of the impact of toxicants/transgenic proteins is to study any consequences for the microbial community structure and for biodiversity. The currently available methods for the analysis of microbial communities have recently been reviewed (Tate, 2000). The techniques can detect changes in community structure that would not be detected from the study of soil processes. This discrepancy arises because there is functional redundancy in microbial communities that allows certain microbial groups to be eliminated with little detectable impact on the functioning of the ecosystem (Griffiths et al, 1997). Consequently, soil respiration is not recommended as a test for contaminant effects, because it is performed by numerous microbial species. There is one major disadvantage in using changes in community structure to indicate the impact of transgenic proteins: relatively little is known about how biodiversity of the subsets of the soil biota affects soil processes.

A compromise approach may be the use of an emerging class of tests known as pollution-induced community tolerance (PICT) (Rutgers et al, 1998). This group of tests relies on the assumption that toxicants increase the tolerance of a microbial community by decreasing the survival and growth rates of the more sensitive individuals. This change in tolerance has been proposed as an indicator of ecological deterioration (van Beelen and Doelman, 1997). There is evidence that tolerant species may display reduced activity. For example, Giller et al (1989) observed that metal tolerant Rhizobia were unable to fix nitrogen.

Clearly, further dialogue between soil ecologists and regulators is required before a cost-effective approach to the study of the impact of transgenic plants on the soil microflora can be clearly defined. Until then, an alternative approach may be to involve farmers in the monitoring of “soil health” in experimental field trials with transgenic plants prior to commercialization.

Changes in the abundance of soil fauna can be detected by regular sampling followed by the extraction of invertebrates. This involves a range of techniques (Coleman et al, 1999). Laboratory studies with soil invertebrates have used techniques and test species originally developed to study the impact of pesticides and heavy metal contaminants. The collembolan Folsomia candida is widely used in such work, but may be inappropriate for studying the toxicity of transgenic proteins from plants as it feeds predominantly on fungi and may not ingest novel proteins in soil.

Transgenic proteins in oil ecosystems

Novel proteins from transgenic plants may enter the rhizosphere via several routes. Firstly, vacuolar and extracellularly localized proteins may be lost passively from roots during senescence and the natural sloughing-off of root cap cells. Roots also secrete extracellularly targeted proteins into the rhizosphere. The natural secretion of proteins from the roots of intact transgenic plants has even been proposed as an efficient method for obtaining recombinant proteins (Borisjuk et al, 1999). The process of “rhizosecretion” is dependent on appropriate signal peptide fused to the recombinant protein sequence. Proteins may also enter the soil when transgenic plant residues are returned to the soil after harvest, or as roots decay.

Exudates from the roots of Bt-maize seedlings contained approximately 105mg of Bt/plant (Saxena et al, 1999). Bt toxin can retain its insecticidal activity in soil for >234 days (Tapp and Stotzky, 1998). It binds rapidly to soil clays (Tapp et al, 1994) and humic acids (Crecchio and Stotzky, 1998), but this does not affect its activity.

The stability in soil of other transgenic proteins has not been studied in detail. Proteinase inhibitors from air-dried tobacco were detected 57 days after their incorporation into a sandy loam soil (Donegan et al, 1997). The inhibitory activity of the protein was not reported over this period. Nematode populations were greater and, relative to controls, the trophic composition was altered in soil surrounding the transgenic litter. In contrast, populations of Collembola were lower in the soil surrounding the transgenic litter. However, microbial respiration rates and protozoa populations were not significantly
different between the transgenic and control plots. A reduction of c 10% in potential microbial activity and a transient c 40% reduction in soil protozoan populations did occur in plots where transgenic potato expressing a lectin, concanavalin A, had been grown (Griffiths et al, 2000). Protozoa are essential for the efficient release of nutrients from microbial biomass, suggesting that more work on this effect is needed.

Test methods to study the impact of transgenic plants

Dohmen (1998) described a sequential testing scheme that is used to examine the effects of pesticides on beneficial insects. The scheme involves conducting an initial laboratory study under “worst case” conditions. If no effects are observed at this first tier of testing, it is predicted that the compound is unlikely to have an adverse effect on non-target species in the field. However, further testing is required if the first-tier screen reveals adverse effects. The extreme conditions in the laboratory make it difficult to predict if adverse effects will occur under field conditions. The second-tier experiments may involve more realistic laboratory studies or semi-field studies. Field studies are required to assess the impact of the compound if significant or inconclusive effects are observed at the secondary tier.

The sequential testing scheme could be adopted to test the impact of transgenic plants on non-target organisms. The appropriate experiments for each tier would differ in terms of the mode of action of the transgenic protein and the mode of exposure, relative to conventional pesticides. However, the framework would be useful in “flagging” transgenic plants requiring more testing at higher tiers.

The difficulties of applying techniques developed for pesticide testing to transgenic plants have been discussed elsewhere (Hilbeck et al, 2000). These problems need to be considered when designing laboratory and field experiments with transgenic plants. In general, an initial laboratory “worst case” design might involve feeding test species diets that contain high levels of transgenic proteins. An alternative in some cases is the incorporation of the protein into suspensions of soil bacteria, or its addition to a soil microcosm. The second tier could involve transgenic plants grown in containment greenhouses or in small plots/cages in the field. In this case the third tier would focus on controlled field release of transgenic plants, plus appropriate control plants, and a treatment representing farmers’ current practices. For example, transgenic potatoes may be intended as replacements for chemical control such as insecticidal spray. If so, an appropriate comparison would between transgenic potatoes and control potatoes sprayed with the insecticide preferred by the grower.

Conclusions

Many issues need to be resolved in the study of non-target effects of transgenic plants. There are currently no international standards for the type and extent of required non-target testing. Many practical details also remain unresolved. For example, the most appropriate approach for studying impact on soil organisms and what level of adverse effect should warrant concern must be better defined. Therefore, a Global Working Group on Transgenic Organisms in IPM and Biological Control has been established under the umbrella of the International Organization for Biological Control. This group will address many of the issues surrounding the deployment of transgenic plants, including the development of appropriate protocols for assessing environmental impact and for monitoring transgenics within the environment.

Farmers also have a role in all stages of the assessment of transgenic plants; their input may be particularly important in monitoring field releases. In many countries, farmer field schools have promoted understanding of field ecology and IPM among resource-poor farmers and have helped to develop local skills and knowledge. These include methods for field inspection and understanding of the life cycles of insects, pathogens and weeds. These skills could be used to monitor transgenic crops and to provide a system for early detection of adverse effects on the environment.
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Strategies for transgene pyramiding

Dave Berger¹

Introduction

The first transgenic crops that were released to farmers contained single gene traits, such as potato engineered with a Bt gene for resistance to the Colorado beetle. However, transgenic solutions to many complex traits in the future will require the introduction of several genes, either to confer improvements in different traits, or by the introduction of several genes of a pathway (Miflin, 2000). There are several strategies for introducing multiple genes, which can be termed “transgene pyramiding,” as the end result is analogous to gene pyramiding in classical breeding.

Transgene pyramiding can therefore be defined as “the stable introduction of more than one useful gene into a plant genome by transformation”. This concept will be discussed within the framework of the number of selectable marker genes that are introduced, as this often dictates the type of strategy employed. The advantages and disadvantages of each method, with special reference to their application in potato, will be addressed.

The most commonly used transformation method for potato is *Agrobacterium*-mediated transfer of T-DNA, and, therefore, the discussion will be limited to this method. However, this does not exclude other approaches. For recent reviews of crop transformation, see Hansen and Wright (1999) and Gelvin (1998). For the purpose of this review, an example of the introduction of four different transgenes has been used throughout. When considering potato transformation, another important factor is that it is a vegetatively propagated crop. Most cultivars are difficult to cross and, in cases where this is successful, progeny exhibit extensive genetic variation. As a result, in contrast to crops such as tobacco and maize, it is difficult to pyramid transgenes in potato by crossing different transgenic parental lines.

Current protocols using *Agrobacterium*-mediated transformation result in random integration of the T-DNA in the target genome. Experience has shown that it is necessary to screen many transgenic events (ideally up to 100) to obtain one that exhibits acceptable expression of the transgenic trait without interfering with normal plant physiology. Therefore, a high transformation frequency is desirable (>5%), something that is not easily attained in some potato cultivars that regenerate poorly in tissue culture.

Methods using two or more selectable markers

Co-transformation with more than one marker

Co-transformation involves the simultaneous introduction of two different T-DNA constructs, each carrying a different selectable marker. This is illustrated in Figure 1, where two useful genes (A and B) are linked to one marker gene (Marker 1) on one T-DNA, and two other genes (C and D) are linked to a second marker gene (Marker 2) on another T-DNA. Co-transformation can be done by one of three methods: mixing two different *Agrobacteria*, each carrying a different binary vector; combining the two T-DNAs on a single plasmid in a single *Agrobacterium*; or using one *Agrobacterium* carrying two compatible plasmids, each with a different T-DNA. These approaches are discussed in Komari et al (1996) and Daley et al (1998).

¹ ARC-Roodeplaat, Pretoria, South Africa
Co-transformation has been employed by a large group of laboratories known as the EU-CYTED consortium involving scientists from Europe and South America in a project from the European Union’s Fourth Framework Program called “Development of transgenic potato cultivars with combined protection against virus and fungal pathogens”. CYTED consortium was formed for collaboration on an overlapping project entitled “Obtención de variedades de papas transgénicas resistentes a virus, bacterias y hongos,” coordinated by Dr. A. Mentaberry from the University of Buenos Aires, Argentina. The EU-CYTED consortium involves at least 11 laboratories that make and share 15 different genetic constructs with different anti-fungal and antiviral genes. Laboratories in each country aim to transform selected gene constructs into locally important potato cultivars and carry out field tests. CYTED provides funding for management of the consortium, workshops, and communication between the partners. The EU has also funded some aspects of consortium activities. The consortium is based on the concept of pre-competitive research conducted within a “club” of collaborators, each with something to contribute. The consortium was designed to create a climate of collaboration and open exchange through the sharing of genes and results. Intellectual property rights (IPR) pertaining to each gene will vary from country to country, and licensing negotiations will only commence once a commercially valuable transgenic potato line is produced.

The constructs used by the CYTED consortium contain different combinations of two genes linked to a selectable marker on single T-DNAs. Three different selectable marker genes are used, namely \textit{nptII}, conferring kanamycin resistance; \textit{bar}, conferring resistance to the herbicide bialaphos (glufosinate ammonium); and \textit{hyg}, encoding hygromycin resistance. This offers the potential to combine up to six transgenes. The first transgenic potatoes produced in this consortium contain only two gene combinations, but some containing four genes (two anti-fungal and two anti-viral) have been produced since then (E. Ritter, personal communication). These were obtained by co-transformation (Fig. 1) with two different \textit{Agrobacterià}. Selection was carried out sequentially, with the first antibiotic placed in the regeneration medium to select transformed shoots, after which the second selection agent was placed in the rooting medium to obtain transformants containing both marker genes.

**“Super”-transformation**

The first stage of this approach involves transformation using a single marker gene linked to the two useful transgenes, A and B. Transformants are screened for expression of the transgenes as well as good agronomic traits to select an event suitable for deployment by farmers. If it is necessary to introduce a second trait or additional transgenes (C and D), the first event is re-introduced into tissue culture for a second round of transformation using a different selectable marker gene. The final product contains all four transgenes and both markers (Fig. 2). This is the method that was employed at the Scottish Crops Research Institute for producing transgenic potatoes with improved quality traits (G. Machray, personal communication).
The advantages of using more than one selectable marker are, first, that it is a very flexible approach in which many different gene combinations can be mixed and matched to determine which is the most effective. This is of special relevance for basic research studies in engineering traits such as fungal resistance, in which synergistic interactions are known to be different for different gene combinations. Second, experience has shown that at least three selectable markers (nptII, bar, hyg) work well in potato.

Disadvantages of this approach are related to the presence of at least two selectable marker genes in the final product. This raises problems in terms of biosafety as well as intellectual property rights. Biosafety assessment based on a “transgene-centered” approach has become the standard means for government regulators to weigh the risks of a general release (Metz et al, 1998). Therefore, despite the large body of knowledge supporting the assertion that commonly used marker genes present minimal risk to the environment or to public health, many government regulators favor transgenic crops that contain minimal DNA other than the useful transgenes. In addition, in some countries, marker genes are protected by IPR; therefore, increasing the number of transgenes increases the complexity of obtaining licensing agreements.

The co-transformation method requires that the two different T-DNAs be transferred simultaneously to the same cell, which then must out-compete adjacent cells during regeneration and selection. It is estimated that if the transformation frequency for a single T-DNA is 10% (1 in 10), the co-transformation frequency will be 10% X 10% = 1% (1 in 100). It is therefore obvious that co-transformation of recalcitrant potato cultivars may be difficult. Furthermore, use of more than one marker gene often results in the integration of T-DNA in at least two sites in the chromosome, which are unlikely to be linked. This presents a problem to breeders, who may want to use the event as a parent in future breeding.

The chances of single-copy insertions of each T-DNA are also reduced. Therefore, a larger number of events must be screened to obtain the desired one—the one that does not exhibit “gene silencing”. This is a poorly-understood phenomenon in which a transgene expressed from one T-DNA can silence expression of the same gene from T-DNA inserted elsewhere in the genome (Depicker and Montagu, 1997).

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**Fig. 2.** “Super” transformation (two-step) using two different T-DNA constructs. A, B, C and D = transgenes. RB = right border of the T-DNA. LB = left border of the T-DNA. M1 = Marker gene 1. M2 = Marker gene 2. The potato tuber represents a potato plant.
**Methods using a single selectable marker**

Two approaches have been employed (Fig. 3): The insertion of multiple genes into a single T-DNA, and co-transformation with two *Agrobacteria* (one with a marker gene and one without). The former method has been employed in several studies and appears to allow for the stable integration of very large fragments of DNA between the T-DNA borders into a plant genome. This was demonstrated by the successful insertion of a 150-Kb fragment of foreign DNA into tobacco (Hamilton et al, 1996). A 40-Kb fragment of potato DNA has also been inserted successfully into the potato genome using the biBAC vector (J P Nap, personal communication; Hamilton 1997). Up to 13 genes could be carried on 40 Kb fragments if one assumes an average gene expression cassette as 3 Kb. However, this requires a very efficient transformation system and the use of DNA fragments that are less prone to rearrangement than others. There is also evidence that because T-DNA integration is initiated at the right border, sequences close to the left border are sometimes omitted. Furthermore, certain duplicated sequences between the T-DNA borders have been shown to cause rearrangements in transgenic potato (Porsch et al, 1998).

A second strategy is shown in which potato is co-transformed with one T-DNA containing two genes (A and B) and the marker gene and a second T-DNA containing the other two genes (C and D). The final product contains all four transgenes (A, B, C and D) and only one marker gene.

Co-transformation with only one T-DNA containing a selectable marker has been shown in the production of transgenic rice with increased provitamin A (Ye et al, 2000). A β-carotene biosynthetic pathway dependent on the insertion of three heterologous genes was introduced by co-transformation with two different *Agrobacteria*, one carrying a T-DNA with one gene and a marker, and the other with a T-DNA containing the other two genes in the pathway but no marker gene. Interestingly, the co-transformation frequency was as high as 20%, because out of 60 random events that grew on selection, 12 had the second T-DNA.

**Translational fusions that can be released by a protease**

Transformation of multiple genes on a single T-DNA can also be achieved by use of a single promoter controlling a multi-gene “transcript,” which encodes several polypeptides linked as translational fusions. Each polypeptide is separated by a protease cleavage site, which could be cleaved after translation, by a protease gene delivered on the transgene (Marcos and Beachy, 1997), or by an endogenous protease (Urwin et al, 1998).

**Positive selection systems**

Another approach is to use a positive selection system for transformed cells, which does not rely on an
antibiotic marker gene. A good candidate is the manA gene, which confers upon transformed cells the ability to grow on mannose (Joersbo et al, 1998). This has been shown to work well in sugar beet, maize and wheat. Use of it in potato, however, has yet to be reported. Another example of a positive selective agent is a gene that enables plant cells to grow on D-xylose (Haldrup et al, 1998), which functions in transgenic potato.

The main benefit of using a single marker is that biosafety and intellectual property complications are reduced. Furthermore, recently developed vectors allow the integration of whole genome fragments on a single T-DNA; thereby placing almost no limit on the number of genes that can be introduced in such a system. There is only one round of transformation/selection compared to super-transformation. Less transgenic events will be required to identify single-site integration events, which will then be available to breeders for introgression of the transgenic trait as a single T-DNA “allele”.

A disadvantage of this approach is that it is less flexible than those using multiple-marker constructs. The precise arrangement and choice of genes for the final product must be decided at the outset, in contrast to multiple marker constructs, which can be shared and tested between labs as in the EU-CYTED project. Single T-DNA constructs present a real challenge to molecular biologists using conventional ligation strategies, because with each additional gene the complexity increases due to loss of direct selection for recombinants, loss of convenient restriction sites, and an increase in the size of the vector at each ligation step. A new plasmid series, pBECKS2000, addresses these problems to some extent by use of a Cre/loxP recombination system within Agrobacterium for successive addition of transgenes within the T-DNA (McCormac et al, 1999). However, as stated earlier, co-transformation with a markerless T-DNA may be difficult, especially in recalcitrant potato cultivars.

**Removal of marker gene after transformation**

This third approach is the most desirable. However, it adds technical challenges that, in potato, may be too much of a barrier for successful deployment. Possible methods are reviewed in Yoder and Goldsbrough (1994).

**Removal by crossing**

Co-transformation is done with one T-DNA construct carrying only a marker gene and a second T-DNA construct that carries the useful transgenes (Fig. 4). Transgenic events with only one integration event for each T-DNA are selected. It is hoped that these constructs integrated into different parts of the chromosome. Out of these, the event that is most valuable agronomically is either selfed or crossed

![Fig. 4](image-url)

*Fig. 4.* Removal of marker gene by crossing after co-transformation with a T-DNA construct containing four transgenes (A, B, C and D) and a second T-DNA with one marker gene (M) only. The potato tuber represents a potato plant.
with an untransformed potato cultivar, and progeny that contain the useful T-DNA, but have lost the marker gene T-DNA by segregation, are selected. A program of back-crossing is then required to get transgenic progeny with a parental phenotype suitable for farm production.

**Removal by recombination**

Several recombinase systems have been tested in model plants. These include the phage Cre/loxP, yeast FLP, phage lambda attP, and Zygosaccharomyces rouxii R/RS systems (Albert et al, 1995; Gleave et al, 1999; Kilby et al, 1995; Zubko et al, 2000; Sugita et al, 2000). The Cre/loxP system is used as an example in Fig. 5. The original T-DNA construct is designed so that the marker gene is flanked by DNA elements (loxP), which serve as a substrate for subsequent excision by the Cre recombinase. Delivery of the Cre recombinase can be effected through a second transformation event or by crossing with a transgenic line harboring the recombinase.

Both methods of marker-gene removal are most effective in crops that can be crossed easily and that exhibit straightforward inheritance in their progeny. In the recombinase system one can envisage introduction of the Cre recombinase by one cycle of crossing. Once the marker gene has been removed, a second round of crossing can be done to remove the T-DNA carrying the Cre gene. Without this latter step, the recombinase system would not offer benefits over and above use of a single marker gene since it would merely result in the replacement of the marker gene in the progeny by a Cre gene. The biosafety and health consequences of such a foreign recombinase gene have yet to be evaluated.

**Conclusions and future directions**

Most systems have been tested in model plants such as tobacco and *Arabidopsis*, which cannot always be extrapolated to use in potato. The recombinase systems for marker removal, as well as the mannose positive-selection system, need to be tested systematically in potato. Currently, most potato research is oriented toward laboratory research rather than toward the dissemination of actual “products.” Therefore, concerns about biosafety and IPR and strategies for minimizing them may not always be fully considered in project design. For example, because the selected marker gene is often of secondary importance, strategies to remove it are ignored. Strategies for eventual removal of the marker gene should be designed and incorporated into research programs at the outset, especially for transgenic potatoes that are targeted for deployment by resource-poor farmers. Freedom to operate should also be negotiated from the outset with multinational companies that own the IPRs for these “clean gene” technologies, so that they can be utilized in resource-poor agriculture without royalties.

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**Fig. 5.** Removal of marker gene using Cre recombinase (Cre rec.). A, B, C, and D = transgenes. M = Marker gene. loxP is the substrate for the Cre rec. The tuber represents a potato plant.
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Expression, stability and inheritance of transgenes in potato

Richard G F Visser

Introduction

Potato (Solanum tuberosum L.) is the fourth most important food crop in the world following wheat, rice and maize. Potato breeding has occurred since about 1800, but because of its tetraploid nature and its vegetative mode of propagation, it is a cumbersome and time-consuming effort. Therefore, relative to other crops, breeding potatoes has not been overly successful. Problems in breeding potato have also been attributed to the crop’s narrow genetic base (Bradshaw and Mackay, 1994). Breeding for a new variety is based on recurrent phenotypic selection and generally begins with about 150 to 200 crosses, which result in about 100,000 seeds. After approximately 12–15 years, one or two clones are left which are being put forward as new varieties (Bradshaw and Mackay, 1994). Whether they will become successful varieties is difficult to forecast, but some, such as Bintje in the Netherlands and Russet Burbank in the USA, have remained important in potato markets for over 80 years. Introgression of traits from wild relatives of potato has been difficult, and has mostly been restricted to disease resistance traits (Hermsen, 1994). In this case, the time needed to obtain new varieties is even longer than the previously mentioned 12–15 years, because unwanted side effects must be eliminated and several more initial crosses are necessary.

All the above aspects make potato an excellent crop plant to improve by genetic transformation. Genetic transformation or modification encompasses the transfer of (alien) genes into the plant genome and was first reported in potato in 1983 (Ooms et al, 1983). At the end of the 1980s the transformation of potato using binary T-DNA vectors was reported by several groups (Sheerman and Bevan, 1988; Visser et al, 1989). In order to make full use of a transgenic approach in potato, one should realize that different parameters determine if and how transgenes can be deployed in potato breeding and cultivation. In the ideal situation, solely the transgene is transferred into the clone or variety of interest, thus creating an even better genotype. At present, however, it is not possible to direct the integration of a transgene into a unique, known position on the genome. Given the fact that potato is a cross pollinator and, in most parts of the world, vegetatively propagated, it is clearly difficult to select for transformed plants containing the desired transgene without a selectable marker. Genetic modification of potato entails the transfer of genes into the genome. This is only possible if isolated genes are available, if an efficient regeneration and transformation protocol exists, and if effective selection of transformed cells is possible. The two most frequently used methods for transformation in crop plants are particle bombardment and Agrobacterium transformation. For potato transformation, the use of Agrobacterium tumefaciens is by far the preferred method. Recently, the use of particle bombardment was reported as an alternative to Agrobacterium tumefaciens when multiple genes are to be transferred (Romano et al, 2000). The method used to transfer DNA into the plant genome will have an impact on the complexity of the transgenes within the transformants. Large differences exist in transformation frequencies for both Agrobacterium (both within and between genotypes) and for particle bombardment. Frequencies for the latter are generally much lower (around 0.1 to 10%). Furthermore, particle bombardment leads to more complex integration patterns that, in other crops, could be simplified by passage through meiosis, but this can’t be done in potato if one wishes to preserve the variety. However, having genes encoding a metabolic pathway in the potato gene pool as one locus enables the further use of this locus in breeding and selection.

1Graduate School Experimental Plant Sciences, Laboratory of Plant Breeding, Wageningen University, Wageningen, Netherlands.
Expression of traits in potato

Differences exist in the expression, which are related to the type of expression desired. (Over)Expression of homologous or even heterologous genes puts more stringent demands on the constructs to be integrated since both mRNA and proteins have to be produced. It is clear that the T-DNA configuration has an effect on transgene expression (Breyne et al, 1992). Homologous genes derived from potato or other solanaceous species might require only different promoters driving the expression in specific tissues such as leaves or tubers, in order to produce the desired outcome. On the other hand, heterologous genes might require a complete makeover in order to obtain the right codon usage and expression patterns. The requirements to suppress the expression of an endogenous gene by the antisense or co-suppression approach are less stringent, because only RNA molecules must be produced to achieve the desired effect. Even if all of these requirements are met, achieving the desired expression depends on a number of other factors for which little direction can be given - such as the site where the DNA is integrated, the insert or copy number and external environmental effects.

Selection for good expression has to occur at different levels: during and after the transformation event itself; based upon evaluations of greenhouse characteristics and performance; based upon studies of field characteristics and field performance; and based upon confirmation of the transfer of the trait to the offspring (preferably in a Mendelian fashion). Good expression of the target gene, along with good agricultural performance by the transformed genotypes, is of utmost importance.

Stability of expression

If a transgene approach is to be successful, stability of expression under all conditions and throughout a long-term timeframe is a prerequisite. Both vegetative and generative stability of expression must be obtained. Stability of expression is directly related to the site of integration in the genome of the insert (Czernilofsky et al, 1986). This is not only crucial for expression as such, but also for the level of expression. If the gene becomes integrated in heterochromatin, expression will be low or absent. However, when building the construct to be used for transformation, one can take into account the position of the gene of interest with respect to the right T-DNA border. At the same time, optimal regulatory signals (promoters, enhancers, matrix attachment sites) and proper codon usage should be used to increase the chances of high and stable expression (Breyne et al, 1992; Gao et al, 1991). During the actual transformation process, and in vitro, there are not many opportunities to direct the process. When transformants are finally obtained, they are identified based upon their ability to form roots and grow on selective media. At this point, the less appropriate plants can be screened out, and selection for the gene of interest can be undertaken. This will result in a drop of useful plants. There is little information on the rate of success, which seems to depend on the origin of the gene encoding the trait, the trait itself and the purpose of the undertaking (expression or inhibition of gene expression). For granule-bound starch synthase (GBSS), an enzyme involved in starch biosynthesis (Visser and Jacobsen, 1993), plants showing full antisense inhibition vary from 0.1 to 25% in a survey of fourteen varieties (Heeres and Visser, unpublished results). Information on stability of transgene traits in potatoes is also limited. However, we have found that some antisense GBSS transformants still show the same expression pattern after as many as 10 vegetative and 5 generative generations. Factors that we have shown to play a role in determining the stability of expression in potato include polyploidization (Flipse et al, 1996), somaclonal variation, hemi- or heterozygosity versus a more homozygous state of the transgene (Wolters et al, 1998), and DNA-methylation.

Inheritance of the transgene

The number of papers reporting on the inheritance of transgene traits in plants is low, and the number of analyzed traits and plants is rather limited. However, from the few reports that do exist (Deroles and Gardner 1988; Heeres et al, 1997), it is clear that inheritance can occur in a Mendelian fashion.
Knowledge about the inheritance of traits is very important when the primary transformant is to be used as a progenitor. Preferably, the inheritance state of a transgene must be known and predictable, so that the number of transformants to be produced (and thus the costs involved) can be calculated in advance. For antisense traits in potato, it seems that no primary transformants can be found containing one insert showing the maximum effect (Kuijpers et al, 1995). This seems strange because after crossing with the primary transformants, single loci causing a maximum effect in the offspring can be identified (Heeres et al, 1997). The reason for this is unclear, but is now under study. It is furthermore apparent that transgene inactivation, which can occur spontaneously (Finnegan and McElroy, 1994; Wolters and Visser, 2000), causes a serious threat to the use of transgenes in potato breeding. Only anecdotal information seems to be available about the inactivation of transgenes in soy, maize and other crops such as lettuce. Often DNA methylation or the loss of the transgene are suggested as causes for the inactivation. However, more detailed research is needed to pinpoint the precise nature(s) of transgene inactivation.

Gene flow

Given the ability to use a transgene approach in potato, one should recognize the potential problems that might be caused by the “stability of the transgene in the environment”. Pollen spread will occur and thus outcrossing of transgene traits will happen. To what extent and over what distance depends on a large number of internal and external factors, including male fertility of the transgene plant or crop, female fertility of other potato (or relative) plants in the vicinity, the presence of bumble bees and climatic conditions in general. A risk assessment based on the characteristics of the trait to be introduced should be conducted prior to the onset of the transgenic research. Much can be done at the theoretical level and by conducting comparative studies with the same (or a similar) trait in other crops. Practice should be gained using small-scale experiments under restricted conditions before large-scale field trials are allowed. Depending on the trait and the information available, different levels of restrictions could be formulated. (For example: Is the trait derived from potato itself, or is it a foreign gene derived from other plant species or a gene encoding a novel protein not found in plants?) If more information about different traits becomes available, then the possible movement of transgenes to non-target organisms, such as insects and soil microorganisms, could be analyzed even if this may seem unlikely. Computer modelling studies could help shed light on the potential fate of a transgene and a specific environment if a transgene would outcross. To fully assess possible benefits and hazards, all data on the genetically modified plant, in conjunction with that on the transgene trait and its agronomic performance, should be collected. This should start at the in vitro level and should be maintained throughout the life of the genetically modified (GM) plant or variety. It should also include important aspects such as a phenotypic description of the transgene plant as well as detailed molecular information on the construct used and how it was integrated into the genome. Normal agricultural practices (crop rotation, intercropping, removal of volunteer plants from seeds or tubers, etc.) should provide the framework for the assessment for the transgenic plant, unless the transgenic crop needs a completely new agricultural approach. If so, the new approach should be incorporated into the assessment and monitoring process.

Conclusions

Potato is a crop that could benefit significantly from a transgenic approach because its inherent features make traditional breeding a time-consuming process. More data should be acquired about the expression, stability, inheritance and outcrossing of transgene traits, and all elements that may influence them, to allow for better-informed policy making for the improvement of this crop.
Transgenic potatoes for the benefit of res...


Uptake systems: State and farmer-based seed systems

Chagema J Kedera

In developing countries potato production per unit area of land is low due to several factors, including lack of input (quality and quantity), diseases, insect pests and environmental factors. Agricultural biotechnology provides opportunities for solutions to some of these production constraints. There is great potential to increase production, especially with packaged technology in seed, as that would have a minimum effect on local cultural production practices. Procedures for the acceptance and use of seed packaged technology by farmers would be of critical importance.

Farmers acquire potato seed through both formal and informal channels. Understanding the nature of both types of access systems is essential for the successful uptake of new technology. The formal seed system, which may be state- or self-regulated, comprises the National Agricultural Research Institutes (NARs) and International Agricultural Research Centers (IARCs), the government (management of official quality-control centers; establishment of seed laws and regulations), and private/state seed companies. The formal seed system usually focuses on the needs of high-input agriculture and includes common procedures for breeding, variety testing, national performance trials, seed release, seed multiplication, seed inspection (field and laboratory) and, finally, marketing. This process can be executed according to an official seed certification system, or under the “truthful labeling system”. In both cases, it is the seed production/marketing company’s responsibility to guarantee the quality of the seed offered for sale. In most cases, this system ensures farmers get a specific quality of seed and thus (excluding unusual environmental constraints) good crop production. Successful acceptance of a new technology within this system depends on whether or not it addresses obvious production constraints (i.e., those recognized by farmers).

In Kenya potato varieties are bred and maintained by the Kenya Agricultural Research Institute (KARI) in collaboration with the IARCs. The developed potato varieties are then subjected to Distinctness Uniformity and Stability (DUS) tests and National Performance Trials (NPTs) before they are recommended for release. The seed potato certification process is overseen by the Kenya Plant Health Inspectorate Service (KEPHIS), which ensures the seed potato is pure, true to type, and free of seed-borne disease. The certification process includes the registration of seed potato growers, field inspection, lot inspection and sampling, labeling and sealing and, finally, the establishment of post-control plots. Seed packaging labels indicate variety, tuber size, status (class), weight, lot number and date of sealing. Labels are white, blue or red depending on the class (status) of the seed. Farmers are encouraged to keep these labels to help them clearly identify what they have purchased and to allow them to trace the seed source in the case of subsequent problems. Thus, in order to ensure acceptance and adoption within Kenyan farming communities, any new seed-packaged agricultural technologies should include clear labeling systems for identification purposes.

The informal or local seed system, which tends to be concentrated in low-input agriculture areas, can include both individual farmers (as both seed and crop producers) as well as their organizations and communities. The informal seed system tends to be unregulated, essentially based on trust between seed suppliers and seed purchasers, and its products tend to be unlabeled. In some instances, informal seed supply systems may receive input (financial, germplasm, or human resources) from Non-

1Kenya Plant Health Inspection Service (KEPHIS), Nairobi, Kenya
governmental Organizations (NGOs). Within these systems, farmers exchange seed among themselves over relatively short distances. The source of “starter” seed may be suitable adopted varieties from the formal seed sector or productive landraces from local or outside areas.

Due to the limitation of land in Kenya, a concerted effort has been made to produce a high-quality standard seed within the informal seed supply sector. This is facilitated through a farmer-based seed supply, with initial planting materials provided by the Kenya Agricultural Research Institute (KARI) and technical advisory services provided by the KEPHIS.

Farmers from both high- and low-input agriculture areas participate in the early assessment of varieties (transgenic or other). The varieties are assessed in terms of disease and environmental impact, on both test farms and “real” farms. This participation process increases farmers’ understanding of the seed development process and thus enhances their uptake of new technologies. As participants in the selection process, farmers both receive information and, by raising questions, provide input. This helps research scientists to develop innovative and appropriate agendas that are acceptable to farmers.

As research in biotechnology and the production of transgenic plants continues, it is essential that developing countries develop the necessary policies, infrastructure and associated mechanisms to address the actual and perceived risks of this new technology and thus facilitate its acceptance and use. Delivering these new technologies and their products to small-scale farmers and facilitating their uptake will require a combination of the following factors: effective biosafety regulations; an increased level of local public awareness; the creation and enforcement of appropriate intellectual property rights; the sharing and exchange of relevant and accurate information (to address issues such the assimilation of biotechnology skills for commercializing country-specific biotechnology applications) and, finally, the availability of resources, both public and private.

**Literature cited**


Insect control: Durability and breakdown of resistance

Walter Pett1, David Douches1 and Edward Grafius1

The Agricultural Biotechnology Support Project (ABSP) is a United States Agency for International Development (USAID) funded project that was initiated in September of 1991. The overall goal of the project is the mutual enhancement of US and developing country institutional capacity for the use and management of agricultural biotechnology research for the production of improved germplasm.

The potato project was started in 1992. US members of the potato team are David Douches (Department of Crop and Soil Sciences), and Edward Grafius and Walter Pett (Department of Entomology) from Michigan State University (MSU). Team members from Egypt include Taymour El-Nasr and Magdy Makour [Agricultural Genetic Engineering Institute (AGERI)] and Ramzy El-Bedewy (CIP-Egypt). Initially, training was an essential component of the project. Scientists from AGERI visited MSU to learn techniques for vector construction, potato transformation, field testing of transgenic potatoes, potato tuber moth bioassays, intellectual property rights and biosafety.

Potatoes in Egypt

Potato is one of the most important vegetable crops in Egypt, with a total production of up to 2 million tons annually. It is also the leading export vegetable in Egypt, with approximately 225,000 tons exported to the United Kingdom and western European countries. Potato is cultivated on about 34,000 ha in the Nile delta region. Most of the exported potato production is centered in the governates of Behira, Menofya and Garbiya, where yields range between 42.5 and 58.5 tons/ha.

The primary insect pest in Egyptian potato production, as in many other countries in the Middle East, is the potato tuber moth (PTM), *Phthorimaea operculella* (Zeller). In the field, the moths lay their eggs on the potato foliage and the hatched larvae mine the foliage and the stems. This feeding damage leads to irregular transparent tunnels in the leaves and weakening of the stem. The larvae attack the tubers through infected stems or directly from eggs, which are oviposited on exposed tubers or where soil cracks allow moths to reach the tubers. Larvae mine the tuber in the field and in storage, reducing potato quality and increasing the potential for pathogen infection. In Sudan about 30–40% of the potatoes are stored in underground pits and can be destroyed by tuber moth within two months.

Previous research

Initially, transformations with the *Cryla(c)* wild type gene were performed using cv. FL1607 as a model system (Hudy, 1997). Yadav and Sticklen (1995) developed a genotype independent potato leaf disk regeneration protocol. This regeneration protocol was adapted to our *Agrobacterium* mediated transformation protocol (Douches et al, 1998). The first *Cry5*-Bt construct (with the GUS gene fused to the *Cry5*-Bt gene) was used in transformations with cvs. Lemhi Russet, Atlantic, L235 (glandular

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1 Michigan State University, East Lansing, Michigan, USA
trichome line), and USDA838~1 (foliar leptine line) (Westedt et al, 1998). The CryV-Bt constructs that differ in the promoter (CaMV 35S, Gelvin super promoter and patatin promoter) were transformed into cv. Spunta (Li et al, 1999). The Cry5-PVYc gene construct was also transformed into Spunta (Li et al, 1999). Spunta is the most important cultivar grown in Egypt, while Atlantic is a desired chip-processing cultivar. Other constructs that have the GUS gene removed are ready to use in transformation. A sample of the Cry1 and Cry5-t transgenic lines was transferred to AGERI as tissue culture plantlets for greenhouse testing.

Detached leaf bioassays are used to determine the level of host-plant resistance to PTM. Various potato lines were screened for natural resistance to PTM. All PCR-positive Bt transgenic lines developed from this project were screened for resistance to PTM. In addition, a series of other transgenes were evaluated but had no effect upon PTM mortality. We also obtained a number of synthetic CryIa-transgenic potato lines from the USDA to test; these lines gave strong control of the tuber. The most promising lines from the detached leaf tests were also advanced to laboratory tuber bioassays. Tuber bioassays identified a series of Cry5-Bt-Spunta and Cry5-Bt/PVY-Spunta with high levels of potato tuber moth mortality (Li et al, 1999). Other Cry5-Bt-transgenic lines (Atlantic, Lemhi Russet and L235-4) were less effective in controlling the tuber moth, but were significantly different from the non-transgenic cultivars.

Agronomic evaluation of the Bt-transgenic potato lines was initiated in Michigan in 1994. Yearly agronomic evaluations have been conducted at this location, and the trial size has increased to accommodate the number of Bt-lines being tested. These trials have shown that many of the Bt transgenic lines perform similarly to their non-transgenic cultivar. These trials also served as a training site for the AGERI scientists for biosafety and potato varietal assessment. With agronomic evaluations established in Michigan, seed tubers were produced for Egyptian field testing.

The first field test of genetically engineered potatoes in Egypt occurred in January 1997 at AGERI, after the Egyptian biosafety regulations were established. The purpose of this trial was to evaluate an array of Bt-transgenic potato lines for field resistance to potato tuber moth. Fourteen lines were evaluated for foliar and tuber damage. To apply greater tuber moth pressure, the field was artificially inoculated during the season. Foliar mining was as high as 38 mines per 10 untreated plants, whereas the Bt-lines had as few as 1 mine per 10 plants. Non-transgenic tuber infestation was 80–92% (severe level of infection). In contrast, some of the Bt-transgenic lines had as little as 38% infection of the tubers. These results were very promising, and expanded field trials were established for 1998 in Egypt. In February, the AGERI trial was repeated, and an insect and an agronomic trial were planted at the International Potato Center (CIP) Potato Research Station (located in the delta potato-producing region).

1999 Field trial results

The field trials in 1999 involved transgenic lines derived from Atlantic (chip-processing), L235-4 (breeding line with glandular trichome-based natural resistance) and Spunta (tablestock). Atlantic and L235-4 lines have been field tested in Egypt and the US since 1997 and 1996, respectively, while 1999 was the first field trial for Spunta lines. The CIP field trials were harvested 7 June 1999 and tubers were evaluated for PTM damage (Table 1). On average, tuber moth damage was 27% and 28% for the Spunta and Atlantic cultivars, respectively. Damage to the Bt-transgenic Atlantic lines averaged between 80–88% clean tubers, and the four best Bt-transgenic Spunta lines averaged 99.8–100% clean tubers. The Bt-transgenic L235-4 line (L235-4.13) had 99% clean tubers, and the L235-4 line had 84% clean tubers. These tuber results parallel the laboratory tuber bioassays of Douches et al (1998) and Mohammed et al (2000).
In the agronomic trial at CIP, yields were low compared to commercial fields, however, the Bt-transgenic Spunta and Atlantic lines performed comparably to their non-transgenic cultivar (Table 2). The PTM trial at AGERI was harvested 8 June 1999. For this trial, tuber moth infection was low. Only 10% of the Atlantic tubers were damaged by PTM (Table 1). The best Bt-transgenic lines showed less tuber damage (92–100% clean tubers). The clean tubers from these trials will be used for tuber bioassays and as seed for a fall trial at AGERI.

Following field evaluation, the clean tubers from the CIP trials were placed in the Nahwalla at CIP for evaluation of PTM tuber damage after approximately one and two months of storage. Results (Figure 1) show that many of the transformed Spunta lines had minimal PTM infection compared to the non-transformed controls.

### Table 1. CIP and AGERI PTM trials (1999)

<table>
<thead>
<tr>
<th>Line</th>
<th>Percentage Clean tubers</th>
<th>Line</th>
<th>Percentage Clean tubers</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP-S1</td>
<td>100.0&lt;sup&gt;1&lt;/sup&gt;</td>
<td>A</td>
<td>SP-G3</td>
</tr>
<tr>
<td>SP-G3</td>
<td>99.9</td>
<td>A B</td>
<td>SP-S1</td>
</tr>
<tr>
<td>SP-G2</td>
<td>99.8</td>
<td>A B</td>
<td>ATL-Bt3</td>
</tr>
<tr>
<td>L235-4.13</td>
<td>99.8</td>
<td>A B</td>
<td>SP-G2</td>
</tr>
<tr>
<td>SP-S4</td>
<td>99.8</td>
<td>A B</td>
<td>L235-4</td>
</tr>
<tr>
<td>SP-P2</td>
<td>95.9</td>
<td>B C</td>
<td>ATL-Bt2</td>
</tr>
<tr>
<td>ATL-Bt3</td>
<td>91.5</td>
<td>C D</td>
<td>ATL-Bt6</td>
</tr>
<tr>
<td>ATL-Bt8</td>
<td>90.9</td>
<td>C D</td>
<td>SP-G4</td>
</tr>
<tr>
<td>L235-4</td>
<td>87.9</td>
<td>C D E</td>
<td>ATL-Bt8</td>
</tr>
<tr>
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<td>87.6</td>
<td>C D E</td>
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<td>E F</td>
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<td></td>
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<tr>
<td>SP-P6</td>
<td>70.8</td>
<td>F</td>
<td></td>
</tr>
</tbody>
</table>

Mean 89.0 97.2
LSD<sub>0.05</sub> 3.9 2.0

<sup>1</sup> Harvested: 7 June 1999.
<sup>2</sup> Harvested: 8 June 1999.
<sup>3</sup> Means with the same letter are not statistically different, as determined by Fisher’s LSD at 0.05.
Table 2. CIP agronomic trial \(^1\) (1999)

<table>
<thead>
<tr>
<th>Line</th>
<th>US#1 (cwt/a) (^2)</th>
<th>Line</th>
<th>Total (cwt/a) (^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP-G3</td>
<td>108 (^1) A</td>
<td>SP-G3</td>
<td>140 (^1) A</td>
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<tr>
<td>SP-G4</td>
<td>88 A B</td>
<td>SP-G4</td>
<td>135 A B</td>
</tr>
<tr>
<td>L235-4</td>
<td>85 A B</td>
<td>L235-4</td>
<td>119 A B C</td>
</tr>
<tr>
<td>SP</td>
<td>81 A B</td>
<td>SP</td>
<td>118 A B C</td>
</tr>
<tr>
<td>SP-G2</td>
<td>81 A B</td>
<td>SP-G2</td>
<td>118 A B C</td>
</tr>
<tr>
<td>SP-S4</td>
<td>72 B C</td>
<td>SP-S4</td>
<td>107 B C D</td>
</tr>
<tr>
<td>ATL-Bt4</td>
<td>71 B C</td>
<td>ATL-Bt4</td>
<td>100 B C D E</td>
</tr>
<tr>
<td>ATL</td>
<td>61 B C</td>
<td>ATL</td>
<td>90 B C D E F</td>
</tr>
<tr>
<td>ATL-Bt6</td>
<td>52 C</td>
<td>ATL-Bt6</td>
<td>83 B C D E F</td>
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<tr>
<td>ATL-Bt3</td>
<td>50 C</td>
<td>ATL-Bt3</td>
<td>88 B C D E F</td>
</tr>
<tr>
<td>ATL-Bt2</td>
<td>48 C</td>
<td>ATL-Bt2</td>
<td>71 B C D E F</td>
</tr>
<tr>
<td>ATL-Bt8</td>
<td>47 C</td>
<td>ATL-Bt8</td>
<td>66 B C D E F</td>
</tr>
</tbody>
</table>

| Mean       | 70                   | 103        |
| LSD \(_{0.05}\) | 27                   | 32         |

\(^1\) Harvested: 7 June 1999.

\(^2\) cwt/a = 100 pounds/acre.

\(^3\) Means with the same letter are not statistically different, as determined by Fisher’s LSD at 0.05.

Figure 1. Egypt Nawhalla storage results (1999)
**Future work**

Potato transformation with our different promoters and new genes are showing excellent control of PTM. Seed increases of these lines will allow for testing on growers’ farms in Egypt. This is an important step toward commercialization, as it allows the producer the opportunity to observe, first-hand, the benefits of the product. Transforming cvs. Atlantic and Lady Rosette is also an important step toward commercialization in Egypt, as these varieties are very important in the Egyptian chip industry.

**Literature cited**


Traits and genes: Benefits and risks

Marc Ghislain

Sense of urgency

It is widely accepted that low crop productivity in developing countries, combined with current world population growth, threatens future food security. A major constraint to increasing current food crop output is pests and disease. Therefore, the resources of international agricultural research organizations should be focused on increasing crop resistance to pests and disease in order to providing enough food to feed another 2 billion people over the next 25 years. Rather than advocating the increased use of chemical inputs to achieve this goal, the International Potato Center (CIP) develops technologies that will enable farmers to sustain better crop production though improved crop management practices, including the use of genetically improved crop varieties, while protecting the environment.

Use of biotechnology applications

The use of biotechnology to improve the production and multiplication of healthy planting material, contribute to the genetic improvement of crop plants for higher resistance to biotic and abiotic constraints and add nutritional value to food by increasing vitamin content or other beneficial elements, will be one component of this gigantic effort.

The application of genetic engineering at CIP is need-driven for the benefit of all players in developing-country agriculture, with particular emphasis on resource-poor farmers. Contrary to the prevalent public perception of genetic engineering as a profit-driven technology, this new field is intrinsically neutral. At CIP genetic engineering programs aim at developing

- Crops that are free of chemical inputs
- Crops with resistance to adverse growing conditions
- Crops with higher nutritional benefit (e.g., more vitamin content, edible vaccines, and/or a lower level of natural toxicants)
- Crops with improved processing qualities, such as lower demand for energy or reduced chemical waste

Benefit/Risk analysis

New ideas have always generated controversy, and new technologies are no different, often generating an initial uproar based on preconceptions about potential risk. However, debates about the risks of using new technology often dissipate once the practical applications become clear. Therefore, whether or not a new technology is accepted seems to depend more on the outcome of public evaluation of actual benefits than on general perceptions of potential risks.

Biotechnology has not been an exception to this rule. For example, during the 1970s scientists were concerned about the risks of using recombinant DNA technology. Thirty years later, this

1 International Potato Center (CIP), Lima, Peru
biotechnology application—which originally evoked the same concerns expressed about the use of genetic crop improvement today—has proved so successful that original concerns about potential risks have been forgotten.

A benefit/risk analysis must be comprehensive and based not only on scientific criteria but also on social and ethical implications. Moreover, it must be evaluated within the context of current, equivalent technologies to allow for analysis of existing benefits and risks in relative terms. An objective approach, evaluating the risks as either acceptable or unacceptable, independent of how they are generated, must be part of the ethic of such analysis. If not, genetic engineering may be caught in a sort of technology-apartheid, eliminated as an option for increasing food security due to technology-averse perceptions and unrealistic demands for proof of absolute safety.

Current risk analysis for biotechnology (gene modification) is based on scientific data related to three classes of risk assessment: the potential impact on non-target organisms; the safety of the gene product(s) and by-product(s); and their “transgene fitness” within specific environments. The first two types of risk are investigated in regulatory assessment of food crops and pesticides. The third category, transgene fitness, is a new concept that emerged with the introduction of transgenic plants into the environment. It relates to the observation that unintended gene flow can occur—as shown in gene transfer between cultivated plants and their wild relatives—and the assumption that the same event could occur with the use of transgenic plants. It is this last type of risk that evokes the most concern. Hence, perceptions about the potential risk of genetic engineering relate more to the potential impact of the transgene in particular environments than to gene flow per se. Therefore, in assessing the environmental impact of genetic engineering, fitness of the transgene should be the predominant criterion. If a hybrid plant or the cultivar containing the transgene does not have a selective advantage over its non-transgenic equivalent within its specific environment, there is no reason to believe it will affect the environment differently from traditional cultivars. To our knowledge, the release of traditionally bred potato cultivars in environments where crossability with wild relatives exists has not resulted in any negative ecological impact.

There are three types of gene flow within an environment: horizontal, across species and kingdoms; vertical, between sexually compatible species; and remnant, when transgenic-plant reproductive materials are left in the ecosystem. Gene flow can also be classified as either “agro-ecosystem” (occurring within the area of agricultural activity) or “wild-ecosystem” (occurring within the wild, outside of current agricultural areas). Horizontal gene transfer has been addressed experimentally for the transfer of genes from plants to *Escherichia coli* (a common human intestinal bacteria) to *Agrobacterium tumefaciens*, a bacteria known to exchange genes naturally with plant species and to soil microflora (saprophytes of plant debris). Stable gene transfer could not be detected in the studies, which were specifically designed to detect such an event (Schlüter et al, 1995). Transient gene transfer in saprophytes was detected, but stable integration failed to occur (Hoffmann et al, 1994).

Within the agro-ecosystem, we know that potato seeds resulting from vertical flow from transgenic plants to relatives, or from selfing, could be produced provided conditions of compatibility, fertility, physical distance and presence of insect pollinators were fulfilled. Thus, vertical flow could produce remnant gene flow provided the seeds could germinate and survive in the field. The potential for persistence and/or spread of the transgenes within the agro-ecosystem would depend on local farmers’ agricultural practices. Commercial farmers in this area collect potato plant debris at harvest time and either burn it or add it to the soil as compost. However, subsistence farmers often tend to keep volunteer plants emerging from remnant seed tubers because they provide extra food between regular harvests. Such farmers may harvest volunteer potato plants for up to two cropping seasons. Beyond that period, the persistence and/or spread of the transgenic variety would depend on the farmer’s individual agricultural practices. It should be noted that integrated crop management practices advocated among farmers in this region often include the elimination of volunteer potato plants, which are considered potential reservoirs for pests and pathogens.

Outside of the agro-ecosystem, however, the implications of gene flow are much different. The release of potato berries from plants produced through cross-hybridization or selfing, or remnant tubers,
within the wild-ecosystem would create the potential for transgene fitness and thus potential dissemination of the plant material bearing the transgene. This potential impact should be analyzed in relative terms, taking into consideration existing events that imply a similar level of risk. Among others, existing risks include the escape of native cultivars from the agro-ecosystem and their subsequent invasion of the wild-ecosystem. Despite the long-term co-existence between these two environments in the Andes, however, there are no reported or documented invasions of native cultivars in the wild-ecosystem, where they are considered “weeds”.

Hence, the fundamental inquiry associated with the potential negative impact of gene flow into the wild-ecosystem is whether or not the spread of transgenic crops is more likely than the spread of native cultivars. Obviously, such questions must be addressed on a case-by-case basis, and any evaluation of “transgene fitness” must consider the selective advantage gene flow might confer to hybrids or escaped varieties over wild species. Some criteria for appropriate evaluation of transgene fitness for specific engineered traits are described below.

Current use of genetic engineering (GE) in potato improvement at CIP

Research and development of agricultural biotechnology at CIP is largely focused on reducing crop production constraints (Ghislain et al, 1999). Pests and diseases are undoubtedly the main threats to sustainable potato production of small-farm holders. Therefore, CIP’s research efforts focus on this area. In addition to higher pest and disease resistance, a decreased level of natural toxicants in potato tuber is another trait CIP scientists seek to develop using a biotechnological approach.

Late blight resistance engineering
Late blight disease, caused by the oomycete Phytophthora infestans, is the number-one worldwide threat to potato production in developing countries. Several genes coding for antifungal proteins have been shown to delay appearance of disease symptoms in transgenic plants. CIP scientists are searching for synergistic effects between the transgene-products osmotin, glucanase, and lysozyme proteins to obtain a higher level of disease resistance in plants. Increased resistance to late blight and other diseases would allow for more stable production and reductions in the use of fungicides. Reductions in the use of pesticide would, in turn, improve farmers’ health and increase profits. The three proteins described above have no known gene-specific risks and relative risks are minimal as such genes and their products are part of the normal human diet. However, their transgene fitness is limited to the agro-ecosystem, because wild species have already natural resistance to late blight. This implies that late blight is not a dominant constraint within the wild habitat of Solanum populations.

Bacterial wilt resistance engineering
Bacterial diseases, caused byRalstonia solanacerarum and Erwinia carotovora, are the second most important constraint in potato production worldwide. Resistance is being engineered with limited success using lytic peptides (cecropin, attacin, sarcotoxin, and synthetic) and lysozyme (T4, chicken, bovine). This limited success has led to the search for new peptides—both synthetic and those from new plant sources. The benefits of potato cultivars with resistance to bacterial wilt, soft rot, black leg and other diseases are more stable production and thus increased profitability. The use of lysozyme is considered low risk in terms of human health because it is already present in the normal human diet. Much less is known about the risks associated with synthetic peptides. The safety of such molecules should be tested in the laboratory for possible cytotoxicity in plant and animal cells. Their transgene fitness is limited to the agro-ecosystem, because bacterial diseases are not a major constraint in the natural ecosystem of potato populations.

Virus resistance engineering
Resistance to virus diseases is important both for seed certification and for potato production. At CIP, the use of the coat protein gene—controversial due to its virus origin—has been restricted to developing resistance to potato leaf roll virus (PLRV). This is because alternative, more promising resistance mechanisms—the Rx and Ry genes—are already available for potato virus X (PVX) and potato virus Y
Transgenic potatoes for the benefit of resistance to viruses and pests

Insect resistance engineering

The potato tuber moth (PTM) is an important pest of the potato, especially during storage, when potato tubers are exposed for several months. At CIP two genes have been evaluated for their ability to confer resistance to PTM: the Bt gene, and the chymotrypsin gene. The latter was found only moderately effective and therefore is not being pursued as an option. The Bt or the cry1A(b) gene was provided to CIP by Plant Genetic Systems (Belgium), along with the freedom to operate in developing countries. To date, ten potato varieties relevant for a variety of agro-ecologies have been transformed. High levels of resistance were found and have been monitored for up to six months during tuber storage. The benefits of this technology would be less use of pesticides and thus a safer environment for producers, and more stable storage, which would increase profitability. There are no known risks for this gene product. Several multinational companies have developed risk assessments of Bt proteins in food crops, and all concur that they are safe. Although Bt proteins are not part of the normal human diet, their use as bio-insecticides has thus far been regarded as safe for humans, and no negative effect on human health has been reported. Risks of using Bt potatoes would be the possible impact on non-pest insects, and the development of pest resistance that could eliminate the efficacy of bio-insecticides used to protect non-transformed varieties. Transgene fitness is non-existent, because PTM is typically a storage pest.

Reduction of glycoalkaloids

One important quality trait for potato is a low level of natural toxicants (glycoalkaloids) in the tuber. CIP has experienced difficulties in breeding for reduced amounts of glycoalkaloids using plants that have higher resistance to pests and disease and are adapted to lowland tropic agroecologies. However, an antisense approach with the solanidine UDP-glucose glycosyltransferase (SGT) gene has allowed for a reduction in solanidine glycoalkaloids (SGA) of up to 40%. This technology was transferred to CIP, along with the freedom to operate in Peru, Bolivia and Ecuador. The benefits would be a reduction in natural toxicants suspected of causing neurologic disorders (even in previously “acceptable” doses of <20mg per 100gr fresh weight). In regions where potatoes taste bitter (an indicator of natural toxicants) and potato consumption is high, this technology has a tremendous potential for improving the health of Andean communities. In addition, unacceptable levels of glycoalkaloids in potato clones with improved resistance to abiotic and biotic constraints could be reduced using this technology by down-regulating the biosynthetic pathway. There are no risks associated with this technology as long as comprehensive evaluations in the field and under stress conditions are conducted and result in successfully identifying clones with reduced levels of SGA in all environments. No transgene fitness is perceived for such a transgene.
**Minimal risk**

Hence, few if any risks are perceived regarding the potential release of any of these technologies within their respective target agroecologies. However, if successful, these technologies will eventually be combined; the potential risks of such combinations, in terms of possible release into the environment, are unknown. Therefore, the question remains whether or not a pest- and disease-resistant clone—a sort of “Superpotato”—would have any level of transgene fitness in the wild. It is abiotic rather than biotic constraints on cultivated potato that are suspected as acting as limiting factors in preventing the invasion of cultivated potato into the wild. For example, cultivated potato would most likely need to acquire the capability to grow in rustic soils and to resist freezing temperature before becoming a serious threat to the wild environment.

Assuming a transgenic potato clone with either neutral or positive competition over wild species did escape into the environment, the impact would hardly ever be observed due to the slow dispersion rate of potato species. Potato plant pollen diffusion is limited to a maximum distance of 20 meters via insect vectors. Other factors that diminish the potential for spread into the environment are (1) potato berries are not palatable to animals and therefore are not dispersed via their food chain, and (2) potato tubers—which provide the dominant means for potato propagation—are subterranean. Finally, wild potato species are usually found at high elevations, scattered throughout a harsh environment separated by tenacious physical barriers, the Andean mountains. Hence, if a Superpotato were to escape into the wild—even one with potential negative impact to the environment—its presence would be minimal and, if detected, could be easily eliminated.

**Use of genetically engineered potato crops: General issues**

As described above, transgenic potatoes present various potential benefits and risks, depending on the transgene itself and the target agroecologies of the improved varieties. Therefore, specific biosafety regulations are needed to mandate proper management procedures for their release and use. In Peru biosafety laws for the management of transgenic potatoes was enacted in 1999. Regulatory procedures are still under development and are scheduled to be published in the year 2000. Regarding the issue of intellectual property rights, often associated with this technology and perceived as an impediment for technology transfer to developing countries, CIP has adopted policies for two categories of use for the technologies it acquires: (1) research purposes and (2) product development. Different degrees of restrictions are applied, according to the category. In most cases, when the technology is acquired for product development, CIP will also seek the patent holder’s permission to apply it (“freedom to operate”) within the context of developing-country needs. CIP has been successful with this strategy for a number of key technologies, including Bt gene, virus resistance Rx and Ry genes, and glycoalkaloid reduction genes.

However, regardless of the method or the application, the origin of genes in organisms remains an important public concern. Therefore, in its biotechnology applications CIP favors the use of genes that are naturally occurring in the closest sources to the crop targeted for improvement. It strongly believes that gene flow between closely-related species evokes fewer and less emotional concerns about the potential risks of genetic engineering modification. Using this strategy, CIP expects to increase the rate of adoption of the most beneficial applications of modern biotechnology.

The use of antibiotic resistance genes as selectable markers for plant transformation has also evoked public concerns, despite the evidence that these products are safe for human and environment health. Therefore, CIP scientists will gradually replace their use of antibiotic gene technology with newer technologies based on the use of alternative selectable marker genes.

The insertion of foreign DNA into plant genomes has also been questioned in terms of the safety of interrupting or modifying the genes present at the site of insertion and the stability of the insertion
itself. The first concern can be addressed by verifying that the insertion did not disrupt a gene. In the case of potato, if an insertion interrupts a gene, at least three additional, functional copies of it exist. The second concern is addressed by proper testing of the expression of transgenes through generations. Due to its clonal propagation the potato gene insertion will be prone to stable expression over generation.

**Risk of inaction**

Not using available genetic engineering applications in developing countries is actually the most important risky alternative in terms of maintaining sustainable agriculture worldwide (Seralgeldin and Perseley, 2000). This is one risk for which there is plenty of evidence and data.

Poverty alleviation will certainly benefit from this technology due to all of the opportunities it creates for generating new income for agro-industry, including farmers, as the suppliers of agriculture products. Although resource-poor farmers may be the last to benefit from new agro-industry opportunities, at least this chance would exist.

Finally, food insecurity and continued damage to the environment are by far the most important risks of not taking advantage of gene technologies.

These risks of inaction can be expressed in the form of three current needs

- **Need to improve crop productivity**
  Today, about 800 million worldwide are undernourished; 25% are children and most live in developing countries. Together with food scarcity, poverty is a main cause of this malnutrition. About 1.3 billion people live on less than US$1 per day, and another 1.5 billion live on less than US$2 per day. Based on the projected population growth rate, an additional 2 billion people will need to be fed by 2025. This increased need for food production will not be achieved by an increase in arable land, as 1 ha is lost worldwide every 7.67 seconds, largely due to urbanization. Therefore, the increase in food output will have to come from an increase in crop productivity.

- **Need to ensure food security**
  In the case of potato, it has been estimated that 21% of production is lost due to diseases. The world average potato yield could be increased from the current 13 t/ha to 40 t/ha if pests and diseases were controlled. Because access to pesticides is restricted in developing countries by both geographical isolation and limited financial resources, host-plant resistance to this biotic constraint is an important trait achievable through biotechnology that will increase potato yields to help ensure food security.

- **Need to protect the environment**
  Pesticides are often inappropriately formulated or handled. The packaging requirements (safety instructions, seal and strength of containers, etc.) are either poorly defined or are not enforced, particularly in remote areas in developing countries. This situation is aggravated by the use of contraband products to evade taxes or because of known toxicity for the environment, including human health. Whether or not they are contraband, all types of pesticides create potential environmental and health hazards. In Peru recent tragedies involving the use of chemical products in agriculture include those in a farmer community in the Andean city of Cusco, where children died after ingesting milk-based breakfasts prepared in bottles previously containing organophosphate pesticides (El Comercio, 25 October 1999). Hence, the need for environmental protection is a serious issue in developing countries.

In conclusion, the potential benefits of CIP’s use of genetic engineering applications for root and tuber crops largely exceed the potential risks. Publicly-funded research at CIP and other international agricultural research organizations needs to be strengthened to ensure the diligent and safe application of GE technology for the benefit of resource-poor farmers. Delaying the use of GE technology transfer
to developing countries not only sustains the current overuse of toxic and costly chemicals, but also slows growth in crop productivity. Active support for agricultural biotechnology is urgently needed to help CIP scientists and other specialists deliver the technology to ensure food security and protection of the environment.

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The case in favor of transgenic, nematode resistant potatoes for Bolivia

Howard J. Atkinson 1 and Jayne Green 1

Introduction

Bolivia has the lowest GNP in South America, and the International Fund for Agricultural Development (IFAD) of the UN estimates that 97% of the Bolivian rural population lives in extreme poverty, a proportion that compares unfavorably with even the poorest African countries (van Lindert and Verkoren, 1994). It has one of the lowest per capita calorie intake in the world (Dyson, 1996). The highland regions of the alto plano (high plain) and the valles (hillsides) are populated with smallholder growers with freeholds created by land tenure reform in 1952. Potato is the principal staple food for Bolivians. The two principal potato-growing areas are the Departments of La Paz and Cochabamba in the alto plano and valles regions respectively. The average landholding of the subsistence growers in these areas is approximately 0.4 ha per family, which is only 25% of the average national landholding (Terrazas et al, 1995).

The nematode pests are Globodera spp. (potato cyst nematode; PCN) and Naccobus aberrans (false-root-knot nematode or rosary nematode). They occur together or individually on 91% of the potato-growing land of Cochabamba Department (Ramos et al, 1996). There is a similar prevalence in other traditional, potato-growing regions of Bolivia. A third nematode pest, Meloidogyne spp., occurs in soils below 2000 meters above sea level (masl). A wide range of pest management measures could contribute to improved PCN control (Atkinson et al, 1999), and genetically modified resistance could be one tactic of such an approach.

Nematodes, along with other cropping constraints, result in mean potato yields in Cochabamba of only 5 t ha⁻¹ (as per government estimates). This is only about 20% of the potential yield in Bolivia. Losses to nematodes result in a traditional smallholder potato-growing area that is twice as large as what would be needed with efficient pest control. Improved nematode control would free land for other crops such as legumes, which would offer improved nutrition for the rural poor.

A genetically modified (GM) based approach to nematode control

A new technology provides resistance to a wide range of nematodes, including all those attacking potato in the Central Andes. Plants expressing a cysteine proteinase inhibitor suppress growth of both cyst nematodes (Urwin et al, 1995) and root-knot nematodes (Urwin et al, 1997). Additive resistance can be achieved by expressing combinations of proteinase inhibitors (Urwin et al, 1998). In a field trial, cystatins expressed in potato conferred resistance to Globodera pallida (Urwin et al, 2000 and unpublished data). The potential of this approach has been reviewed in detail (Atkinson et al, 1998). Although its efficacy is still being developed, this approach is timely and should be considered in terms of its high potential to increase food security and environmental biosafety.

1 Centre for Plant Sciences, Leeds Institute for Plant Biotechnology and Agriculture, University of Leeds, Leeds, United Kingdom
Addressing concerns about food safety

Genes introduced to plants from other organisms pose ethical problems, according to certain religions. We seek to address this concern by favoring the use of plant genes in GM crops, thus avoiding the issue of cross-kingdom gene transfer, as some gene transfer already occurs naturally between plants. Our approach seems appropriate for Bolivia, given the fact that The Vatican has affirmed that development of GM crops does not raise ethical concerns according to Roman Catholicism (Barnett, 1999).

Any toxicity or allergenicity associated with a particular food is universal to all human populations. Therefore, we believe that GM traits that have been approved for use in the developed world should be considered for use in the developing world. We also subscribe to the view that compounds that require particular attention are those that are either new to the human diet or are present in a much greater concentration than before. It is these new ingredients that should be scrutinized in terms of human health— not the method used to breed the plants.

Our work is based on five main lines related to food safety: (1) the cysteine proteinase inhibitors (cystatins) we use to confer nematode resistance already occur in plant-based foods such as the seeds of rice, maize and sunflower; (2) cystatins are unlikely to persist beyond the cooking and digestion process, and are therefore unlikely to reach the intestine; (3) cystatins lack toxicity to mammals and birds, and also lack allergenicity; (4) a functionally similar cystatin occurring naturally in human saliva is swallowed in amounts of up to 40 mg min\(^{-1}\) when we chew food (Veeran et al, 1996); there is no need for the protein to be produced by the transgene to be expressed in the potato tuber; and (5) the nematodes we seek to control normally occur in roots, and a range of root-specific promoters have been identified that can limit expression of the transgene to these roots. Our aim is that the level of cystatin present in a future transgenic potato should be less than or comparable to the level of cystatin present in human saliva when the transgenic potato is eaten. The risk should also be considered in relative terms. For example, natural toxins of potato tubers are prevalent in green tubers and tissues and are known to be harmful to humans, and Bolivians consume up to 50% of their total calories from potato (Quiroga, 1995). Therefore, the natural risk accompanying the consumption of tubers, particularly from plants grown under stressful conditions, is likely to exceed considerably that from the genetic modification we propose.

Therefore, we consider there is an overwhelming case for suggesting that cystatins pose no new toxic or allergenic risk to humans. Work is ongoing to substantiate the biosafety of cystatins in food. Such information will be provided to regulatory authorities before non-experimental cropping of the new GM potato is contemplated.

Addressing concerns about environmental safety

The introduction of new traits into a crop species may alter its ability to invade natural habitats. However, potato is not a weedy crop and fails to persist in Bolivian fields. It must be re-planted for each crop with or without genetic modification. This lack of invasiveness is not due to nematodes, and PCN is restricted by its host range to places where potato is grown. Therefore, nematode resistance would not confer an important ecological advantage on GM potato plants. Ecological risks may accrue if genes are transferred to other organisms. The term “genetic pollution” was originally defined to describe gene transfer between two sexually compatible organisms (dog and wolf). This term could also be applied to potato in Bolivia to describe outputs from both conventional and transgenic manipulation of the potato. However, introgression of DNA or “gene pollution” (Butler and Reichhardt, 1999) from potato to other Solanum species already occurs naturally in Bolivia, which is a center of biodiversity for the potato. Hybrids are usually less adapted to local conditions than their parents and therefore do not persist for many generations. New genes introduced to the potato from distinct species occurring in other geographic regions (e.g. Argentina) were most likely passed by introgression to wild
Solanaceae (Raybould and Clarke, 1999). No concern has been expressed in response to this phenomenon, and no evidence of harm has been reported. Nonetheless, our GM research is designed to reduce exposure. We have measured the spread of pollen from a male-fertile to a male-sterile \textit{S. tuberosum} ssp. \textit{andigena} in Bolivia by counting berries on the male-sterile plants at a known distance from those producing pollen. The results suggest the relative risk was reduced from about 10% (cross-pollinated plants at 1 m) to 0.001% at 100 m. We are now examining if exposure varies considerably with locality in Bolivia, depending on the activities of insects such as bumblebees. Our aim is to reduce the risk of transfer by many orders of magnitude from this quantifiable level.

Another concern is environmental risk to non-target invertebrates. Our work to-date has concentrated on the consequences of expressing a cystatin in green tissue. This work is covered elsewhere in these Proceedings by Sue Cowgill.

**Benefits of future uptake of nematode resistant potatoes**

The initial aim of GM nematode resistance is not to produce more potatoes (although this will be a future goal as the human population increases), but to produce similar amounts of potatoes using less annual acreage. The principal environmental change would be increased production of other crops on already cultivated land. This would promote better nutrition for indigenous people and would increase the level of between-species varietal biodiversity in their fields.

Nematode resistance would also provide other benefits. Currently, rare indigenous forestland in the Chapare area of Bolivia is being destroyed to provide PCN-free land on which to produce seed potatoes. Reducing the nematode problem would lessen the need for this activity. However, as any new agricultural procedure can have unexpected consequences, we hope to identify and minimize any negative impact GM nematode resistance might have by collaborating with socio-economists at all stages in the development and adoption of an appropriate form of the technology.

**Publicly funded research for the public good**

Many consider the disengagement of GM crops from the interests of biotechnology companies an essential, priority issue for the developing world. A main hope for the future is that companies will be encouraged to donate their technology to the public good. If restricted to crops and countries outside the realm of their commercial areas, this would not compromise their interests. Many who campaign against GM crops express concerns over multinational monopolies, failing, either though lack of information or bias, to consider the value of the company-free, publicly funded approach that is already well established.

Because publicly funded and charitable research can help meet developing-world needs (Atkinson, 1998, 1999), strengthening GM capabilities within CGIAR institutes should be a priority. The donation of nematode resistance technology by the University of Leeds provides a paradigm for such efforts. This technology has been donated for developing-country applications through a royalty-free license agreement with the Plant Sciences Research Programme of the UK’s Department for International Development. Several crops and developing countries are covered under the agreement. The cost of developing the technology for resource poor farmers is reduced by a parallel investment targeted at first world needs. Public funds can concentrate on the specific issues concerning the safe and effective uptake of GM crops in the developing world.
Conclusions

Supporters and critics of GM technology should judge each opportunity for its use within a specific context rather than in general terms. In the case of nematode resistance for potato, the benefit in Bolivia would be less national acreage committed each year to potato cultivation and the possibility for increased production of other nutritious food crops on the additional land that is made available. Other potential benefits to the rural economy include better nutrition, increased production and increased employment opportunities. Unlike many agricultural interventions, the cultivation of GM crops would require little or no extra expenditures, as the resistant transgenic potatoes would be in the public domain and, therefore, royalty-free and would not require any changes in how the crop is grown.

Acknowledgements

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Literature cited


Monitoring and regulating uptake of transgenes

Maddalena Querci¹

Introduction

This document summarizes the information presented at the international workshop on “Transgenic Potatoes for the Benefit of Resource-Poor Farmers in Developing Countries” held in Manchester (United Kingdom) 5–9 June 2000. Although it refers to the legislative framework of biotechnology regulation, it should not be seen as a text that clarifies the legal provisions of the regulation. The document does not present the official position of the European Commission. Any opinions expressed are those of the author.

European legislation on genetically modified organisms (GMOs)

The development of new genetically modified crops is proceeding rapidly and several transgenic crops have already entered the phase of large-scale agriculture in some countries. The next step in the chain - the use of genetically modified crops as food and in food products - is becoming more and more widespread.

To harmonize the approach of the Member States of the European Community regarding the regulatory oversight of genetically modified organisms (GMOs), and to respond to the concerns expressed by many consumers about their use in everyday products, the European Union has implemented a set of strict procedures. These procedures concern the approval for the release into an open environment, cultivation, importation and, particularly, utilization of GMOs as food or food ingredients.

¹ European Commission, DG Joint Research Centre, Institute for Health and Consumer Protection, Food Products and Consumer Goods Unit, Ispra (Varese), Italy

The authorization for the release of GMOs into the environment for research and development purposes (small-scale field trials) is a national decisional process. National Competent Authorities evaluate and either approve or disapprove the notifications submitted to them. According to Article 9 of Council Directive 90/220/EEC, all Member States should, however, be informed about experimental releases planned within the Community. For this purpose, the European Commission has set up a system for exchange of this information in which a summary of each notification received is forwarded by the corresponding Competent Authority to the European Commission’s Joint Research Centre (JRC) and then distributed among the Community. GMOs comprising at least 27 distinct plant species have been tested in field trials in the EU and, to date, close to 1600 dossiers have been submitted for approval and distributed. A regularly up-dated summary containing details about all deliberate field trials carried out in the EU is available online2.

As indicated above, the placing on the market of products containing GMOs is dealt with in part C of Directive 90/220/EEC and the authorization is, in this case, a Community decisional process. Before a GMO or a combination of GMOs is placed on the market, the notifier (the manufacturer or the importer) is called to submit a notification to the Competent Authority of the Member State where the product is intended to be placed on the market for the first time. The receiving Competent Authority examines the dossier, evaluating in particular the environmental risk assessment and the recommended precautions related to the safe use of the product. The dossier is then either forwarded to the Commission with a favourable opinion, or it is rejected in case the proposed product does not fulfil the conditions of the Directive. In the case of a favorable opinion, the Commission forwards the submitted dossier to the Competent Authorities of all Member States. If the Competent Authority of another Member State raises an objection – for which the reasons must be stated – the Commission shall take a decision in accordance with the procedure described in Article 21 of the Directive. In this case, and before a decision is taken, the dossier is forwarded to the Scientific Committee of Plants, one of the independent scientific committees presently under the responsibility of the Health and Consumer Protection Directorate-General1. Once a product has received a written consent, it may be used without further notification throughout the Community provided that the specific conditions of use and the geographical areas stipulated in these conditions are strictly adhered to. In some cases, Member States have appealed against the community approval of GMOs and have submitted new scientific evidence to prohibit the utilization of certain GMOs in their territory (European Court of Justice, 2000).

On 23 February 1998 the Commission adopted a proposal for amending Council Directive 90/220/EEC with the aim of making the system more effective (establishing differentiated procedures), more efficient (establishing tight time limits for authorization) and, most important, more transparent (informing the public, labeling procedures). The common principles for the risk assessment have been maintained equal to those described in the former Directive. This proposal is currently undergoing the co-decision procedure between European Parliament and Council.

The use of GMOs in food and food products is controlled by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997, concerning novel foods and novel food ingredients (Regulation EC, 1997). The Novel Foods Regulation applies to all foods and food ingredients to be placed on the market within the EU with a new or intentionally modified primary molecular structure, including those containing, produced from or consisting of genetically modified organisms

within the meaning of Council Directive 90/220/EEC. The labeling of foodstuffs and food ingredients containing additives and flavorings that have been genetically modified or have been produced from genetically modified organisms has been recently regulated (Commission Regulation EC, 2000b).

After receiving an application, the Member State Competent Authority informs the applicant that the food or food ingredient can be placed on the market, or that an authorization decision is required. The trigger between the two might be the “substantial equivalence”; i.e. the assumption that the novel food does not differ from the food or food ingredient which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

The specific labeling requirements apply to foodstuffs in order to ensure that the final consumer is informed of any change in food properties – composition, nutritional value or nutritional effects, intended use – which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient. A novel food or food ingredient shall be deemed to be no longer equivalent if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics (Regulation EC, 1997).

Because two genetically modified products (Roundup-Ready® soybean and Maximizer maize) had already been placed on the market before the Regulation (EC) No 258/97 (Regulation EC, 1997) came into force4, their labeling requirements are regulated by the EC Council Regulation 1139/98 (Council Regulation EC, 1998). In addition, Commission Regulation (EC) No 49/2000 (Commission Regulation EC, 2000a) of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from GMOs of particulars other than those provided for in Council Directive 79/112/EEC has been adopted. This so-called “threshold regulation” stipulates that foodstuffs shall not be subjected to the additional specific labeling requirements if the material derived from the GMO is present in food ingredients in amounts not higher than 1 % of the food ingredients individually considered. It is important to note that the threshold regulation applies only to authorized GMOs and that GMOs that have not received consent under the Novel Foods Regulation cannot be utilized at all. In addition, in order to establish that the presence of this material is adventitious, operators must prove that appropriate steps have been taken to avoid the use of GMOs.

Analytical methods for the detection and monitoring of GMOs

Although the release and use of GMOs are tightly regulated, the proper implementation of the legislative framework, including monitoring of the flow of GM products in the market, inspection and control of their presence in final products requires, in practice, the availability of a complete set of “traceability” tools.

In accordance to the EC Regulation 258/97 (Regulation EC, 1997) and the Council Regulation 1139/98 (Council Regulation EC, 1998), novel foods and food ingredients are considered to be no longer equivalent to conventional counterparts and are subjected to labeling if the DNA or the protein from the genetic modification is detectable.

The differentiation between conventional food or food products and food containing or consisting of GMOs, shall be achieved by applying appropriate scientific methods.

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Transgenic plants are characterized by the insertion of a new gene (or a new set of genes) into the DNA. The new gene is translated and the new protein expressed. This gives the plant a new characteristic, such as resistance to certain insects or tolerance to herbicides. The basis of every GM detection technology is to find the difference between an unmodified and a transgenic plant. This can be done by detecting the new DNA that has been inserted or the new protein expressed or, if the protein acts as an enzyme, by using chemical analysis to detect the product of the enzymatic reaction. Therefore, the development of analytical methods for the detection of DNA or proteins resulting from genetic modification and the validation of such methods are of utmost importance to verify compliance with labeling requirements. In addition, the development, validation and use of methods for GMO analysis demand the availability of specific reference materials.

Because of its high sensitivity, the polymerase chain reaction (PCR) seems to be the technique best suited for the detection of GMOs in food - although other assays such as enzyme-linked immunosorbent assay (ELISA) for the detection of the proteins expressed by these GMOs are being developed. The first method validated at the EU level is a PCR-based screening method able to detect most of the GMOs presently approved for marketing (Lipp et al., 1999). This method, developed by Pietsch et al. (1997) is based on the detection of the control sequences flanking the newly introduced gene, the 35S promoter and the nos terminator. The validation was coordinated by the Food Products and Consumer Goods Unit of the Joint Research Center (JRC) and carried out in collaboration with the JRC Institute for Reference Materials and Measurements (IRMM), which was responsible for the production of appropriate Certified Reference Materials.

As mentioned above, research efforts are also directed to the development of protein-based methods. A highly specific method for the detection of Roundup Ready® soybean using the ELISA has been recently validated (Lipp and Anklam, 2000) and others are being developed.

Since the threshold legislation came into force establishing a threshold level of 1% GMO in food, the correct quantification of GMO content, as well as the characterization of which specific GM line is present in a product, are needed in order to meet regulatory and consumer demand. Therefore, numerous PCR-based methods have been developed which can not only assess the presence of genetically modified material, but also identify and quantify GMOs in agricultural crops and food products. One of the first methods developed for this purpose is the quantitative competitive PCR (QC-PCR). The principle of the method is the amplification of internal DNA standards together with target DNA. The quantification of the GMO present in a sample is achieved by comparing, by electrophoresis, the intensity of the band of the amplicon of interest (GMO specific band) with the band of the internal standard (Hardegger et al., 1999; Studer et al., 1998). A probably more accurate and now widely used approach is the real-time PCR. In this case specific and sophisticated instrumentation allows the amplification of the DNA to be monitored during the whole reaction and the quantification to be done during the exponential phase of the DNA synthesis (Vaitilingom et al., 1999).

Although the high costs of the instrument itself, and of the specific products, are still an obstacle for many laboratories, real-time PCR can probably be considered the most precise and advantageous method for quantitative PCR at the moment.

Conclusions

From the practical point of view, the availability of specific and suitable validated methods is not enough to ensure the proper implementation of a GMO monitoring process. The detection of genetically

modified organisms and their monitoring throughout the complete chain (from production to consumers) is an expensive and complex multiparameter problem. A number of critical issues in respect to quality control and inspection also need to be considered and harmonized.

Improvement of current methodologies, along with the production of appropriate reference materials, are still needed to prove the validity of the tests, not only in raw materials but also particularly in key food fractions (e.g. protein concentrates, protein isolates and lecithin preparation). Currently, ring trials are being carried on to better understand the difficulties that can be encountered when using processed materials.

An increasing number of control laboratories in the EU are adopting PCR technology for GMO detection, but still the work load and complexity of the issue urges an increased cooperation among the different actors - from seed developers to processors and manufacturers in order to achieve proper verification of methods performance and standardization of procedures.

The development of appropriate, accepted and harmonized sampling procedures, based on scientific and statistical principles, is still urgently needed. In addition, the efficient utilization of modern techniques for GMO detection depends on the availability of accurate information: GMO detection requires at least a partial knowledge of the target gene sequence and type of genetic modification. For this purpose an ongoing research project is addressing the development and establishment of a database containing specific data on GMOs produced and derived foods introduced into the market. This is particularly important considering the concern with respect to non-approved GMO products that may enter the international market.

**Literature cited**


Commission Regulation (EC). 2000b. No 50/2000 of 10 January 2000 on the labeling of foodstuffs and food ingredients containing additives and flavorings that have been genetically modified or have been produced from genetically modified organisms. Official Journal of the European Communities No. L 006, 11/01/2000, p. 0015.


Regional harmonization of biosafety standards: An essential component

Marcio C M Porto¹ and Robert Griffin²

The biosafety aspect of transgenic potatoes does not differ from the biosafety issues for other crops (transgenic or not) except that the type, quantity and quality of the system and the relevant information vary, depending on the crop, the situation and the country or group of countries under consideration.

The subject of harmonization of phytosanitary measures and the development of International Standards for Phytosanitary Measures (ISPMs) has been a priority for the Food and Agriculture Organization of the United Nations (FAO). This subject is addressed by a number of technical units in FAO and several different international bodies that are assisted by FAO. In the evolution of the process of establishing international standards, it is important that agreed principles are established, concepts are described, common terms and definitions are adopted, guidelines or recommendations are formulated, and specific recommendations or regulations are elaborated.

International standards are defined as “documents established by consensus and approved by a recognized body that provide, for common repeated use, rules, guidelines or characterizations for activities or their results, aimed at the achievement of the optimum degree in order in a given context”. The Agreement on the Applications of Sanitary and Phytosanitary measures specifically identifies the International Plant Protection Convention (IPPC) as the international standard setting body with respect to phytosanitary measures. FAO and its Member Countries recognize this as a crucial aspect in harmonizing biosafety measures. The definition of “consensus”, based on the principle of general agreement and following a process that involves seeking to take into account the views of all parts concerned and to reconcile any conflicting arguments, is also an important factor for the negotiation, adoption and implementation of standards and rules.

Harmonization is based on several factors that, if properly followed, will have direct influence on the success or failure of the process. These factors are

- Adoption of common values and objectives.
- Shared interest and concerns.
- Existence of economic and other benefits.
- Need to overcome differences and avoid disputes.
- Need to co-operate against other interests.
- Need to simplify.

In general, harmonization for biosafety can be simplified to focus on three distinct areas: authority, analysis, and administration, as described below:

Authority enables legislation (acts, laws, decrees and orders from national governments) giving authority to an agency or agencies responsible for biosafety. This is primarily authority to undertake the following (this is not an exhaustive list, but examples of the more important functions): promulgate regulations; supersede sub-national authorities (states, provinces, etc.); enter properties and intercede

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¹ Crop and Grassland Service, Plant Production and Protection Division, Agriculture Department, FAO, Rome, Italy
² International Plant Protection Convention. Plant Protection Service, Plant Production and Protection Division, Agriculture Department, FAO, Rome, Italy
in trade or domestic movement (enter, detain, treat, destroy - with or without compensation) of plants and plant products; and provide resources for implementing agencies. Establishment of regulations (or executive-level rules) is necessary for describing the prohibitions, restrictions, and requirements done under authority and with support of national legislation. Finally, authority is also used to create policy instruments such as permits, manuals, guidelines and related bits of everyday policy.

Harmonization of authority can be difficult as countries can have very diverse legal systems. The objective should not be model legislation/regulations, but rather a checklist of essential elements that can be built into different national legal systems in different ways. Harmonization should focus on identifying and agreeing on these core elements, while giving adequate consideration to international or regional obligations and principles. An important concern is design so that not only are the desired objectives met, but they are also feasible to implement. An element of reality must balance the wish to manage all risks perfectly. Professional legal assistance is generally needed to incorporate such changes into national legal systems and is often provided by FAO.

**Analysis** is the scientific and technical basis for establishing biosafety systems. The key component is risk analysis. Elements of risk analysis include risk assessment (or the process that enables the identification of hazards), their probability to occur, and their potential consequences. Other important components are: determination of the acceptable level of risk (needed as a matter for consistence); identification of risk management options; evaluation of risk management options for efficacy, feasibility and impact; and the selection of appropriate options or phytosanitary measures.

Harmonization of analysis occurs at two levels. The first is conceptual, i.e., agreement on fundamentals. The second level is technical and involves agreement of approaches, methodologies, criteria for determining unacceptable risks, etc. In general, developing countries are discouraged by the impression that significant resources and sophisticated technologies and equipment are required for harmonization and implementation of phytosanitary measures and undertaking risk analyses — which is not true.

There are currently 10 ISPMs that have been adopted by IPPC contracting parties (a number of them of a technical nature) and there are a number of other technical ISPMs under development. Two are on pest risk analysis for quarantine pests and regulated non-quarantine pests. An example of harmonization efforts by FAO and its Member Countries for risk assessment is a document being prepared that aims to establish international standards for ecological risk assessment of herbicide-resistant and insect-resistant crops. Risk assessment keys covering volunteer problems, hybridization with weedy or wild relatives, hybridization with non-herbicide resistant or insect-resistant crops, build up of herbicide resistant weeds, and build up of resistant insects are being proposed for use in the process of risk assessment of transgenic crops. In the process, different scenarios that consider the environment and the presence of wild relatives are envisaged into better assess the potential risks of the release of genetically modified crops.

**Administration**, the third area for harmonization for biosafety, as it is important to describe the framework for the implementation of norms, rules and standards. It includes such things as record keeping, communication (public relations), information exchange and notification systems, consultation systems, and certification.

There are many opportunities for harmonization in biosafety and the various components can be separated based on priority and/or ease of agreement.

In conclusion, particular characteristics of transgenic potatoes need to be taken into consideration for their development and release. Regional harmonization is an essential component to be considered by countries located in the same region and sharing common similarities, problems and opportunities. Such harmonization should facilitate the development, release and trade of transgenic potatoes.
Those countries located in the Center of Origin, or in the Centers of Diversity, of the species could have different regulations and standards when compared with those located outside the areas of origin or diversity, but a number of general phytosanitary measures could be applied to all countries in different geographical areas.

As mentioned in the beginning of this paper, FAO is deeply involved in the development and implementation of standards for harmonization of phytosanitary measures for transgenic and non-transgenic crops. Countries are encouraged to contact the Organization for technical support and policy advice in this area.
Transgenic potatoes for the benefit of res...
The following four working groups were formed on topics selected by the participants as being the most relevant to the adoption and critical for the uptake and utilization of potato transgenics in developing countries:

- Strategies for addressing public concern
- Seed system issues and intellectual property rights
- Gene flow, effects on non-target organisms and biosafety issues
- Health and food safety

Each working group was asked to consider the following four questions:

What is the issue within this topic that is specifically relevant to potato transgenics?
What action is needed to address the issue?
What research is needed to provide further information?
What future steps are needed, and can be supported by this Workshop?

Brief reports of the discussions of each working group are shown in the following pages. A summary of the actions steps suggested by the groups is shown in Box 1 on page 7 of Introduction and outputs.
Report from working group on strategies for addressing public concern

Julian Smith, Facilitator; Howard J Atkinson, Rapporteur

The public perception that transgenic potatoes could be dangerous to both human health and the environment must be adequately addressed. The Working Group agreed that many elements of society — from international donors to trade associations — should be engaged in this dialogue (Box 1). Activists, both those positively and negatively disposed to transgenics, require special attention and treatment (Box 2).

Box 1

Who to engage with in dialogue?

- International Donors
- Government
  - Ministries
  - Biosafety & other committees
- Politicians
  - National and local
- Media
- Activists
  - + ve and - ve
  - NGOs and NGOs
- Religious groups
  - Awareness of their stance
- Supermarkets & cash crops
- Civil Society
- Farmers’ Associations
  - Not for profit
- Unions/co-operatives
- Professional bodies
- Crop advisers
- Consumers
- Academic sector
  - Higher
  - Schools
- Research institutes
- Private sector
- Trade associations

Box 2

Listening to concerns of activists

- Need to listen to the arguments of those against GM
  - Dialogue as a basis for compromise
- Need policy statements to be made by “correct” spokesperson
- Feedback from the groups you target
  
  Responding to Community Outrage based on Sandman, P.M. 1993
  - Activists do not create but they build outrage
    - Try to prevent outrage building
  - Do not deny public concerns but acknowledge them
    - They may be wrong on hazard
    - They are always right on outrage
  - Tell what steps you are taking
    - Be accurate, no false impressions
    - Overestimate any risk that is valid
  - Exaggeration of activists
    - Acknowledge the risk
    - Defend when you are right
    - Apologise when you are wrong
Freely available information is the foundation for a successful endeavor. This information, gathered from diverse sources, can be presented in multiple modes and should be prepared and targeted for specific users (Boxes 3 and 4).

**Box 3**

**Types of information underpinning our dialogue**

- Technical
  - dossier
  - summaries
  - updates
- Popular
  - farmers
  - consumers
- Responses to misinformation
  - briefing paper denials
  - highly targeted
  - positive responses
  - wider audience
- Sources of Information for protagonist
  - Website lists
  - background information
  - selectable markers
  - answers to common myths
- Sources
  - a resource of audited positive information sources
  - brief guide to sources
  - utilise sources known
  - APHIS
  - CIMVSTAV, Mexico

**Box 4**

**Provisional matrix of information types for different interest groups**

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Broadcasting or disseminating the information should be accomplished using carefully planned communication strategies ranging from the employment of socio-economists trusted by growers to the development of a public database on the benefits, quantified to the extent possible (Box 5). Examples of benefits include, but are not limited to, reduction in loss of wilderness, decrease in pesticide usage, decrease in costs and environmental harm, and nutritionally enhanced foods. Information on risks and existing risk analyses should be provided in order to raise public awareness of the regulatory work on risks and of the “safety” issues. Future steps include capacity building, access to information, training courses, and the formation of National Groups to address these issues (Box 6).

**Box 5**

**Broadcasting information**

- Personal Contacts
- Socio-economists trusted by growers
- Guidelines for press releases
- Worked examples
- Workshops with +ve NGOs
  - Journalists being informed by pro farmers + municipalities
  - Photographs
- Field Schools
  - Beneficial solutions and the technology
- Data base on benefits e.g.:
  - Loss of wilderness
  - Pesticides
  - Cost and environmental harm
  - Functional foods

**Box 6**

**Future Steps**

- Capacity-building
- Regulations and monitoring
- Access to information
- Training courses
  - Media relations
  - Biological, ethical and other aspects
- Formation of National Groups to address these issues
Report from working group on seed system issues and intellectual property rights

Chagema J Kedera, Facilitator; Marc Ghislain, Rapporteur

Seed Systems

The Working Group felt that the formal seed system should be strengthened to enable and encourage seed labeling. Physical and descriptive markers should be developed for formal and informal systems (e.g., phenotypic for informal seed systems, and descriptive and phenotypic for formal systems).

Market or farmer participatory research studies for acceptable/feasible phenotypic labeling using tuber or plant characteristics should be conducted. Local production / management practices should be studied as a starting point for the introduction of transgenics. Subsequently, advice and support for the production technologies and the crop management of transgenics should be provided for community based seed systems. Technical support for the national regulatory system should be available.

Intellectual property rights (IPR)

The Working Group agreed that the IPR issues related to the creation of transgenic potatoes are of great importance. The technologies that are relevant for potato improvement and their respective IPR status need to be identified. A joint strategy for the acquisition, with “freedom to operate” for resource-poor farmers, of these identified technologies should be developed. The information should be made available through a ‘Potato Biotechnology Network’, possibly hosted by CIP. The primary focus of this network would be on core technologies with broad applicability, such as agroinfection and the CaMV 35s promoter, and trait-specific technologies. National contacts on intellectual property rights issues should be identified and training schemes, such as workshops or seminars that provide information on the implications and impact of IPR issues on small scale farmers, should be developed. The ‘Potato Biotechnology Network’ should facilitate a brochure on “The steps for technology transfer and IPR implications”.

Working group summaries
Report from working group on gene flow, effects on non-target organisms and biosafety Issues

Theresa Sengooba, Facilitator; David Berger, Rapporteur

The Working Group acknowledged that the capacity to deal with issues related to gene flow and the potential effects on non-target organisms should be built up in developing countries. This capacity should be developed or strengthened through regional courses. These courses should emphasize biosafety issues, risk assessment and management, which is trait dependent and location dependent (i.e. whether or not the site is located in a center of diversity). Previous information (e.g., published documents) should be used as the framework. Emphasis should be made that GMO products do not differ from non-GMO products in the necessity for these considerations. Research activities underpinning biosafety decisions and regulations for regulatory bodies should be undertaken. Specific activities might include:

- Assessment of gene flow and transgene fitness in centers and non-centers of biodiversity (with reference to the FAO model)
- Development of a simple method to assess effects on soil function
- Interaction with the International Organization for Biological Control (IOBC) working group to define the best practice procedures for experiments.
Report from working group on health and food safety

Maddalena Querci, Facilitator; Walter Pett, Rapporteur

There is a need to collect information and data regarding transgenic potatoes and possible toxic effects, relating to and relying upon existing bodies, such as Codex Alimentarius. Actions to determine what testing is actually needed for GMOs should be promoted — the testing should not go beyond what is “normal” or already available.

The Working Group recommended that information at the gene construct and plant–gene interaction levels be developed and included in the construction of minimum standards by national governments to ensure that transgenics do not differ in safety from non-transgenics. Countries with specific national standards should be identified, and ways of encouraging the sharing of these standards between countries should be found. Codex Alimentarius could take this role. The capacity for addressing health and food safety issues, including knowledge, facilities and maintenance, should be built up using on-going short- and long-term training and aiming for self-sufficiency. Regional or sub-regional groups should be established to examine issues related to potato. Sectors of the population or stakeholders should be identified and participatory approaches to health and food safety issues should be encouraged. Labeling should not be considered a food safety/health issue.
Transgenic potatoes for the benefit of res...
Appendices

Agenda

Participants

Abbreviations
Agenda

Transgenic potatoes for the benefit of resource-poor farmers in developing countries

Manchester, United Kingdom
June 5 - 9, 2000

Sponsored by: DFID Plant Sciences Research Programme, UK
DFID Crop Protection Programme, UK
International Potato Center, Peru

Agenda

Monday, June 5:
Participants arrive
Evening event: Introduction to the Workshop: Objectives and Participants
Details provided on arrival

Tuesday, June 6:
Welcome and Introductions
Country and Organization Briefs

Moderator: Chagema J Kedera

08:15 - 08:30 Welcome and Introductions
Country Profiles:
08:30 - 09:00 Kenya, Charles Lung’aho, Kenya Agric. Research Institute
09:00 - 09:30 Uganda, Theresa Sengooba, Namulonge Agric. and Animal Production Institute
09:30 - 10:00 South Africa, Dave Berger, ARC-Roodeplaat

10:00 - 10:30 Coffee Break
Country Profiles:
10:30 - 11:00 Argentina, Marcelo Huarte, Instituto Nacional de Tecnología Agropecuaria
11:00 - 11:30 Cuba, Julia La Rosa, Centro Nacional de Seguridad Biológica
11:30 - 12:00 Bolivia, Javier Franco and Antonio Gandarillas, PROINPA
12:00 - 12:30 Mexico, Ariel Alvarez-Morales and Rafael Rivera, CINVESTAV

12:30 - 13:30 Lunch

* Paper presented by W. Collins
Country Profiles:
13:30 - 14:00 Colombia, Orlando Acosta, National University
14:00 - 14:30 China, Zhang Yongfei, Root and Tuber Institute
14:30 – 15:00 India, Prakash S Naik, Central Potato Research Institute*

15:00 - 15:30 Coffee Break

Country Profiles:
15:30 - 16:00 Nepal, Namita Maskay, Katmandu, Nepal

Programs and Organizations Briefs – Specific Interests, Activities, Goals:
16:00 - 16:20 International Potato Center (CIP), Wanda Collins
16:20 - 16:40 Agricultural Biotechnology Support Project (ABSP), Walter Pett
16:40 - 17:00 Department for International Development (DFID), John Witcombe and Jill Lenné
17:00 - 17:20 CABI Bioscience UK Centre, Julian Smith

17:20 Discussion

Wednesday, June 7:
Analysis Session for Constructing Working Matrix of Countries/Concerns
Technical Issues in Uptake and Deployment of Transgenic Plants in Developing Countries

Moderator: Maddalena Querci

08:30 - 09:00 Constructing a Matrix of Countries and Concerns
Wanda Collins, CIP
John Witcombe, DFID

09:00 – 09:30 Gene Flow to Other Potatoes and Wild Species
Richard G F Visser, Wageningen University

09:30 – 10:00 Effects of Transgenics on Non-Target Organisms
Sue Cowgill, University of Leeds

10:00 – 10:30 Coffee Break

10:30 - 11:00 Pyramiding Genes
Dave Berger, ARC-Roodeplaat

11:00 - 11:30 Transgene Expression, Stability, and Inheritance
Richard G F Visser, Wageningen University

11:30 - 12:00 Uptake Systems (State and Farmer Based Seed Systems)
Chagema J Kedera, Kenya Plant Health Inspection Service (KEPHIS)

12:00 - 12:30 Discussion

12:30 - 13:30 Lunch
The objective of the working groups is to establish what areas of research are needed for uptake and deployment to be approved and to be efficient. Questions specific to potato should be developed in terms of what the issues are, what scientific information is available to support conclusions, and what scientific information needs to be added before sound decisions can be made. These topics and discussions should use the information presented in technical/policy sessions to start to define the specific case for potato. Working groups will be decided as the meeting progresses.

Thursday, June 8:
Policy Issues in Deployment of Transgenic Plants in Developing Countries
Panel Discussions
Working Groups

Moderator: Howard Atkinson

08:30 - 09:00 Monitoring and Regulating Uptake of Transgenes
Maddalena Querci, European Commission Joint Research Center

09:00 - 09:30 Harmonizing Biosafety Standards Regionally
Marcio Porto, FAO

09:30 - 10:30 Panel Discussion: Intellectual Property Rights (Rapporteur: John Witcombe) Marc Ghislain, CIP; Dave Berger, ARC-Roodeplaat; Walter Pett, ABSP; Victoria Henson-Apollonio, ISNAR

10:30 - 11:00 Coffee Break

11:00 - 12:30 Working Groups:
1. Strategies for Addressing Public Concern
   Facilitator: Julian Smith
   Rapporteur: Howard J Atkinson

2. Seed System Issues and IPR
   Facilitator: Chagema J Kedera
   Rapporteur: Marc Ghislain
3. Gene Flow, Effects on Non-Target Organisms and Biosafety Issues
   Facilitator: Teresa Sengooba
   Rapporteur: David Berger

4. Health and Food Safety
   Facilitator: Maddalena Querci
   Rapporteur: Walter Pett

12:30 - 13:30 Lunch
13:30 - 15:00 Working Groups
15:00 - 15:30 Coffee Break
15:30 - 17:00 Working Group Reports

**Friday, June 9:**
**Finalizing the Strategy and the Action Plan**

08:30 - 09:30 Presentation of a Draft Action Plan Based on Working Group Reports
09:30 - 10:30 Discussions
10:30 - 11:00 Coffee Break
11:00 - 12:00 Finalizing the Strategy and Action Plan
12:00 - 12:15 Close the Workshop
List of Participants

**Acosta, Orlando**  
Biotechnology Institute  
National University  
A A 14490  
Bogotá, Colombia  
E-mail: oacostap@ibun.unal.edu.co  
Tel.: 57 1 3165358  
Fax: 57 1 3165415

**Atkinson, Howard**  
Centre for Plant Sciences  
Leeds Institute for Plant Biotechnology and Agriculture  
University of Leeds  
Leeds LS2 9JT, United Kingdom  
E-mail: h.j.atkinson@leeds.ac.uk  
Tel.: 44 113 2332900  
Fax: 44 113 2332900 or 3144

**Alvarez-Morales, Ariel**  
CINVESTAV, IPN Unidad Irapuato  
Dept. of Plant Genetic Engineering  
Apdo. Post. 629  
(Courier address: Km 9.6 Lib. Norte Carret) Irapuato, Gto.  
C P 36500, Mexico  
E-mail: Aalvarez@irapuato.ira.cinvestav.mx  
Tel.: 52 462 39600 / 39668  
Fax: 52 462 45849 / 45846

**Berger, Dave**  
ARC-Roodeplaat  
Vegetable and Ornamental Plant Institute  
Agricultural Research Council  
Private Bag X293  
Pretoria 0001, South Africa  
E-mail: dberger@VOPI.AGRIC.ZA  
Tel.: 27 12 8419656 (Office)  
27 12 8419646 (Lab)  
Fax: 27 12 8080844 / 8081499

**Collins, Wanda**  
International Potato Center (CIP)  
P O Box 1558, Lima 12, Peru  
E-mail: cip-ddg-research@cgiar.org  
Tel.: 51 1 3175307  
Fax: 51 1 3175303

**Cowgill, Sue**  
Centre for Plant Sciences  
Leeds Institute for Plant Biotechnology and Agriculture  
University of Leeds
Leeds LS2 9JT, United Kingdom
E-mail: btcsec@south-01.novell.leeds.ac.uk
Tel.: 44 113 2333035
Fax: 44 113 2333144

Eden-Green, Simon
Programme Manager, CPP
Natural Resources International
Central Ave.
Chatham Maritime, Kent ME4 4TB
United Kingdom
E-mail: s.j.eden-green@greenwich.ac.uk
Tel.: 44 1634 883957 / 827455
Fax: 44 1634 883937

Franco, Javier
PROINPA
Av. Blanco Galindo km. 12.5
Calle Prado s/n
Cochabamba, Bolivia
E-mail: Jfranco@proinpa.org
Tel.: 591 4 360800 / 360801
Fax: 591 4 360802

Gandarillas, Antonio
PROINPA
Av. Blanco Galindo km. 12.5
Calle Prado s/n
Cochabamba, Bolivia
E-mail: Gandarilla@proinpa.org
Tel.: 591 4 360800 / 360801
Fax: 591 4 360802

Gallo, Roberto
Technical Officer
National Seed Program
P O Box 4793
La Paz, Bolivia
E-mail: Semillas@ceibo.entelnet.bo
Tel.-Fax: 591 2 441608 / 591 2 441153 / 591 811 3629

Ghislain, Marc
International Potato Center (CIP)
P O Box 1558, Lima 12, Peru
E-mail: m.ghislain@cgiar.org
Tel.: 51 1 3496017
Fax: 51 1 3175326

Green, Jayne
Centre for Plant Sciences
Leeds University
Leeds LS2 9JT, United Kingdom
E-mail: bgyjgr@leeds.ac.uk
Tel.: 44 113 2333035
Fax: 44 113 2333144
Transgenic potatoes for the benefit of res...
E-mail: a.levesley@leeds.ac.uk
Tel.: 44 113 2333098
Fax: 44 113 2333144

**Lucas, John**
Institute of Arable Crops Research
IACR-Rothamsted
Harpenden, Hertfordshire AL5 2JQ
United Kingdom
E-mail: john.lucas@bbsrc.ac.uk
Tel.: 44 1582 763133
Fax: 44 1582 760981

**Lung’aho, Charles**
Kenya Agricultural Research Institute
National Potato Research Centre
P O Box 338
Limuru, Kenya
E-mail: clungaho@arcc.or.ke
Tel.: 254 154 73060/61
Fax: 254 154 73060

**Maskay, Namita**
Kathmandu, Nepal
P O Box 1948
E-mail: madhuban@mos.com.np
fax 00977 1 534753

**Naik, Prakash S**
Central Potato Research Institute (CPRI)
Indian Council of Agricultural Research
Shimla (H.P.) 171001, India
E-mail: Naikps@excite.com
Fax: 91 177 224460

**Peri, Liz**
Department for International Development
Environment Policy Department
94 Victoria Street
London SW1E 5JL
E-mail: l-peri@dfid.gov.uk
Tel: 44 020 7917 0934
Fax:44 020 7917 0679

**Pett, Walter**
Department of Entomology
Michigan State University
E. Lansing, Michigan 48824, USA
E-mail: pett@pilot.msu.edu
Tel.: 1 517 3555154
Fax: 1 517 3534354
Porto, Marcio
Food and Agriculture Organization of the United Nations (FAO)
Chief, Crop and Grassland Service, Plant Production and Protection Division of the Agriculture Dept.
Viale delle Terme di Caracalla
00100 Rome, Italy
E-mail: Marcio.Porto@fao.org
Tel.: 39 57054129
Fax: 39 657053152

Querci, Maddalena
European Commission Joint Research Center
IHCP - Food Product Unit - TP 201
Via Fermi
21020 ISPRA, Italy
E-mail: maddalena.querci@jrc.it
Tel.: 39 332 789308
Fax: 39 332 785483

Rivera, Rafael
CINVESTAV, IPN Unidad Irapuato
Dept. of Plant Genetic Engineering
Apdo. Post. 629
(Courier address: Km 9.6 Lib. Norte Carret) Irapuato, Gto.
C.P. 36500 Mexico
E-mail: Rrivera@irapuato.ira.cinvestav.mx
Tel.: 52 462 39600 / 39655
Fax: 52 462 45849 / 45846

Sengooba, Theresa
Namulunge Agricultural and Animal Production Institute
National Agricultural Research Organization
P O Box 7084
Kampala, Uganda
E-mail: naari@naro.bushnet.net
Tel.: 256 41 341554
Fax: 256 41 236918

Smith, Julian
CABI Bioscience UK Centre [Egham]
Bakeham Lane, Egham,
Surrey TW20 9TY, United Kingdom
E-mail: j.smith@cabi.org
Tel.: 44 1491 829048
Fax: 44 1491 829111

Thwaites, Richard
Natural Resources Institute
University of Greenwich
Chatham Maritime
Chatham, Kent ME4 4TB
United Kingdom
E-mail: r.thwaites@gre.ac.uk
Tel.: 44 1634 883077
Fax: 44 1634 883379
Visser, Richard  
Laboratory of Plant Breeding  
Department of Plant Sciences  
Wageningen University  
P O Box 386 6700 AJ Wageningen  
The Netherlands  
E-mail: richard.visser@users.pv.wau.nl  
Tel.: 31 317 482836/482857  
Fax: 31 317 483457

Wilson, Mike  
Head of Research Section  
Rural Livelihoods Department  
Department for International Development  
94 Victoria Street  
London SW1E 5JL United Kingdom  
E-mail: MJ-Wilson@dfid.gov.uk  
Tel.: 44 0 207 917 0939  
Fax: 44 0 207 917 0105

Witcombe, John  
DFID Plant Sciences Research Programme  
Centre for Arid Zone Studies  
University of Wales, Bangor  
Gwynedd LL57 2UW, United Kingdom  
E-mail: J.R.Witcombe@bangor.ac.uk  
Tel.: 44 1248 382922 / 382283  
Fax: 44 1248 371533

Zapata, Beatriz  
Ministerio de Desarrollo Sostenible y Planificación  
Viceministerio de Medio Ambiente Recursos Naturales y Desarrollo Forestal-Dirección General de Biodiversidad  
Av. Mariscal Santa Cruz Esq. Oruro  
Edificio Ex-Comibol, 4to. piso, Oficina 406  
La Paz, Bolivia  
E-mail: beazafe@latinmail.com  
Mobile: 012 73118  
Fax: 591 2 310966

Zhang Yongfei  
Root and Tuber Institute  
Yunnan Normal University  
Kunming, Yunnan Province, China  
E-mail: zymlsh@public.km.yn.cn or c/o y.wang@cgiar.org  
Tel.: 86 871 5515820  
Fax: 86 871 5516240
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>APW</td>
<td>andean potato weevil</td>
</tr>
<tr>
<td>Bt</td>
<td><em>Bacillus thuringiensis</em></td>
</tr>
<tr>
<td>BW</td>
<td>bacterial wilt</td>
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<tr>
<td>DNA</td>
<td>deoxyribonucleic acid</td>
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<tr>
<td>cDNA</td>
<td>complementary deoxyribonucleic acid</td>
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<tr>
<td>GM</td>
<td>genetically modified</td>
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<td>GMO</td>
<td>genetically modified organism</td>
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<td>IPM</td>
<td>integrated pest management</td>
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<td>IPR</td>
<td>intellectual property rights</td>
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<tr>
<td>PLRV</td>
<td>potato leafroll virus</td>
</tr>
<tr>
<td>PTM</td>
<td>potato tuber moth</td>
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<tr>
<td>PVX</td>
<td>potato virus X</td>
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<td>PVS</td>
<td>potato virus S</td>
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<td>PVY</td>
<td>potato virus Y</td>
</tr>
<tr>
<td>T-DNA</td>
<td>Transfer DNA</td>
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</table>
Phthorimaea operculella, the potato tuber moth, damages potato leaves and tubers (left and bottom), but transgenic plants (right and center) are resistant to the pest. Photos courtesy of A Lagnaoui and V Cañedo (CIP)
The International Potato Center (CIP) seeks to reduce poverty and achieve food security on a sustained basis in developing countries through scientific research and related activities on potato, sweetpotato and other root and tuber crops, and on the improved management of natural resources in the Andes and other mountain areas.

CIP is a Future Harvest Center and receives its principal funding from 58 governments, private foundations and international and regional organizations known as the Consultative Group on International Agricultural Research (CGIAR). Future Harvest builds awareness and support for food and environmental research for a world with less poverty, a healthier human family, well-nourished children and a better environment. Future Harvest supports research, promotes partnerships and sponsors projects that bring the results of research to rural communities, farmers and families in Africa, Latin America and Asia.