OBJECTIONS TO THE APPLICATION MADE BY
ARC – INSTITUTE FOR INDUSTRIAL CROPS

IN RESPECT OF AN EXPERIMENTAL TRIAL RELEASE APPLICATION FOR EVENT TMS60444 (CASSAVA)

TO THE NATIONAL DEPARTMENT OF AGRICULTURE
SOUTH AFRICA

PREPARED BY

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BACKGROUND

Cassava

Cassava (*Manihot esculenta* Crantz), known in different parts of the world as manioc, tapioca and yucca amongst others, is a perennial plant grown widely in the humid tropics.[i] Cassava is particularly suited to conditions of low nutrient availability and able to withstand drought conditions. Cassava can thrive under adverse growing conditions, losing its leaves to conserve moisture during dry spells and producing new leaves when rains resume.ii Additionally, cassava can grow across a wide pH range of 4.0 to 8.0. The greatest food value is in the cassava root which is typically consumed within a few days of harvesting because of the rapid post-harvest deterioration.i The carbohydrate yield in cassava is 40% higher than rice with fresh roots containing about 30% starch and very little protein[ii] making cassava the major source of low cost carbohydrates for populations in the humid tropics.ii

Cassava is the primary source of calories for approximately 600 million people in the tropics and ranks forth in calorific intake among all crops directly consumed by humans.[iii] Cassava is valued in many parts of the world for the food security it provides. It tolerates low soil fertility and drought and is resistant to many herbivores due to the presence of cyanogens.[iv]

Cassava has complex genomic, morphological, physiological and ecological characteristics. The centre of origin of cassava is Brazil, although some historians claim it to be the Yucatan in Mexico. Cassava was introduced into the West coast of Africa and the Democratic Republic of Congo in the sixteenth century, by slave ships as a "gift of the Amazonian people to their African brothers and sisters." Brazil is one of the world's largest commercial cassava producing countries. Its cassava boom in southern Brazil is a starch led boom. Starch industries are keen on genetic engineering to generate new products/uses and expanded markets at patented protected prices. Private industry aims to maximise research investments where patenting has the best prospects for payoffs namely, new products.

Starch

Starch comprises between 20-30% amylose and 70-80% amylopectin. Starch production is cheap and is very versatile, being used as a thickener, water binder, emulsion stabilizer and gelling agent.[v] Cassava starch is relatively odourless with high paste clarity and stickiness. This enables easy and ready blending with other flavouring or colouring reagents.[vi] Starch with reduced or absent amylose results in gels that have increased clarity and stability. Consequently, this does away with the requirement for chemicals such as epoxides (propylene oxide and ethylene oxide) and acetic anhydride,which are typically used to improve starch gel stability.xxx

Cassava as an Industrial Crop (Starch Production)

Cassava has characteristics of a competitive industrial crop that produces inexpensive high-quality starch. Yet, researchers[vii] point to the rapid post-harvest deterioration of fresh cassava and the labour and time intensive processing of dried cassava and cassava starch, as representing major constraints that put cassava at a disadvantage to other crops designed for starch and animal feed production such as maize. Although the same research points to the success of Thailand as a cassava starch exporter, but it is also pointed out that Thailand exported to Europe, where it received preferential access to the EU's markets until the EU reformed its common agriculture policy (CAP) in the late 1990s. The reliance on the production of one cash crop for export purposes has its own inherent dangers, quite apart from the widespread ecological and socio-economic adverse impacts accompanying large plantations of monocultures of cassava.

Cassava Mosiac Virus Disease (CMVD)

The Missouri Botanic Gardens, Monsanto Company and the Donald Danforth Centre for Plant Sciences ("Danforth Centre") are all part of the Cassava Biotechnology Network (CBN) and the Global Cassava Improvement Plan.

According to Aerni, the Swiss Federal Institute of Technology (ETH)vii Zurich has developed transgenic cassava that is resistant to Cassava Mosiac Virus Disease (CMVD). Transgenic varieties had been raised in ETH greenhouses and were all set, for field-testing in Africa.

The Donald Danforth Plant Science Centre ("Danforth Centre"), whose partners include Monsanto Company and the Missouri Botanic Gardens has been involved in research involving transgenic varieties of cassava. According the Danforth Centre's website, it appears to have been heavily involved in a Disease-Resistant Cassava for Kenya Project, with funding from USAID to develop and deliver transgenic, disease-resistant cassava planting materials to farmers in Kenya to increase their harvests and improve their food security.

However, on the 26 May 2006, the Danforth Centre, without much fanfare, quietly announced that it had discovered that GM virus-resistant varieties of cassava, first developed seven years ago, had lost resistance to the African CMVD and that expert consultants had been asked to review why and how the modified cassava had changed and to assess future plans.[viii] This failure underlies the reason why African governments, save for pro-GM South Africa, have adopted the precautionary principle in not allowing Africa to be turned into a laboratory for an utterly self defeating and wholly unpredictable technology.

According to Danforth's press release, the group reviewed the data and concurred with the conclusions that resistance to the African CMVD was achieved in cassava line Y-85, "that the resistance was subsequently lost, and that methylation of the plant's DNA had taken place."

This failure thus utterly refutes the information on the Danforth Centre's website that "transgenic plants developed at the Danforth Centre have demonstrated strong resistance to the disease in greenhouse trials over multiple years.[ix]

This turn of event will thus seriously scuttle plans by the Danforth Centre's International Programs Office to push Kenya Agricultural Research Institute (KARI) to test transgenic cassava plants under natural field conditions. The false promises on Danforth's website that "virus-resistance technology will initially be deployed in the East Africa's region's most popular cultivar-*Ebwanatareka*-for adoption by the 22,000 Kenyan farming families….the project will help 200,000 Kenyan cassava farmers and their families and increasing cassava harvests by 50% of a sustainable basis."

Similar promises are made to benefit neighbouring Uganda, and to millions of farmers throughout Africa.

It appears thus, that the Danforth Centre has turned its attention away from this failed project, and is now spearheading the sequencing of the cassava genome. [x] In a dramatic about turn, Dr Claude Fauquet, of the Danforth Centre revealed in the press release, that the "acquisition of the cassava genome sequence will …provide a platform to explore the vast biodiversity within cassava wild species. Ultimately, these activities will position cassava as a valuable source of renewable bio-energy." According to the U.S Department of Energy Joint Genome Institute (DOE JGI), funder of the project, the DOE JGI chose to sequence cassava because it is an excellent energy source-"it is grown worldwide as a source of food for approximately 1 billion people, raising the possibility that it could be used globally to alleviate dependence on fossil fuels. x

The cassava genome project is spearheaded by a consortium made up of the Danforth Centre, the USDA, Washington University in St Louis, the University of Chicago, the Institute of Genomic Research, the Missouri Botanical Garden, the Broad Institute, Ohio State University, the International Centre for Tropical Agriculture, and the Smithsonian Institute.

Southern Africa Biotechnology for Cassava Improvement

According to a recent United State's Agricultural Service Report,[xi] South Africa is working jointly with other missions in the Southern Africa to fund research devoted to the improvement of cassava both as a food crop but more importantly as in industrial starch crop. According to the report, "the United States Agency for International Development (USAID)/South Africa has obligated $800,000 over two years (2004-2005) to this research and the initial focus has been on further development and roll-out of a transgenic pest resistant variety of cassava for use as industrial starch. The project is managed by Michigan State University in collaboration with the CGIAR.

Cultural/Ethical Issues

For the Amazonian cultures, cassava or yucca as is it is known in that part of the world, is culturally extremely important as it forms part of their everyday lives, celebrations and rituals. The most common use of yucca is the production of chichi, a fermented drink. The cultivating of yucca and the production of chichi constitutes a powerful source of cohesion between the women since they are all involved in some or other way and offered to visitors as a valued gift from mother earth "Pacha Mama."[xii]

SOCIO-ECONOMIC ASSESSMENT

1. GM CASSAVA IN AFRICA

Cassava originated in Latin America and found its way to Africa during the 16th Century. Wild varieties in Latin America have served as important gene pool for the sourcing of useful characteristics to breed into domesticated varieties. Cassava has long been recognised as a vital staple food in developing countries and breeding has focused on improving varieties for this purpose and to protect the crop against its major pests. Cassava's use as an industrial crop has so far mainly focused on the production of starch, but increasingly there is a need for alternative sources of energy and because it is so easy to grow cassava, it has now also drawn the attention of the bio fuel lobby. This interest in cassava as an industrial crop shifts the focus from cassava as a food security crop to an industrial monocrop grown for export, bringing with it the threats that accompany this transition: loss of markets, price distortions, massive land and forest clearing, destruction of biodiversity, ownership of commercially valuable germplasm, IPRs, loss of farmers varieties and wild varieties, etc.

The Importance of Cassava in Africa

Cassava is widely grown in Africa, Latin America and Asia as a food crop, livestock feed and for industrial uses. Where it has been recognised for a long time as an essential crop for food security, the interest and investment in cassava is also increasingly moving towards feeding the growing needs of industrial society – that of livestock feed and industrial uses such as starches and bio fuels.

When you visit a farmer in tropical Africa, the chances are very good she will be growing cassava. Cassava has been especially popular amongst small farmers and in poor communities for many reasons but also because of its versatility and nutritional value. People in the Democratic Republic of Congo call cassava "all sufficient" because "we get bread from the root and meat from the leaves". It is a major carbohydrate food for an estimated 500 million people and in tropical Africa it is the single most important source of calories in the diet. The per capita consumption in Africa is the highest, at approximate 80kg/capita and in Central Africa it tends to be twice this figure.

Cassava has a number of qualities that have made it an attractive crop for small farmers with limited resources in marginal agricultural areas:[xiii]

- *Food security*: Cassava is very cheap, it is available all the year round, and its roots can stay in the ground for long periods as a reserve, providing an insurance against famine. It is one of the most efficient carbohydrate-producing crops; the leaves are also edible and high in protein and vitamins, complementing the high starch content of the roots.
- *Sturdy, tolerant, and pest-resistant*: Compared to grains, cassava is more tolerant of low soil fertility and drought. It also has the ability to recover from the damage caused by most pests and diseases.
- *Suitable for African crop systems:* Cassava is well adapted to traditional mixed cropping agricultural systems and subsistence cultivation in which farmers seek to minimize the risk of total crop failure. It may however lower its productivity.
- *Many different uses*: Cassava roots are very rich in carbohydrates, in particular starch and can be processed to be used in many different ways.
- *Cash income*: The selling of cassava for processing is also a source of cash income for farmers.

Poor or landless farmers, who mostly have only access to marginal lands, can grow at least cassava on these lands. Because it is available year round and cheap to grow, cassava has an advantage above many other basic food crops because the very poor can afford it.

Cassava is a very important crop for poverty alleviation and has been recognised as such in Latin America, Africa and Asia. Because of these production advantages cassava plays a major role in efforts to alleviate poverty and hunger in Africa and in recent years efforts to improve its productivity have been stepped up.

Apart from it use as a food crop, cassava is of growing importance, however, both for animal feed and as a raw material for producing starch, starch-based products and starch derivatives. In poor farming communities, cassava is often the only crop that can be grown in sufficient quantities to generate income and the processing needed for cassava increasingly is making a contribution to increasing incomes and generating employment in the rural sector.[xiv]

Where cassava is seen as a food crop for Africans, in Europe it is seen as an important and cheap livestock feed and this is seen as one of the major future markets for increased cassava production.

Challenges in Growing and Marketing Cassava

Productivity of cassava in Africa is seen as very low compared with Asia and there is a huge gap in cassava production between the ideal (80tons/ha) and what the average African farmer harvests, around 8 – 12 tons /ha.vii This may be a result of intercropping, as cassava is not a good competitor for nutrients under competition stress. Also Africa is often plagued by droughts, floods and soil erosion, leading to poor crops.

Pests and diseases that do not occur in Asia and Latin America plague African cassava farmers. The main pests are the mealy bug, the white fly that carries the cassava mosaic virus, mites and Lepidoptera. Plant diseases include the Cassava Mosaic Virus Disease

(CMVD), Cassava Bacterial Blight and others. For both CMVC and CBB resistance have been developed through conventional breeding methods.

Cassava contains cyanide in its roots. Therefore cassava has to be processed to improve palatability and nutritional value, to get rid of the cyanide, improves the shelf life, facilitate transport and marketing. These processes are time and labour intensive.

A major limiting factor in cassava growing is the fact that the root rots within 3 – 5 days. For this reason it is usually harvested as needed and most subsistence farmers leave cassava in the soil until needed. This has two disadvantages: the land cannot be used to plant other crops and the longer the root stays in the soil, the more fibrous it gets, requiring longer processing. Farmers wanting to sell cassava need to get it to the market as fresh as possible and this is not always possible in Africa where lack of infrastructure is a big problem.

Cassava is well adapted for local consumption in rural areas and villages, but not for urban consumption. The demand for fresh cassava in urban areas depends on factors such as relative price of the product, storability, convenience and market access. Marketing in urban areas is only effective where there are good transport routes and where the marketing system is well developed and integrated.

This is another reason why the processing of cassava is so important. Processed cassava is an important and cheap food in urban areas, where the poor often congregate. The production advantages of cassava make it an ideal crop to develop, as an urban food and the post harvest problems of cassava is the main problem in doing so. Much emphasis is placed in research and development to overcome these problems in an attempt to make cassava more suitable for the urban consumer and to provide benefits for those that have access to processing technologies.

Cultural Value

Women are the main producers of cassava in Africa, Asia and Latin America, and are almost entirely responsible for its processing.[xv] Cassava is such a basic food in many African societies that it has become part of the local culture. When you visit African farming communities' water is traditionally the first thing offered to the traveller and often cassava is then offered and shared as a sign of welcome.

Cassava is used in indigenous communities in Latin America as part of the dowry during marriages

2. CASSAVA PRODUCTION

The total world production of cassava was estimated to be 183 million tons in 2001 and is 209 million tons in 2005.vii Africa is the biggest producer and in Africa, Nigeria is the biggest producer at 34 million tons in 2002.

TABLE 1. Cassava production, area harvested and yield and in Africa, and selected major producer countries (Source, FAO Yearbook, 2002)

Country	Area Harvested (ha)	Production (millions)	Yield (kg/ha)
Africa	11,204,924	100,689,149	8,986
Angola	575,000	5,400,000	9,391
Brazil	1,687,275	23,108,076	13,695
Colombia	208,377	2,214,990	10,629
Congo, Dem.Rep.	1,839,962	14,929,410	8,114
Ghana	794,440	9,731,040	12,248
India	270,000	6,900,000	25,555
Indonesia	1,290,000	16,723,257	13,963
Nigeria	3,455,000	34,476,000	9,978
Tanzania	660,000	6,888,000	10,422
Thailand	1,030,000	16,870,000	16,378

Nigeria grows more cassava than any other country in the world. Production is driven primarily by the demand for food for nearly 130 million people. In comparison, very little cassava is used for livestock feed and agro-industry. Nigeria's cassava output is now threatened by a virulent form of the cassava mosaic virus disease advancing rapidly from East Africa. This is a new challenge, as the disease is capable of wiping out the cassava crop in Nigeria and West Africa. In response, the Nigerian government has, with support from Shell and USAID launched a project to address the spread of the virus and to develop cassava processing. This project is called the Integrated Cassava Project (ICP) and has several initiatives to promote the cassava industry, and to develop post harvest processing technologies as up to 50% of cassava is lost after harvesting.

Thailand is often put forward as the model for the commercialisation of cassava. Thailand is the biggest exporter of cassava products, reaching a volume of 9.09 million tons in 1992. Since 1993, the volume and value has dropped due to the launch of the Common Agricultural Policy by the EU, pulling down their feed grain prices in a major effort to provide incentive to use domestic grains instead of imported cassava.[xvi] Currently Thailand expects to export about 2 million ton annually. Processing of cassava has changed from mostly being done by small-scale processors to large scale processing.

3. CASSAVA MARKETS IN AFRICA

There are two kinds of markets for cassava, local markets and export markets. The main cassava producing countries are positioning themselves to supply the export market to earn foreign currency. The president of Nigeria announced the Presidential Initiative on Cassava production and export in 2002. The goal of the initiative is to promote cassava as a foreign exchange earner in Nigeria as well as to satisfy national demand.[xvii] Nigeria hopes to generate $5 billion in revenue annually, from the export of cassava and related products. It has moved from no exports recently to the export of 34 million tons in 2005.[xviii] Nigeria can therefore not argue that GM cassava is needed to feed the hungry.

On the contrary, this export policy in the absence of surplus production has pushed up the price of gari, putting it out of reach for the poor.

In an effort to create a local market for the commercialisation of cassava, the government is also targeting bio fuel production. The Nigerian National Petroleum Corporation (NNPC) has embarked upon a programme of linkage between the nation's oil and gas industry and the agricultural sectors in order to accelerate Nigeria's economic growth through the production of ethanol, an alternative fuel produced from fermenting and distilling cassava and sugar cane.[xix]

Cassava is generally known as a subsistence crop for low-income families or as a "famine-reserve crop", but increasingly local cassava markets have become important to farmers and local economies. In Nigeria there is a large cross border trade happening to neighbouring countries. The trade is, driven by the need to sustain the food security needs of such countries as Niger, Chad, Burkina Faso, and some parts of Northern Cameroon. Two major cassava products, gari and cassava chips milled from cassava chunks, are exported from Nigeria to these Sahelian regions.[xx]

In a 1986 study it was already calculated that about 60 percent of the cassava output of households in the Oyo area of Nigeria is sold for processing (mostly into gari) while the remaining 40 percent is consumed at home.[xxi] A high proportion (50 percent) of cassava was also sold to food processors in the western region of Cameroon, suggesting a changing status for cassava as a commodity in cross border and regional trade.[xxii] A more recent survey estimated that on the main market for cassava products, the Kano market, the trade in any given week is estimated at about 3000 tons.[xxiii]

These local and cross border markets are important for the local economies. However, the successful competition of cassava in the future with other sources of carbohydrate will also depend on certain other conditions, such as the reduction of market distortions that favour imports or other locally produced staple crops. Future efforts to overcome rapid post-harvest deterioration of cassava should take into account the needs and constraints of the farmers, traders and processors and also the preferences of the consumer.[xxiv]

4. R&D IN CASSAVA

The largest germplasm collection of cassava is held at the International Center for Tropical Agriculture (CIAT) in Cali, Colombia. The largest national collection is held in Brazil under the direction of the Brazilian Agricultural Research Network (EMBRAPA). A germplasm collection for African needs is maintained at the International Institute for Tropical Agriculture (IITA) in Ibadan, Nigeria.

On their website IITA says that it is implementing projects with the aim of developing and deploying cassava cultivars with high-carotene content in addition to stable productivity, higher yields, and resistance to drought, diseases and pests. IITA is implementing a project to prevent CMVD spreading in partnership with the oil industry and funded by USAID.[xxv]

IITA manages two root crops research networks in eastern and southern Africa focusing on cassava (the East African Root Crops Research Network and the Southern Africa Root Crops Research Network) to take new agricultural technologies to the farmers.

The resources committed globally to improving cassava has been much less than for other major cash crops, but in the 1990s' there seems to have been an upsurge in interest – with some calling it a "cassava cash crop renaissance." The FAO and IFAD initiated the Global Cassava Development Strategy and Implementation Plan (GCDS) to develop the cassava industry,[xxvi] and the Global Cassava Plan for Genetic Improvement in the 21st Century (GCP21) to use biotechnology. The international Centre that form part of this consortium includes the Donald Danforth Centre for Plan Science, funded by Monsanto, EMBRAPA and IITA.

NEPAD has now identified cassava as Africa's top fighter against poverty and launched the Pan-African Cassava Initiative to maximise its potential.[xxvii] Stepping up the investment in cassava, a bio fortification initiative supported by the Bill and Melissa Gates foundation appointed CIAT and IFPRI as the main research institutions to spearhead the use of genetic engineering to develop more nutritional crops for Africa.

In this context, the African Agricultural Technology Foundation (AATF) took it upon themselves to facilitate a continent-wide awareness on cassava production an utilisation. It is spearheading this initiative to industrialise cassava in Africa in collaboration with IITA. Policy development is a big part of the initiative – clearly aimed at biosafety policies, as that is what AATF sees as one of its mandates.

5. SOCIO-ECONOMIC IMPACT OF GM CASSAVA IN AFRICA

Depending on the genetic trait, GM cassava can impact in many different ways on cassava production, both by small and larger scale farmers as well as poor consumers in Africa.

Contamination of Wild Relatives

Wild cassava relatives are found only in Latin America (Brazil and Mexico). However, one wild species namely *Manihot glaziovii* was introduced to West Africa as a source of rubber during the Second World War. The same species was introduced to Tanzania in the 1920´s where it was successfully used in a breeding program as a source of resistance to cassava mosaic virus. In both of the two regions it escaped and grow wildly now.[xxviii]

There seem to be some disagreement amongst scientists about the usefulness of wild varieties in terms of the contribution it can make to genetic improvement.vii However, using conventional breeding techniques, a number of very useful genes have been found and used for breeding resistance to the Cassava Mosaic Virus Disease, the development of bigger roots, improved nutritional value (high in beta carotene), higher sugar content, variation in starch quality, and so forth.xxviii

The success in rooting out most of the Cassava Mosaic Virus Disease with an improved variety is reason alone to ensure that as big as possible diversity of cassava germplasm remains in the wild and *in situ*.

Contamination of Farmers' Varieties, Impact on Health and Productivity

The possible threat of contamination in Africa comes from fact that cassava is an allogamous plant, which means there is 100% chance of out crossing. Insects pollinate cassava.

GM cassava will therefore contaminate farmers' varieties or other varieties cultivated for other purposes such as animal feed, as it happens in maize. In the case of Bt cassava it will for example transfer the toxins to animals and humans.

In the case of RR Cassava, there is a big risk of toxins accumulating in the roots. Glyphosate concentrates in the roots of plants and for this reason it is not really recommended to use herbicides in cassava. It also deforms the root and reduces its productivity.xxviii

Ownership of Cassava Germplasm and Farmers Rights

Cassava is one of the oldest cultivated crops and it is estimated that humankind have been cultivating it for about 5000 years. GM cassava with its accompanying patents claims ownership for the owners of those foreign genes ahead of the farmers and indigenous communities that came before them. This is unjust and socially and ethically unacceptable.

Apart from this basic abuse of farmers and community rights, the risk of contaminating farmers varieties with GM cassava and then claiming ownership of the new hybrid, cannot be justified. International precedent says however that that is so and for that reason alone Africa's farmers should be protected from the control and ownership dilemmas that multinational companies bring with GM crops.

Benefits will not go to the Poor

Cassava has to be used, processed or sold within the first 3 – 5 days. This limits it to stay a subsistence crop in the more remote rural areas with weak infrastructure. It is therefore unlikely that these farmers will any time soon be able to participate in the benefits that the more industrial use of cassava promotes. The development of GM varieties that is suited for industrial use is therefore only really suited for large-scale growers close to processing plants.

The Nigerian export policy have already caused domestic cassava prices to rise, making it unaffordable to the poor and in all likelihood also having an impact on food security in neighbouring countries.

In Central Africa there has been a decline in the per capita consumption of cassava, along with all major food crops, indicating the seriousness of the food crisis and also begging the question that if these farmers have access to cassava, what is really preventing them from growing it and will GM crops solve this problem?

Broader Environmental Impact of Increased Starch Production

The processing of starch has many problems and high resource consumption and impacts on the environment, especially sulphur, cyanide, solid and liquid waste[xxix] and not the least, the destruction of indigenous forests and biodiversity to make space for large tracts of cassava.

SCIENTIFIC ASSESSMENT

6. THIS APPLICATION

This application is for a confined experimental trial release of genetically modified cassava plants containing a gene isolated from cassava and inserted to result in the production of amylase-free starch.xxx This event, designated TMS60444 was produced by genetic modification of cultivar TMS60444. The following discussion details the main features of TMS60444 and those features or aspects of the application that are cause for concern.

7. TMS60444: DESCRIPTION AND CHARACTERISTICS

The event TMS6044 (transgenic lines 3.1 and 3.2) refers to the genetically modified cassava cultivar by the insertion of two genes. The first is a firefly luciferase gene as the reporter gene i.e., a transfected gene that produces a signal, in this case fluorescence, when expressed enabling the study of the temporal and spatial pattern of expression of the larger cloned gene that is introduced into. The second is the cassava granule bound starch synthase protein (GBSS1) cDNA in antisense orientation,[xxx] fused between the potato GBSSI promoter and the nopaline synthase terminator. GBSS is responsible for the production of the amylase fraction of starch and encoded by the GBSS genes and its insertion in antisense orientation prevents the production of GBSS protein.

CaMV Promoter

The cauliflower mosaic virus (CaMV) is a DNA-containing para-retrovirus replicating by means of reverse transcription. It contains within its genome a viral promoter called 35S, a general strong plant promoter which has been used to secure expression of transgenes in a large proportion of commercialised GMOs. There are several studies indicating the potential for transcriptional activation of the 35S CaMV promoter in mammalian systems.[xxxi,xxxii]

The CaMV 35S promoter has been found to have a recombination hotspot where it tends to fragment and join with other double stranded DNA in a very non-specific manner.[xxxiii] These hotspots are flanked by multiple motifs involved in recombination and functions efficiently in all plants, green algae, yeast and *Escherichia coli*. The potential exists for the viral genes to recombine with other viruses to generate new infectious viruses,[xxxiv] carcinogens and mutagens as well as to reactivate dormant viruses.

Detractors claim that virus infected cabbages and cauliflowers have been consumed for years with no ill effects and that similar pararetroviral sequences occur widely in plants, causing no apparent harm.[xxxv] That the intact virus causes no obvious harm in the natural host is related to the fact that its integrity is maintained and that it is adaptive to the host biology. This is unlike the fragments of naked DNA as in the transformed plant where the natural regulatory mechanisms are not present.xxxiv A call has been made that the use of the CaMV promoter in transgenic plants be phased out due to the structural instability arising out of its use.[xxxvi]

8. UNINTENDED EFFECTS OF GENETIC MODIFICATION

GM Potato EH92-527-1 vs. TMS60444

Sections 4.2 (page 3), 5.2 (page 12), 5.3.3 (page 13) 5.8.1, (page 16), 5.8.5 (page 16) and 12.4 (page 20) of the applicationxxx states that event TMS60444 is not expected to have any pathological or ecological impact different from the conventional cassava. An appeal is made to the EFSA Panel ruling on similarly genetically modified potato (event EH92-527-1) that there was no threat to human health. Lack of adverse effects in one event cannot be used to suggest a similar lack in a totally new event. Potential harmful unintended effects are specific to the gene, crop and site of growth of any transformation event. Even in the USA where regulation of the movement and release into the environment of GE crops has been widely criticized as inadequate,[xxxvii] such extrapolations are not considered acceptable. Each event must be evaluated on its own merits.

For example, Bayer has developed several rice lines which have been approved in the USA including LL06 and LL62. This is unlike the Bayer developed rice line LL601 which Bayer decided not to commercialise.[xxxviii] The approved and unapproved varieties differ in several potentially important respects, e.g., in lectin and phytate concentrations, two known anti-nutrients. This is despite the same genes in the same crop (different varieties of rice) in these transformation events.

Any parallel drawn between the genetically modified potato and TMS60444 is a cause for great concern. Not only are these two completely different plant species, but differences may exist in the gene insertion site in the chromosomes of the plant in each event (which are random), rearrangements of the inserted gene and interactions between the transgenic protein and the plant (which will differ in different plant species).[xxxix,xl]

A recent study on transgenic peas from Australia illustrates how even the same gene in two different plant species can have different health effects because the transgenic protein may be modified differently in each plant. Peas expressing a gene for R-amylase inhibitor-1 from the common bean were generated to protect the seeds from damage by inhibiting the R-amylase enzyme.[xli] This transgenic bean is harmless in beans but displayed immunogenicity to mice when expressed in peas.

None of the current transgene insertion techniques permit control over location of the insertion site or the number and orientation of the genes inserted.[xlii] The extent of unintended effects arising out of genetically engineering food plants are only now being truly realised and current risk assessment protocols do not measure for these unintended effects. Indeed, the technologies for measuring these effects are still being developed.xl

Metabolic profiling combined with the application of bioinformatic tools was explored as a technique for analyzing complexity within plant systems. The investigators studied altered sucrose metabolism in potato. The authors found nine novel compounds (metabolites) in transgenic potatoes (the same compounds are not found in regular potatoes), some of which were not characterized. This potato was modified purely for experimental purposes with no intention of bringing it to market.

Imprecision of Plant Modification Techniques

Despite the expression of the introduced gene sequences having been confirmed by molecular characterisation, unintended effects that are not detected in the lab and that may only become apparent in the long term, cannot be ruled out. Transformation by particle acceleration is associated with multiple fragments and gene rearrangements[xliii,xliv]. Inserted gene sequences may interrupt native gene sequences and/or their promoters and additional code fragments are not necessarily non-functional and may be transcribed. Extra gene fragments in Monsanto's Roundup Ready Soya were also claimed to be non-functional and not-transcribed[xlv], but were later found to be transcribed to produce RNA[xlvi,xlvii].. The lack of sophisticated methods for targeted insertion, especially in higher organismsxliv necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment. Further, if transgenes behave just like naturally occurring genes, then they have the potential to be inherited in the same way and persist indefinitely in cultivated or free-living populations. Any mixing of native and transgenic plants whether by dispersal, improper handling etc., can result in the spread of transgenes. The consequences, both ecological and evolutionary of crop-to-crop gene flow are only now beginning to be investigated in any meaningful way and the possible exposure of non-target organisms, including humans to novel proteins cannot be discountedxliv.

Case-by-case Risk Assessment

We believe that it is illegitimate to extend findings from one specific transformation event to another and even more so to use findings regarding food safety in one crop to justify safety of another different GM crop, even if the genetic modification is similar. The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity which is currently ratified by 132 countries including South Africa[xlviii] is clear that "Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment".[xlix] Point 22 of the applicant's risk assessment (page 28) again makes an appeal to the approval obtained for GBSS1 in potato. The CPB further states that "Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques."liii Ignorance of the agreed-upon protocols for conducting risk assessments of GE plants underline the inadequacy of this risk assessment.

9. OUTCROSSING AND GENE TRANSFER

In point 2.7 (page 30) of the risk assessment, it is conceded that there could be movement of material from the site through "flooding, animal feeding or unlawful harvest".xxx As stated in the application, the purpose of this field trial is for "research purposes to establish the efficacy of the modification under field conditions" (point 23 page 28 of the risk assessment). No formal safety assessment has been conducted on this particular event, in particular no data is given on environmental assessments relevant to cassava and this particular modified cassava. The risk management practices that are proposed by the applicant do not go far enough. Typically, field trials are conducted to assess agronomic properties like yield, fruit/grain quality and pest susceptibility and are not typically designed for safety. Although the agronomic data may reveal some potential environmental harm, informal observations are likely to miss many potential environmental impacts.[l] There is a lack in the application of any mention of protocols for collecting environmental impact data from the field trials. Impacts on non-target organism should be evaluated and measured. Creeping bentgrass containing the bacterial gene that makes it immune to the potent herbicide glyphosate, better known as Roundup, was found up to 3.8km from the site where a bentgrass field trial was being conducted.[li] The GM grass had spread both by pollinating non-GM plants to form hybrids, and by seed movement.li

10.GENETIC MODIFICATION: DEGREE OF CERTAINTY

In general, genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful, often viral, promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed[lii]. Additionally, the gaps in the knowledge regarding composition and functioning of the genomes that are often subjected to genetic manipulation and ill-designed experiments compound such scientific uncertainty.lii

Uncertainty is a key element of the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity)[liii]which South Africa has ratified. The lack of sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects allows the Precautionary Principle referenced in the Biosafety Protocol to be triggered. The precautionary principle states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be use as a reason for postponing cost-effective measures to prevent environmental degradation".

11.CONCERNS REGARDING PUBLIC INFORMATION

According to the application and description by the applicant of the genetic modification, one of the donor organisms to the transformed line is the firefly (*Photinus pyralis*) (point 19, page 28 of the risk assessment). Yet the ARC's research and science manager Dr Graham Thompson, in the Farmer's Weekly of 16 August 2006 has been quoted as saying that in this specific test no foreign genes from other plants or organisms were being introduced into the genetically modified cassava. "All we've done is inverted, or switched, two existing genes that control starch in the plant,".[liv] Any engagement by the public with the applicant needs to be made on the basis of complete and accurate information being made to the public. Without basic information relating to the GE events, the public cannot have confidence that adequate safety is being ensured. This, especially in the light of the reports of incidences of contamination from GE trials.

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