Objections to application for a permit for additional trials with insect resistant Bt Cry V Genetically Modified Potatoes (*Solanum Tuberosum* L. Variety 'Spunta' G2 and G3), as applied for by Dr G. Thompson, Director Plant Protection and Biotechnology , South African Agricultural Research Council, dated 24 May 2003

Compiled by G. Ashton, G. Baker, M. Mayet, E. Pschorn-Strauss, W. Stafford.

Submitted on 28 June 2004

TABLE OF CONTENTS

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28 June 2004

We, the abovementioned individuals and organisations acting in the public interest, hereby submit our objections to the proposed field trials on transgenic potato containing the *Bacillus thuringiensis* cry V gene for resistance to the potato tuber moth, as submitted by Golden Genomics on behalf of the Agriculture Research Council ("ARC") and others ("the Applicant"). The Applicant is seeking authorisation to conduct field trials at various locations in South Africa, including ARC Roodeplaat (Gauteng), Kouebokkeveld (Ceres), Eastern Free State (Petrus Steyn), KwaZulu Natal (Kokstad), Limpopo (Dendron) and Eastern Cape (Patensie).

We have a reasonable expectation that in considering our objections, the Executive Council (EC) will act in accordance with the principle of procedural and substantive fairness as enshrined in section 33 of the Constitution and the Promotion of Administrative Justice Act 3 of 2000.

Structure of Objections

This document is structured as follows:

1. Summary of grounds for rejection of application
2. Preliminary Issues
3. Scientific Assessment
4. Socio-economic Assessment
5. Legal Assessment

1 Summary of grounds for rejection of the application

1.1 Rights of Access to information severely prejudiced

The extensive deficiencies in the information supplied by the Applicant in response to our request for access to information in terms of the Promotion of Access to Information Act, 2000 ("PAIA) coupled with the conflicting time frames provided by the Regulations under the Genetically Modified Organisms Act 15 of 1997 ("GMO Act) and those provided by PAIA, have severely restricted our rights to access to information as contemplated by section 32 of the Constitution and PAIA.

The issue of the public's right to access to information concerning genetically modified organisms (GMOs) has been thoroughly canvassed in the court papers submitted by Biowatch South Africa, Case number 23005/2002. We associate ourselves with the relief sought by Biowatch. In the light that judgment is due to be delivered by Dunn JA in early August 2004, we are of the belief that the EC should, in the interests of justice and fairness, not consider the Applicant's application until after such judgement has been delivered, taking particular account of our fundamental objections to the paucity of relevant information provided by the Applicant to us.

2. Scientific Objections

2.1 Overall Summary

The Agricultural Research Council have been conducting field research on the efficacy and safety of potatoes genetically modified to resist attack by the tuber moth (Phthorimaea operculella) since 1992 and plan to continue these studies at six locations in South Africa in 2005. Their research has shown that in the field, tuber moths do not damage tubers. The leaves of non-GM plants are moth-infested significantly more than GM plants, but this has no effect on tuber yield. They also show that the extent of viral infection is higher is certain GM lines. The point at which the genetic modification becomes effective is during storage. At one study site there were no natural populations of tuber moths, so 100, 000s of moths were released at this site. These moths have also been shown to feed on other Solanaceae plants and could constitute a serious risk to wild and agricultural species. In two years the researchers have provided no data on gene flow or other aspects of ecological or feed safety. Genetically modified waste material has been dumped in the ground without autoclaving and without studying the effect of this transgenic material on surrounding soil biota and microbiota. Considering the fact that tuber moths mainly affect tubers during storage and that there are ecological and food safety risks associated with planting and consuming genetically modified crops, we recommend a halt to GM potato field studies and suggest that researchers concern themselves with improving storage conditions to prevent infection of tubers after harvesting.

2.2 2001 – 2002 application and study. This study was poorly designed and failed to respond to key questions regarding the efficacy or safety of GM potato lines. The justification used to obtain the permit was based primarily on supposition and on highly biased data or biased interpretations of such data. Many of these claims were shown to be incorrect by the study itself.

2.3 2003 –2004 permit and study. In this study, the researchers repeat the flawed experiments conducted during the previous year. They claim no difference in yield and viral infection, but provide no data to support these claims. Additionally, they show that the tuber moth has alternative hosts. This is of great concern. The moth is an introduced species that damages potato tubers. If Bt potatoes are released on a large scale this pest will move onto other Solanaceae, some of which have agricultural importance and other which have ecological importance. Data on the effects of non-target arthropods and effects of storage are not yet available. Future studies should not be permitted until results have been obtained from this study in order to determine their relevance and effectiveness in answering questions about the effects of GM lines on non-targets.

2.4 Considering the fact that tuber moths mainly affect tubers during storage and that there are ecological and food safety risks associated with planting and consuming genetically modified crops, we recommend a halt to GM potato field studies and suggest that researchers concern themselves with improving storage conditions to prevent infection of tubers after harvesting.

2.5 The scientific design in the proposal for the 2005 trial has serious flaws. Ecological impact on non-target species has only been addressed with a limited scope and key experiments to measure transgene stability and horizontal gene flow have not been carried out. Before adequate biosafety is established we demand that further trials are halted.

2.6 The proposed study is unlikely to provide the information necessary to make conclusions about ecological or feed safety and will replicate previous experiments unnecessarily, exposing the environment to unnecessary risks

3. Legal Assessment

3.1 Contraventions of permit conditions

The Applicants have failed to comply with several permit conditions in that it failed to:

(a) dispose of transgenic potatoes from the previous field trials in a manner so as to prevent dissemination of transgenic material;
(b) fumigate the soil; and
(c) ensure 2 m around experiment with vegetative growth

as it was required to do, in terms of conditions imposed by the EC, in respect of Permits 17/3(4/03/0680); Permit 17/3(4/03/0680); and Permit 17/3(4/03/0680), respectively.

> In terms of section 21 of the GMO Act, any person who contravenes or fails to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of the shall be guilty of an offence.
>
> It therefore appears that the Applicant is liable for prosecution under the GMO

Act. We therefore request that the EC bring the matter to the attention of the Minister of Agriculture in order for the law to takes its proper course.

3.2 Failure to comply with ECA and ECA Regulations

The Applicant has failed to comply with section 21(1) of the Environment Conservation Act (" ECA") and the Regulations promulgated in Notice R 1182 and Notice R1183, Government Gazette of 5 September 1997 ("the ECA Regulations"). The Applicant is obliged to submit a Scoping Report in terms of the ECA Regulations, and comply with its provisions and requirements. These include *inter alia,* employment of an independent consultant having no financial or other interest in the GM field trial; identification of environmental issues and information of all alternatives as well a credible public participation process.

The Applicant has failed to comply with these provisions and is thus, obliged to withdraw its application, as contemplated by section 3(2) of the ECA Regulations.

3.3 EC has a constitutional and statutory duty to protect the environment

The EC has a constitutional and statutory duty to protect the environment. It is our contention that the EC is obliged to refuse the approval sought by the Applicant because the EC has a duty to do so in terms of section 24 of the Constitution, in order to protect the environment. Indeed, it is our submission that the application must be refused because the statutory framework obliges the EC to *inter alia* adopt a risk averse approach in assessing environment hazards and to evaluate the social and environmental impacts of the proposed activities and to have regard to the cumulative potential impacts of such activities on the environment.

4. Socio-economic concerns

The socio-economic impact of GM potatoes has not been dealt with in the permit application at all, thereby leaving a major gap in assessing its viability for resource poor farmers that it is purported to benefit.

Apart from the general consumer concerns about a lack of consensus on the health and environmental impacts, the lack of access to information and no legal requirements for mandatory labeling of GM crops and food, GM potatoes give rise to particular negative socio-economic impacts for small scale farmers.

It is not possible that resource poor farmers will benefit from a crop that:

- they can only afford if they purchased on credit (normally double the price);
- has 10 patents-holders that will be looking to reap financial benefits;
- will be released in a context of Intellectual Property Rights regime that favours the commercial seed industry;
- they cannot use to produce their own planting material; and
- which consumers in all likelihood will not buy.

5. Preliminary Issues

5.1 Rights of access to information restricted

On the 2 June 2004, Glenn Ashton applied to the DoA in terms of the PAIA for access to the following information:

a) all data from previous field trials (including inspection reports from NDA inspectors),
b) baseline studies and side by side comparisons of similar test lines,
c) food and environmental safety testing (including long term studies),
d) molecular characterisaton of the line,
e) toxicity studies,
f) records of impacts on non-target organisms,
g) expression and degradation rates of both the bt lines and the antibiotic marker (ARM) gene in the field,
h) risk management outlines,
i) monitoring outlines,
j) emergency procedures,
k) records of destruction of previous trials and tests, including the methods of destruction,
l) records of oversight and proposed improvements on these,
m) a list of contact people,
n) location of the field trials to enable independent oversight,
o) stability of 35 s promoter in this event,
p) any other relevant data pertaining to this trial.

In the intervening period, Mariam Mayet approached Dr Graham Thompson from the ARC directly and requested access to data relating to the previous field trials conducted in South Africa. In response to the said request, Ms Mayet was furnished with certain information pertaining to 2 field trials conducted during 2001-2002 and 2003-2004. The inadequacies relating to this data is canvassed below in the scientific assessment.

On the 24 June 2004, Mr Ashton was furnished with limited information in response to his PAIA application. The inadequacies inherent in the information furnished are addressed in the scientific assessment below. However, we deal here with a number of specific issues.

5.2 No Baseline Data

No baseline environmental data was provided in respect to the previous two field trials. In this regard, we note that in the absence of such data, the accuracy of the evaluation of ecological impacts is questionable.

Indeed, we found no evidence of any baseline data pertaining to the proposed field trial for the period 2005. Any field trials conducted on the proposed locations will similarly be questionable.

5.3 List of contacts

We note that no information has been furnished to us regarding the independent consultant the Applicant is required to hire, in order to discharge its obligations under the ECA in respect to the compiling the requisite Scoping Report.

5.4 Field trial locations

We have taken special note of the failure of the Applicant to furnish to us with the exact location of the proposed field trials.

The Applicant has cited this information as Confidential Business Information (CBI) and in this regard, the main reason given is that "**activists will seek out and destroy the trial sites**, inadvertently risking the spread of the material, or that spillage during transport may occur. This will be managed by keeping the exact locations confidential for the 2 year trial period…"

"The only CBI information in this application is the exact location of the trial sites. This is to **protect the trials from activist interference, the developers from the cost of this action and the farm managers from intrusion and intimidation. Emerging and subsistence farmers will be invited to the trials to view the technology, ask questions and to be consulted on its potential value to them."(**our emphasis)

There is no history of any vandalism at test sites in South Africa having taken place to date, despite the exact locations of a number of field trials of GMOs being well known.

Certainly, there have been incidents of protest action elsewhere in the world-on other continents. However, there is no justification for the Applicant and the DoA to without reasonable justification extrapolate what has happened on other continents, to a non-existent situation in South Africa, and in so doing, severely curtail the public's rights to such information.

We note with extreme disquiet, that the failure by the DoA to provide this information to us, must surely mean that it accepts the unsubstantiated and unjustified reasons furnished to it by the Applicant. This effectively implies that those of us who raise biosafety concerns are nothing more than vandals! Not only do we find this disturbing, we also find it deeply disappointing that a democratically elected government such as ours, should display such a profound lack of understanding of our work and the right to information.

The issue of inviting subsistence farmers is dealt with in the discussion on socio-economic issues elsewhere in this report.

5.5 Constraints due to overlapping time frames

We draw the attention of the EC to the fact that the public participation mechanisms as set out in section 6 of the Regulations made under the GMO Act, concerning the very short time frame that the public is given to respond to public notifications, seen

in the light of the time frames which the NDA has to respond to applications in terms of PAIA, has been extremely prejudicial to us.
In regard to the current application, the public notice was published during the period 14 – 18th May in various newspapers. Members of the public were accordingly obliged to submit objections as required by the Regulations to the GMO Act, within 30 days from the date of publication of the notice, or in this case, by June 17. For various reasons pertaining to consultation between groups working in the public interest on this issue and evaluation of resources and capacity to respond to the said public notice, we were only able to submit our PAIA application on the 2 of June 2004.

However, even if we had submitted a PAIA application on the 19th May 2004, we would have been prejudiced in that the DoA would only have been obliged in terms of PAIA to furnish the information requested after the expiry of the comment period. It is purely fortuitous that the Applicant was amenable to the extension of time, simply because the meeting of the EC had been postponed.

Even in the light of the extension being granted to us, we still only received the data in response to our PAIA application **on the morning of the 24th June at 09h30.** Given that we had still to arrange for the copying and distribution of the information to relevant experts, work on the data supplied was only able to commence on the 25th June, giving us less than two working days to compile our objections.

This is clearly not only insufficient, but extremely prejudicial.

Detailed Analyses

6. Scientific Assessment

The information necessary for this report was only provided two working days before the submission date. A thorough analysis could thus not be conducted and this critique is based only on the glaring errors and omissions observed by reading the material provided. If given an opportunity to check reference material thoroughly a more extensive report could have been prepared.

6.1 Inherent Problems with the technology

These studies aim to make transgenic potato lines that express Cry proteins, which are known to be highly toxic to Lepidopteran insect larvae. The Ti- Agrobacterium system was used to mediate transformation and selection of suitable transgenic potato lines. This results in a random incorporation into the host genome and the co-incorporation of the strong CaMV 35S promoter and Nos11 gene coding for resistance to the antibiotic kanamycin. The studies fail to assess correct integration of the tubers used in the trials and the stability of the construct after one or more generations.

The PCR detection of Cry1a gene alone does not determine the order or gene copy number of the entire transgenic construct and so deletions, rearrangements, duplications and insertions may have occurred. This is particularly important in the

potato where the ploidy may vary and previously recessive or silent genes may be phenotypically expressed in subsequent generations. The construction of transgenic lines in this way poses several problems of stability with unknown effects. The transgenic potato lines also contain the sequences for the kanamycin gene and promoter as well as some elements of the Ti vector.

Since these bacterial DNA sequences have homology to other bacteria present in the soil, the transfer of these transgenes to other bacteria that inhabit the soil (or gut microflora) is significant. Current evidence suggests that the horizontal gene transfer from transgenic crops to soil bacteria does indeed occur and is detectable using modern molecular biology methods (Jansson *et al.*, 1989 and Kowalchuk *et al.* 2003). If selection for this trait (transgenic construct containing both bty1 and npt11 genes) is applied over several generations the number of soil bacteria harbouring a transgenic construct will increase resulting in a plethora of soil bacterial strains harbouring the npt11 gene and being resistant to kanamycin.

Changes in soils bacterial diversity may also result in changes in nutrient cycling and plant-pathogen protection (van Elsas *et al*. 2002). Of further concern is that the CaMV 35 promoter is subjected to a high rate of recombination (Kohli *et al.*. 1999). Interestingly, this recombination was mediated by double stranded DNA break requiring little sequence homology; indicating that this promoter is a mobile genetic element (Ho *et al.*. 1999). The results are the spreading of antibiotic resistance, and the potential expression of entirely new genes causing activation of proviruses, and cellular cancer transformation.

The fact that the CaMV 35S promoter has been shown to be active in animal and bacterial cells exacerbates this problem and the horizontal gene transfer to other species poses unknown risks of increased rates of gene rearrangements and mutations (Ho *et al.* 2000).

Additionally, since Cry1 proteins require proteolytic cleavage (in the alkaline insect gut) for activation, the screening for Cry1 gene mutants in non- target organisms is required. A Cry1a gene mutation could result in the production of an active Cry1 truncated protein that does not require insect gut activation or a Cry1 mutant protein having altered insect target activity or specificity.

6.2 2001 – 2002 application and study

Summary: This study was poorly designed and failed to answer key questions regarding the efficacy or safety of GM potato lines. The justification that was used to obtain the permit was based mainly on supposition or on highly biased data or interpretations of such data. Many of these claims were actually proven wrong by the study itself.

Document	Page/ Point	Question/Problem
Original Application Report 2002/3	2 pg 15 - 17	"In the field larvae …reduce yields by 30%. This is huge exaggeration we can see from the field report that there are virtually no differences in yield between those with no infestation and those with infested leaves.

Original Application	4.2.1	"There are no safety issues associated with the consumption of raw transgenic potatoes" These detailed studies have not been carried out; the only available study (Sanhoty *et al.*) failed to look at DNA uptake and lateral gene transfer to the rat host. It also lacked any detailed physiologic studies to determine tissue damage, cancerous growths etc. Studies of a different transgenic potato line found stomach ulceration in rat feeding trials (Ewen *et al.*. 1999)
Original Application	4.3	No description of genetic modification available to comment on. These details MUST be provided to establish scientific validity
Original Application	4.6	There will be batch to batch inconsistency since there is inherent somaclonal variation (Karp, 1989). The arrangement and copy number of the transgenic construct was not determined. PCR and quantitative Southern blotting needs to be carried out to determine such variability
Original Application	4.7	The monitoring of gene escape by inspecting planted areas (and sites buried with potatoes after the experiment) for emergence of potatoes is insufficient. The monitoring of environmental microbiota (particularly surrounding soil bacteria) is also required. Molecular methods can be used to gain insight into complex soil microbial communities (Huer 1997)
Original Application	4.7.2	"Spread of marker genes was shown to be negligible at 10m" (McPartlan and Dale, 1994). BUT this paper also shows that 24% of non-GM plants in the next row acquired marker genes and that at 3m separation distance there was a 2% frequency on marker uptake by non-transgenics. In Skogsmyr (1994) they report gene dispersal at 72% in immediate vicinity and 35% at consecutive distances. The distance of 200m is clearly not sufficient. It is also not clear if soil fumigation of the GM planted site was carried out.
Original Application	5.1.10	Spunta-G3 is not mentioned in application
Original Application	5.2.3	The authors fail to observe limitations of their approach and therefore have not addressed why monitoring of soil microbiota was not carried out.
Original Application	5.3.3	Exact details on genetic constructs are lacking. "The transformation constructs, method of transformation method and introduced genes differ little" is unscientific and requires details for independent scientific assessment.
Original Application	5.5	As noted in comments above (4.7 and 4.7.2 and above) there is evidence for transfer of genes to other plant species and to soil bacteria. The application makes no reference to these and fails to address this factor in their experimental design
Original Application	5.6	No detailed long-term studies have been carried out for this transgenic potato line Molecular studies have not addressed possible changes in transgene copy number or the degree of rearrangements taking place in their transgenic lines. The observation of phenotype or molecular detection of npt11 or

		Cry1a gene in the potato alone does not constitute effective environmental monitoring. The stability of the transgenic lines needs to be established by analysing the entire construct (CamV-Bty1a-npt11) to ensure correct gene order, dosage and integrity. Again the effect on soil microbiota has not been addressed despite being a well recognised concern with this technology (Kowalchuk *et al.*. 2003)
Original Application	5.7.	These is no reference made to the possible consequences of release of 'such a modified organism' despite evidence from the literature. Namely: Increased recombination events and lateral gene transfer to non- target species. This includes up to 25% transference to non-GM plants of the same species (McPartlan and Dale, 1994) and the recombination with soil bacteria (Jansson *et al.* 1989) as well as inherent problems with the CamV promoter being a recombination hotspot (Hull *et al.*., 2000). In short, the study fails to adequately address these issues satisfactory and therefore poses undetermined risks and hazards
Original Application Report 2002/3	6.4 pg 15	Application states that "no undesirable effects may result from the release," BUT, data in report there is significant increase in the mean number of virus infected GM plants above controls. Since the transgenic potato contains a genetic construct with Bty1a gene driven by CamV promoter and the npt11 gene mediating kanamycin resistance all these genetic modifications need to be assessed. Recombination and lateral gene transfer to non-target species may feasibly result in insecticide resistance, biodiverse soil bacteria with kanamycin resistance and a loss of specificity of Cry1 protein for target insect species.
Original Application	6.5	The gains of moth resistance are linked to losses in yield (see Roodeplaat trial, pg 17)
Original Application	6.7 6.8	"No" is not correct. The genetic recombination events and lateral gene transfer are widely known and established. There is evidence from similar CamV promoter constructs showing transfer to non-target non-GM plant species and soil bacteria (McPartlan and Dale, 1994, and Jansson *et al.*. 1989). The effect on soil microflora could be profound since soil microbiota control nutrient cycling and plant pathogen protection (Nannipieri, *et al.*. 1990).
Original Application	6.10	Where is the evidence to show non-toxicity?
Original Application	6.11	The gene escape to non-GM plants of the same species needs to be determined. Phenotypic assessment of Cry1a gene product alone is insufficient for this assessment. The order and integrity of the entire construct needs to be determined.
Original Application	6.12	Since bumblebees prefer to pollinate the edges of the plots., this 2002/203 trial layout was flawed in addressing this issue since all the border plots were non-GM. Additionally, the fumigation and treatment of the test site represents an unnatural agricultural system which is stressed- these

		conditions favour recombination with soil bacteria (Jannson *et al.* 1989)
Original Application	6.13	The transfer of the construct to non-BM species may increase insect resistance to Bty1 toxin by decreasing the refugia to maintain nonBty1 resistant insect populations (NBIAP news report, Appendix 11 provided)
Report 2002/3	Pg 4	"Losses relating to tubers …< R40 million …." But this is not all due to tuber moth. There is huge exaggeration regarding the impact of the tuber moth in the field. In fact most losses occur during storage and are due to activity of tuber moth but also other pathogens (bacteria, fungi and nemeatodes)
Report 2002/3	Pg 5	Experimental design: unequal and non-random spread of GM and non-GM. Non-GM always on outside – therefore more likely to be attacked.
Report 2002/3	Pg 6	Why trap insects if you are not going to analyse them? In later studies you want to do insect studies … if you had analysed these then you would have some baseline data on which to design new studies. "Some tubers have mould growing on them" …. So tubers were infected before the trial!!?
Report 2002/3	Pg 12	"Despite release of 30,000 moths level of infestation was low". It is thus totally unjustifiable to allow moths to be released at this site.
Report 2002/3	Pg 14 – 15 and 21	The number of plants examined for viruses is unacceptably low. The results clearly show an increase in viral infection of some GM strains (including G3 – chosen for future studies), but in the discussion it states that there is no difference in the incidence of viruses between treatments. This is blatantly incorrect – there may be no difference in the presence but the extent is very different between strains.
Report 2002/3	Pg 16	Bias in collection. By discarding potatoes that are too small there is a bias in that different potato varieties will produce different size potatoes. The rotten/damaged potatoes were also discarded giving question to the values of yields determined and masking difference in susceptibility of the strains to other pathogens (e.g. virus, fungus, nematode)
Report 2002/3	Pg 17	These results show that there is no advantage in planting Bty1 potato in Roodeplaat's, where there is no moth infestation. In fact, the yields for the transgenic potatoes S4, Spunta and 6A3 are 10-15 tons/ha less than the non-transgenic controls (S1,Bp1) when insecticidal sprays were not used. This result is of concern since it suggests that the transgenic lines are more susceptible to other insect pests or plant pathogens harboured by them. This is supported by the result in Fig 4 which shows that some transgenic potato lines have a higher viral infection (e.g. BP-1 and Spunta)
Report 2002/3	Pg 18-19	Microscopic methods should be used to determine the frequency and incidence of infection by the various insects.
Report	Pg 20	Tuber damage does not occur in the field. The construction

2002/3		and release of a GM plant into the environment only to benefit storage is illogical. Improving methods and technology to limit infection in storage would be more applicable and relevant.
Report 2002/3	Pg 22	They ask for review of destruction process – their recommendation may prevent growth of potatoes, but still leaves transgenic material that may be transferred by recombination to other organisms. This poses unknown risks and is not acceptable. If autoclaving is not feasible then a bioreactor for potato plant and tuber waste should be constructed. In this closed environment fermentation can be stimulated with bioconversion to valuable products (e.g. methane) and a concomitant reduction in the volume biohazardous waste.

6.3 2003 -2004 permit and study

Summary: In this study the researchers repeat the flawed experiments conducted in the previous year. Again they claim no difference in yield and viral infection, but provide no data to support these claims. Additionally, they show that the tuber moth has alternative hosts. This is of great concern. The moth is an introduced species that damages potato tubers. If Bt potatoes are released on a large scale this pest will move onto other Solanaceae, some of which have agricultural importance and other which have ecological importance. Data on the effects of non-target arthropods and effects of storage are not yet available. Future studies should not be permitted until results have been obtained from this study in order to determine their relevance and effectiveness in answering questions about the effects of GM lines on non-targets.

Document	Page/ point	Question/Problem/Comment
Contravention of the permit		
Permit 17/3(4/03/06 80) Report 2003/04	11 pg 27	Permit requires disposal in such a manner as to prevent dissemination of transgenic material. Transgenic potatoes will be buried in a trench 2 m deep. The potatoes may be unviable at this depth, but this does not necessarily preclude to possibility of dissemination of transgenic material.
Permit 17/3(4/03/06 80) Report 2003/04	23	Permit requires fumigation of the soil This is not mentioned in the report. Gramaxone herbicide was not used throughout according to pg 15.
Permit 17/3(4/03/06 80) Report 2003/04	9	2m around experiment with no vegetative growth This is not evident in report.
Poor Science		
Report 2003/04	Pg 6	Bias in design since the size of tubers at the beginning of the experiment was different and small tubers were removed

		from the sorting tables and not counted!
Report 2003/04	Pg 8-10	Experimental Design: There is no justification for using BP1 as a control. The use of border-side rows containing BP1 acts as a sink to attract potato pests. Pests present in these plots will easily move to other BP plants in the test blocks. Borders are also more likely to be visited by insect pollinators (bumblebees).
Report 2003/04	Pg 16	Counting and collection of Parasitoids is required. A valid comparison can be made: 0% potato tuber moth mines for GM plots and x % for control non-GM plots.
Report 2003/04	Pg 12	Moths were released at Roodeplaat as there was no/low infection at this site. No written authorisation for release of non-indigenous pests into this area has been provided.
Report 2003/04	Pg 19	This only looks at effect of moths on the plants themselves and not the tubers. Is there a difference in yield or quality of tubers between treatments?
Report 2003/04	Pg 20	Timing of harvest seems to have a dramatic impact on degree of moth larvae detected. This variable needs further investigation (different times of year).
Report 2003/04	Pg 22	"GM did not influence incidence (i.e. presence/absence) of viruses", but no data given on extent of virus attack (see critique on 2002 study, where GM plants had significantly higher levels of infection from PVS and L235.
Report 2003/04	Pg 24	" This shows that the introduction of GMO potatoes will not be responsible for the eradication of the tuber moth ….ample alternative hosts". Tuber moths which now affect potato industry could move to other solanaceae thus enforcing other solanaceous crops to require higher levels of pesticide or to become GM.

6.4 Current Application (24th May 2004)

Summary: The aim of this proposal to carry out further efficacy and ecological studies on Bt potato lines G3 and G4.

The leaf damage, tuber damage and yield studies proposed have already been conducted twice before. The site at Roodeplaats does not have natural populations of the target tuber moth, so 10,000's of moths are typically released in order to conduct the efficacy studies. These moths are a non-indigenous pest that is known to damage potatoes and other plants within the family Solanaceae.

Considering that there is no need to further prove the effectiveness of the GM lines in preventing damage by the tuber moth, the further release of moths should be prohibited. In the protocols for assessment of damage to tubers there are two potential methods given. It should be made clear before the trial which method will be used.

The proposed study of non-target organisms is not given in sufficient detail. Specific hypotheses should be tested and the appropriate methodologies designed. No studies

of the difference in microbial diversity between GM and non-GM plots are suggested and no testing of gene flow into soil microbiota is proposed.

The soil microbiota plays an important role in nutrient cycling and may take up transgenic material by horizontal gene transfer. Testing of soil for differences in microbial community structure and for the presence of transgenes must be conducted as part of the ecological impact analysis. The applicant claims that they aim to collect food and feed safety data, but details of this are not given. The only analysis proposed is based on nutritional composition. This does not constitute a feed or food safety study.

In conclusion, the proposed study is unlikely to provide the information necessary to make conclusions about ecological or feed safety and will replicate previous experiments unnecessarily.

6.5 Analysis of Current application

Document	Page/ point	Question/Problem
Current Application	6 pg 3	"G2 and G3 warrant further efficacy testing" Why? There was no moth infection of plants in these lines at the three sites in 2003/4 and 2002/3 – why do further efficacy testing? Further ecological testing and food safety analyses are warranted. There are only going to be 3 ecological trials and 5 more efficacy trials. There should be ecological studies at every site, because (as they argue) the different sites are ecologically different
Current Application	6	What is item 13 of 2002 permit …we don't have a copy.
Current Application	11-21	Missing information.
Current Application	22	"Bt is toxic to specific genera of insects" but in 2002 application pg 12 says specific to target and Coleoptera (over 400,000 species) and Lepidoptera (lots of non-targets that fulfil important ecological functions) Studies have shown that Bt can be toxic to non-targets.
Current Application	25	"procedures provide reliable and sensitive detection of fresh GM potato material" What does fresh mean? Is PCR amplification of Cry1Ia1 reliable from elsewhere?
Current Application	27	Potato is sexually incompatible with other solanaceae, and horizontal gene transfer to *S. dulcamara* and *S.nigrum* in field trials after one season apparently does not occur (McPartlan and Dale, 1994). However, studies have not addressed transfer to soil microbes. As mentioned earlier the CamV promoter represents a recombination hotspot and, together with homolgous bacterial sequences in the transgenic constructs used, makes this process likely. Modern molecular biology methods should targ*et al.*l genetic elements in the construct (CamV, Cry1, Npt111 promoter

		and gene and nos terminator) to determine transgenic construct stability and frequency of recombination events with non-target species. PCR with gene targeted primers and Southern blotting using multiple restriction enzyme digests, together with DNA sequence analysis is required to provide a definitive analysis and to demonstrate stability, integrity and lack of horizontal gene transfer of this transgenic construct.
Current Application	29	"5m fallow area around trials to manage gene flow by insects." Can insects really only travel 5m?!
Current Application	Pg 5	Before the trial begins there should be a survey of natural flora, fauna and soil microbiota. This is required to establish baseline data.
Current Application	Pg 5	There is no request for or mention of release of moths at this site. It should not be done without a specific permit
Current Application	Pg 6	They are arguing for a low number of pitfall and sticky traps. I agree that too many traps may negatively impact on insect populations, but 2 traps per plot may not be sufficient to record diversity. If plots are 9m wide and there are only 2 traps (and above they say that have fallow area of 5m to present insect gene flow) then traps may not reflect insect diversity. In sweep net catches the insects are left in bags until they can be analysed. They can also eat each other in this time!
Current Application	Pg 7	The monitoring of soil microbiota is required, including soil pathogens
Current Application	Pg 8	How by collecting mites from flowers will they determine whether the GM lines are detrimental to non-target insects? The aphids will be dead because they were put in ethanol, how can they tell whether they were not already killed by Bt toxicity? How can you force a tuber moth to lay eggs on marked leaves?!
Current Application	Pg 9	Gene Flow …" volunteer potatoes that emerge will not be destroyed "– why? Does this not go against the permit?
Current Application	Pg 10	Where are details of feed trials?
Current Application	Pg 12 Pg 14 Pg 17	Roodeplaat, EFS and Ceres plots – not exactly random … on LHS ¾ plots are non-GM. Ceres multiplication plots – why are GMs on one side and non-GMs on the other?

7. Socio Economic Considerations for the introduction of GM potatoes in SA

- The socio-economic impact of GM potatoes has not been factored into the GM potato project. This is not acceptable as potatoes are an important crop to the people of South Africa and are becoming an increasing important staple food. It is now second to maize in importance as a source of carbohydrates. It is the most important vegetable for South African consumers especially since fresh potatoes are available throughout the year. In addition, there is an important informal sector of resource-poor farmers producing potatoes under dryland, low input conditions

- The project is aimed at benefiting small-scale farmers, but provide no information on how it will overcome the severe constraints commercial agriculture systems, and in particular expensive GM seed present to these farmers. In this regard, it is important to distinguish between projects that seek to integrate black farmers into the commercial agricultural sector and those that are aimed at making a real impact on poverty and support subsistence, resource poor farmers. All GM seeds in South Africa sell for double the price of hybrid seed, making it accessible only to those farmers with access to credit.

- Even though this project is publicly funded, there are 6 – 10 patents still to be negotiated negating the whole purpose of a public interest project. These patents confer ownership of the technology to industry or institutions, making it illegal for farmers to propagate their own planting material – a common practice resource poor farmers in Africa cannot survive without.

- In addition to paying the technology fee, all farmers planting GM crops in South Africa sign a technology agreement stipulating that they may not:
  - use the licensed seed for more than one season;
  - use the seed for any other purpose including breeding, research, seed production and analysis;
  - resell or transfer the seed to any other person or grower; and
  - save any crop produced from the GM seeds for future planting, or supply saved seed to anyone else.

- Even if the patent issue would be addressed, a further constraint in South African legislation for small-scale farmers is that the current seed legislation (the Plant Breeders' Act, 15 of 1976 and Plant Improvement Act 53 of 1976), is only designed to both regulate and support commercial seed producers and distributors. Many of the provisions are inappropriate for, and prejudicial to the informal seed sector (legal analysis produced by Biowatch SA, available to the EC, upon request). The effect of these provisions is to restrict the practices traditionally carried out by small scale-farmers, exclude them from participation in the seed market, and promote reliance on commercial seed producers.

- South Africa was the first country to experiment with GM and small-scale farmers, providing them with Land Bank loans for Bt cottonseed, extension assistance, donations and ready markets to create optimal conditions for success. In spite of this extensive support, these farmers are now in debt and cannot repay their loans. The farmers on the Makathini Flats involved in the Bt cotton project, illustrate the pitfalls of resource poor farmers becoming too dependent on outside inputs and taking on debts to afford high input costs. This kind of high input, single-trait technology is clearly not sustainable in marginal conditions where the focus should rather be on financial independence and technologies based on real needs.

- GM potatoes was first grown in the US and was withdrawn from the market after a few years because consumers were not prepared to eat it. There does not seem to be a market elsewhere in the world, and informed African consumers will also not choose to eat GM potatoes. This begs the question whether this funding is not being spent on a misguided project in a country where the needs of resource poor are enormous.

- The introduction and regulation of GMOs in South Africa is characterised by a lack of transparency, public participation and access to information for the public as the recent court case between Biowatch SA, the Department of Agriculture and several biotech companies have clearly shown. It is not possible for the public to engage in a meaningful way with the legislative aspects around GMOs, as has been fully discussed elsewhere.

This severely prejudices those poorer sectors of the community most likely to consume staple foods such as GM maize and potatoes as a major part of their diet.

- Exacerbating the lack of transparency and choice that GM food presents to consumers, is the fact that South Africa's labeling regulations do not require producers to label GM food.

- Food safety is an important socio-economic issue to consider in the South African context. The toxicity of GM potatoes has been hotly debated for many years and many scientists are still concerned about the impact on the human gut as well as that it may compromise immune systems. The British Medial Association has also recommended that GM food be not being given to babies. We are concerned that GM potatoes might compromise the immune systems of: Babies, where potatoes are often the first solid food for babies; and people with HIV/Aids trying to cope with already compromised immune systems. If the health impact in the particular context of South Africa cannot be certain, it is not worth the risk when we are completely self-sufficient in potatoes.

8. The Statutory framework

The Statutory framework governing the EC's powers and duties is comprised of:

- The Constitution of the Republic of South Africa (Act 108 of 1996) ("the Constitution")
- The Environment Conservation Act 73 of 1989 ("ECA);
- The regulations concerning activities identified under section 21 of the ECA and embodied in Government Notice R1182, Government Gazette No. 18261 of 5 September 1997 ("the ECA Regulations);
- The Genetically Modified Organisms Act 15 of 1997 ("the GMO Act"); and
- The National Environmental Management Act 107 of 1998 ("NEMA")

The statutory framework obliges the EC *inter alia* to adopt a risk averse approach in assessing environmental hazards such as the release of genetically modified organisms (GMOs) into the environment and evaluate the social and environmental impacts of proposed activities and to have regard to the cumulative impacts of such activities on the environment.

8.1 THE CONSTITUTION

The Constitution of the Republic of South Africa 108 of 1996 is the supreme law. The supremacy clause in the Constitution is contained in section 2 which provides:

" This Constitution is the supreme law of the Republic; law or conduct inconsistent with it is invalid; and the duties imposed by it must be performed."

The introduction of the interim Constitution and the final Constitution marked a decisive break with the past. The Constitution is not neutral on fundamental values. The Constitution contains a vision for the transformation of society. The centrality of the Bill of Rights and its foundational values to the newly created democracy is expressed in section 7 of the Constitution, which provides:

"Rights

7 (1) This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.

(2) The State must respect, protect, promote and fulfil the rights in the Bill of Rights.

(3) The rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill."

Section 24 of the Constitution entrenches the rights of all South Africans to an environment that is not harmful to health or well-being and imposes and obligation on the state to protect the environment, for the benefit of present and future generations.

The guarantee contained in section 24 of the Constitution forms part of the cluster of socio-economic rights. Other rights include the right to health care, food, water and social security in section 27 and housing in section 26.

Indeed, the Constitutional Court has delivered two important decisions on the ambit and justiciability of socio-economic rights:

Government of the Republic of South Africa and Others v Grootboom and Others 2001 (1) SA 46 (CC)

Minister of Health and Others v Treatment Action Campaign and Others (No.2) 2002 (5) SA 721 (CC)

The obligation imposed on the State by section 24(b) of the Constitution is to take reasonable legislative and other measures to protect the right in question. Pursuant to its Constitutional obligations, therefore, the Legislature has indeed adopted a number of statutory measures, including NEMA, and has devised policies and tools for its guidance for the implementation of legislation.

8.2 The Environment Conservation Act and the ECA Regulations

Section 21 (1) of the Environment Conservation Act 73 of 1989 ("ECA") provides as follows:

" The Minister may by notice in the Gazette identify those activities which in his opinion may have a substantial detrimental effect on the environment, whether in general or in respect of certain areas."

Acting pursuant to this power, and by Government Notice R1182, Government Gazette 18261 of 5 September 1997, the Minister identified certain activities, which may have a substantial detrimental effect on the environment. One of the activities listed in schedule 1 of Government Notice R1182 in item 6, is described as follows:

"the genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism"

The effect of the identification of the activities listed in Government Notice R1182 is that it triggers the prohibition in section 22 of the ECA and requires written authorisation to carry on the activity in question by a competent authority designated by the Minister in the Gazette.

Regulations governing activities identified under section 21(1) of the ECA were promulgated in Government Notice R1183, Government Gazette of 5 September 1997 ("the ECA Regulations").

The ECA Regulations set out, *inter alia*, the requirements for an application for authorisation to pursue an identified activity. The ECA Regulations make provision for the submission of a Scoping Report together with the required contents of such a report (Regulation 6(1)).

In other words, the Applicant is obliged to submit a Scoping Report in terms of the ECA Regulations, and in compliance with its provisions and requirements. These include *inter alia*, employing an independent consultant having no financial or other interest in the GM field trial; identification of environmental issues and information of all alternatives, in the said Scoping Report, as required by the ECA Regulations.

On the 3 June 2004, the African Centre for Biosafety wrote to the Director-General (DG) of the Department of Environmental Affairs and Tourism (DEAT) to seek his confirmation that these statutory obligations have been complied with in respect to several GM events, including in respect to GM potatoes.

The failure by the DG of DEAT to provide the Centre with access to the said EIA as requested (see above), has left us with the impression that the Applicant may not in fact have complied with its said statutory duties.

In any event, it is our contention that if the EC is satisfied that the applicants have been able to produce a Scoping Report, it is our contention that the Applicant has not fully complied with the requirements of the ECA Regulations.

8.3 Independence of Consultants

In terms of section 3 (1) of the ECA Regulations an Applicant-

(a) must appoint an independent consultant who must on behalf of the applicant comply with these regulations;

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(c)must ensure that the consultant has no financial or other interests in the undertaking of the proposed activity, except with regard to the compliance of these Regulations.

Based on the information furnished to us, we were unable to find any reference to the employment by an independent consultant as the Applicant is obliged to do, in terms of section 3(1) of the ECA Regulations. It is

therefore our contention that the Applicant has failed to comply with its statutory obligations. However, since the Application has been made on behalf of ARC by Ms Muffy Koch and in the event that the Applicant contends that Ms Muffy Koch has been employed by it as the consultant contemplated by the ECA Regulations, we contend that section 3(1)(c) has not been complied with, in that Ms Koch is not an independent consultant as contemplated by section 3(1) of the ECA Regulations.

Ms Koch established her own biotechnology consultancy, a company trading as Innovation Biotechnology, later re-launched as Golden Genomics. Ms Koch is a member of Africabio, the industry lobby group, which is comprised of the following corporations involved in the production and sale of GM plants, seeds and the herbicides that crops have been genetically modified: AgrEvo South Africa (Pty) Ltd; 8. Carnia Seed (owned by Monsanto); Delta and Pine Lands SA. Inc; Monsanto SA (Pty) Ltd; Novartis South Africa (Pty) Ltd; Pioneer Hi-Bred RSA (Pty) Ltd; Sensako (note, this is a seed company and has been bought by Monsanto) etc.

In a communication to SAFeAGE, Ms Koch defended her involvement in the industry lobby group, *'I am indeed a member of AfricaBio and this is to fulfil my second passion - the need for public access to balanced and accurate information about biotechnology and biosafety. This is essential to enable stakeholders, consumers and communities to make informed decisions about biotechnology and GM products in general.'*

According to an article in the science journal *Nature*, however, AfricaBio is far from being a source of 'balanced' information: *'AfricaBio, along with agribiotech companies and other pro-biotech campaigners, is now fighting tooth and nail, often by somewhat controversial methods, to spread the word about GM crops...'* The article also says of AfricaBio, *'the group's methods would be considered in some countries to be blatant media manipulation.'*

Despite the partisan nature of this lobby group, its industry funding and her active role within it, Koch always presents herself at meetings and elsewhere as an 'independent' biosafety expert.

Ms Koch is also a member of the sub-committee of the Advisory Committee established in terms of the GMO Act. Koch and her company, it seems, have been paid to guide the field trials of GM potatoes crops through a regulatory system that she herself is part of.

It is thus our contention that in the light that Ms Koch clearly has an interest in the GM potato field trials, and as such, subsection (1) of section 3 of the ECA Regulations have not been complied with.

In terms of section 2(2), if any provision of sub-regulation (1) is not complied with by the applicant and not immediately attended to, after having been made aware of it by the relevant authority, the application is regarded to have been withdrawn.

We therefore, request that the EC, bring this matter to the attention of the Applicant so that it may attend to the serious conflict of interests and accordingly, withdraw the application.

The Applicant is obliged in terms of section 6(1) of the ECA Regulations to submit a scoping report to the EC, **which must include:**

(a) a brief project description;
(b) a brief description of how the environment may be affected;
(c) a description of all alternatives; and
(d) an appendix containing a description and public participation process followed, including a list of interested parties and their comments.

It is our contention that the Applicant failed to fulfil these criteria.
In the circumstances, the Applicant is obliged to withdraw its application.

8.4 The National Environmental Management Act 107 of 1998 ("NEMA")

The Preamble to NEMA reflects that it is promulgated pursuant to the environmental protections guaranteed by the Constitution. There are a number of provisions in NEMA that has a direct bearing on the regulation of GMOs, more particularly, environmental releases of GMOs. These include-

Section 2(4) stipulates that sustainable development requires consideration of a wide variety of factors, which are more fully set out in section 2(4)(a). In this regard, attention is particularly drawn to the following:

"(ii) that pollution and degradation of the environment are avoided, where they cannot be altogether avoided, are minimised and remedied;
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(vii) that a risk averse and cautious approach is applied, which takes into account the limits of current knowledge about the consequences of decisions and actions;

(viii) the negative impacts on the environment and on people's environmental rights be anticipated and prevented, and where they cannot be altogether prevented, are minimised and remedied. (emphasis added).

Section 2(4)(i) provides:

"The social, economic and environmental impacts of activities, including disadvantages and benefits, must be considered, assessed and evaluated, and decisions must be appropriate in the light of such consideration and assessment. (emphasis added).

Section 24 of NEMA (which falls within Chapter 5) provides in relevant parts:

"24 Implementation

(1) In order to give effect to the general objectives of integrated environmental management laid down in this Chapter the potential impact on-

(a) the environment;
(b) socio-economic conditions; and
(c) cultural heritage;

of activities that require authorisation or permission by law and which may significantly affect the environment, must be considered, investigated and assessment prior to the implementation and reported to the organ of State charged by law with authorising, permitting or otherwise allowing the implementation of an activity.

(7) Procedures for the investigation, assessment and communication of the potential impact of activities must, as a minimum ensure the following:

(a) investigation of the environment likely to be significantly affected by the proposed activity and alternatives thereto;
(b) investigation of the potential impact, including cumulative effects of the activity and its alternatives on the environment, socio-economic conditions and cultural heritage, and assessment of the significance of the potential impact. (emphasis added).

8.5 THE GENETICALLY MODIFIED ORGANISMS ACT, 1997 (GMO ACT)

The objectives contained in the preamble of the GMO Act state that that Act is intended to provide for measures to, among other things, to ensure that all activities involving the use of GMOs are carried out in a way that limits possible harmful consequences to the environment and, further to ensure that GMOs do not present a hazard to the environment. For a number of reasons as set out below, it is out contention that GMOs generally speaking and GM potatoes in particular, present a hazard to the environment.

The Applicants have failed to comply with several permit conditions in that it failed to:

(a) dispose of transgenic potatoes from the previous field trials in a manner so as to prevent dissemination of transgenic material. In this regard, we point out that the Applicant dumped genetically modified waste material in the ground without autoclaving and without studying the effect of this transgenic material on surrounding soil biota and microbiota;
(b) fumigate the soil; and
(c) ensure 2 m around experiment with vegetative growth

as it was required to do, in terms of conditions imposed by the EC, in respect of Permits 17/3(4/03/0680); Permit 17/3(4/03/0680); and Permit 17/3(4/03/0680), respectively.

In terms of section 21 of the GMO Act, any person who contravenes or fails to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of the shall be guilty of an offence.

It therefore appears as if the Applicant is liable for prosecution under the GMO Act. We therefore request that the EC bring the matter to the attention of the Minister of Agriculture in order for the law to takes its proper course.

8.6 Legal assessment conclusion

It is clear from the above that the EC is subject to a wide range of constitutional and statutory duties. The EC is entitled and obliged to take into account *inter alia,* the following:

1. The obligation to prevent pollution and ecological degradation and to secure ecologically sustainable development (section 24 of the Constitution);
2. The obligation to promote development that is **socially, environmentally and economically sustainable** (section 2(3) of NEMA);
3. The obligation to minimise negative impacts on the environment and on people's environmental rights (section 2(4)(I) of NEMA);
4. The obligation to minimise pollution and degradation of the environment where this cannot be altogether avoided. (section 2(4)(a)(ii) of NEMA);
5. The obligation to apply a risk-averse and cautious approach (section 2(4)(a)(vii) of NEMA;
6. The obligation to minimise negative impacts on the environment and on people's environmental rights (section 2(4)(a)(viii) of NEMA;
7. The obligation to evaluate the social, economic and environmental impacts of proposed activities (section 2(4)(I) of NEMA;
8. The obligation to have regard to the cumulative potential impacts and effects of proposed activities on the environment, socio-economic conditions and cultural heritage (section 24(7)(b) of NEMA.

It is well established that a decision-maker is required to take into account all relevant considerations. In the present case, NEMA, the ECA, the ECA Regulations, NEMA and the Constitution delineate explicitly a range of considerations, which must be taken into account. Failure on the part of the EC to take the range of considerations into account would amount to an irregularity.

We therefore submit that the Application must be refused because the statutory framework obliges the EC to *inter alia* adopt a risk averse approach in assessing environment hazards and to evaluate the social and environmental impacts of the proposed activities and to have regard to the cumulative potential impacts of such activities on the environment.

9. References -Scientific Assessment

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