OBJECTIONS BY AFRICAN CENTRE FOR BIOSAFETY IRO APPLICATION FOR GENERAL RELEASE OF GENETICALLY MODIFIED POTATO MADE BY THE AGRICULTURE RESEARCH COUNCIL (ARC)

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These objections have been prepared by Dr William Stafford, Ms Haidee Swanby and Ms Mariam Mayet.

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1. FOREWORD

The African Centre for Biosafety (ACB) is a section 21 non-profit organisation, based in South Africa. The ACB plays a role in protecting Africa's biodiversity, traditional knowledge, food production systems, culture and diversity, from the threats posed by genetic engineering, biopiracy, agrofuels and generally, industrial agriculture.

The ACB has a track record of working on biosafety issues in South Africa and has been involved in submitting 2 objections to field trials involving the SpuntaG2. These objections are on record with the Registrar: Genetically Modified Organisms Act and can be found on the ACB's website, www.biosafetyafrica.net

The ACB has also produced a comprehensive study by Vanessa Black titled 'Hot Potato GM potatoes in South Africa-a critical analysis'. We have made copies of the booklet available to every member of the Executive Council: GMO Act, under the direction of the Registrar. The booklet provides valuable background information against which both the application and our objection should be evaluated. (The booklet is hereinafter referred to as 'Hot Potato')

2. INTRODUCTION

South Africa produces over 1 million metric tons of seed and table potatoes each year. Potatoes are grown in all 9 provinces of South Africa, which encompasses many different climatic regions. This enables a continuous supply of fresh potatoes throughout the year. Potato is the second highest food producer of protein (second only to soy beans) and has a more balanced content of minerals and vitamins than any of the other major carbohydrate food crops currently produced globally. (Hart p.7). Around 57 000 ha are planted to potatoes in SA –fetching a gross income of 2.6 billion ZAR per annum and accounting for 3.7% of the total income from agricultural production. (Hart, p.7)

The Agriculture Research Council (ARC) has made application in terms of the Genetically Modified Organisms Act (Act 15 of 1997), for a general release permit in respect of potatoes that have been genetically modified to confer resistance to the tuber moth. The GM potato is called SpuntaG2 because it uses a potato cultivar called Spunta. Spunta is not currently grown in South Africa. ARC has been involved in field trials in South Africa since 2004, and has proffered certain data that it claims provides 'clear evidence of the efficacy of the CryIIa1 protein against the pest' [potato tuber moth] (p.12 of application).

The transgenic potato, SpuntaG2, has been touted as a new agricultural technology that benefits both smallholder and commercial farmers and the

first publicly funded GM crop to enter the safety approval process for general use in South Africa.[i]

According to ARC, SpuntaG2 has shown complete protection against the tuber moth during six years of testing in six major potato growing areas of South Africa.

We have perused the application and supporting documents, and have had the scientific data independently reviewed. We have come to the conclusion that the tuber-moth resistant potato was not developed in answer to pressing problems faced by South African farmers, industry or consumers. It is a solution developed in a foreign laboratory in search of a problem. The socio-economic studies commissioned by the Agricultural Research Council clearly show that neither commercial nor small-holder farmers will benefit from the technology.

Our scientific evaluation of ARC's dossier has shown up the numerous flaws in the design and interpretation of experiments as well as gross omissions in the biosafety tests carried out to date.

The SpuntaG2 poses unacceptable risks for human health, the environment and the farming community. The Executive Council should, in accordance with the precautionary principle, summarily reject the application. ARC in turn, should shelve the entire project and turn their research talents to more sustainable agricultural interventions.

3. SUMMARY OF KEY FINDINGS

3.1 Socio economic summary:

ARC has deliberately manipulated the results of the socio economic study concerning small scale farmers produced by Hart et al to make the case for farmer participatory trials. It is shameful that the most vulnerable people in our society are being asked to take on the burden of experimenting with new and very expensive technology that does not address their needs and that they have not asked for.

- The Hart Study found that small-holder farmers in the Western Cape were concerned that the PTM resistant cultivar would not reduce inputs and associated costs. Farmer preferences were for a new cultivar that was drought, pest and disease tolerant and indeed, PTM was not mentioned as a specific pest;
- In KZN –where majority of small holder potato farmers are to be found- farmers are in dire need of assistance with current potato production practises such as the introduction of locally appropriate IMP strategies to reduce the effects of a variety of pests afflicting their potato crops. Significantly, the most frequently mentioned storage problem was that rodents ate the potato tubers.

- ARC's curious form of 'general release' is aimed at passing the buck onto small holder farmers to conduct further tests of the GM potato and monitor its efficacy. It is also pointless for the applicant to undertake growing, cooking and tasting tests on a cultivar as the transgene does not typically confer these characteristics to the cultivar.
- Commercial farmers do not agree with ARC that the potato tuber moth is a major problem for them, indeed, tuber diseases are ranked sixth, as the most serious problem they face.
- Commercial farmers are of the view that the GM potato would not have any significant impact on their production. Indeed, they have cultivars at their disposal with a higher yield potential than the GM cultivar.
- Commercial farmers did not expect a rapid adoption rate with the new potato.

3.2 Summary of Industry reaction

- **Potato South Africa (PSA), representing commercial and small holder potato farmers** told the ACB that GM potatoes would not benefit the potato industry, in fact it threatens to destabilise an already shaky potato market, and that they would oppose the application;
- **McCain**, which dominates the food processing industry in South Africa, has taken a decision not to use genetically modified potatoes;
- **McDonald's and Spur**: both are supplied by McCain and would thus not be using GM potatoes.
- **Simba** stated that they would not consider using GM potatoes;
- **Fruit and Veg City, which** supplies both the lower end of the market with low priced vegetables and the higher end of the market, are opposed to genetically modified produce.

3.3. Consumer and civil society petition

A web- based petition rejecting the application has been signed by over 2000 individuals and organisations. Consumers do not want to take the risk of eating a controversial product. The lack of labelling and segregation systems also robs them of their right to choose not to eat GM if they so choose.

3.4 Scientific Summary

- Generally, we found numerous flaws in the design and interpretation of the field trials, gross omissions in the food safety tests carried out and deliberate obfuscation of biosafety data.
- No evidence was provided of genome stability over several generations.
- Whilst experiments were carried out to quantify the levels of npt11 as well as Cry1Ia1 in the SpuntaG2, these were only carried out on

the leaf tissue and not the tubers. Obviously, (indeed it is elementary that) the levels in both the leaves and tubers need to be analysed, since the claimed benefit of this GM event is the protection of potato tubers during storage!

- Because the levels of Bt in the potato tubers and the effect of storage on these levels have not been addressed by the applicant, the risks to human health are therefore uncertain;
- The food safety testing of SpuntaG2 was limited to acute toxicological testing in a rat feeding study. On the whole, we found the food safety assessment to be hopelessly inadequate, shoddy, unscientific and leading to fundamentally flawed conclusions as to the safety of the GM potato for human and animal health.
- The PTM does not seem to be a prevalent pest in South Africa. Of all the field trials documented to date, many failed simply because there was poor infestation of PTM at that location.
- The applicant avoids the responsibility of monitoring and intends to rely on the feedback from small-holder farmers. This does not constitute a biosafety monitoring program.
- There is no proposal to observe the emergence of resistance before it becomes an unmanageable problem, and the impression created is that if resistance occurs, the GM potato project will be abandoned, leaving farmers out in the cold.

PART ONE

1. RATIONALE FOR THE GM POTATO AND SOCIO ECONOMIC CLAIMS MADE BY ARC

The genesis of the GM potato project in South Africa can be traced to 2 secret ex ante analyses undertaken by a USAID funded project, the Agriculture Biotechnology Support Program (ASBP). The ASBP evaluated potato production in South Africa (p.46 of application) and made the argument that GM potatoes resistant to the PTM will bring socio economic benefits to farmers in South Africa. The ABSP has a vested interest in GM technology – and it is well documented that it aggressively promotes the uptake and adoption of GM technologies in the developing world. (Black, p.40).

ARC's application is a curious form of 'general release' because it is aimed at passing the buck onto farmers to do its job, namely, to conduct further tests of the GM potatoes and monitor its efficacy. "..will involve certain potato producers to test the trait and determine its value to specific growing areas." (page 5, Application for General Release of Genetically Modified Organisms in SA). ARC intends to "initiate farmer participatory trials under unconfined conditions." (p.10), and that this will amount to a partial commercial release as a full commercial release is only likely to occur in 2011.

In making a case for this strange form of general release, ARC has deliberately manipulated the results of the socio economic study concerning small scale farmers produced by Hart et al. According to ARC, the participatory trials are to be conducted first on smallholder farmers' areas to control local PTM infestation. Commercial farmers will also be able to test SpuntaG2 as well as new cultivars under development by ARC for commercial farmer applications into which the PTM resistance trait has been introduced by standard breeding methods from SpuntaG2.

ARC states that the PTM 'is a serious insect pest of potatoes in South Africa, and is responsible for losses of up to R40 million per annum to the South African potato industry." (page 6) and that no insecticide is registered against the potato tuber moth in South Africa under storage conditions. That the only control strategy that gives consistently good control against the tuber moth is the use of GM insect resistant potatoes containing the cry IIaI1 gene, belonging to Swiss Agrochemical and gene giant, Syngenta. In this regard, ARC consistently and repeatedly relies on Visser as a reference for the conclusion that the only control strategy that gives consistently good control against the potato tuber moth is the use of GM insect resistant potatoes containing the CryIIa1 gene.

ARC also claims that based on the socio economic studies, there is a consistent need for protection against moths in stored potatoes. In this regard, ARC states that small- scale farmers have no alternatives for controlling PTM, especially in storage. (p.16). "The reduction of tuber moth damage in the field and in stored potatoes could improve the efficiency of potato production and storage for smallholder farmers. This could result in better harvests and reduce the loss of saved seed, both of which would contribute to improved return on investment. Improved harvest and storage could provide additional tubers that could be sold for income." And "The proposed farmer participatory trials we will conduct after general release will determine under real-life conditions the true utility of this technology for smallholders."(p47).

SOCIO-ECONOMIC REPORTS CONTRADICT ARC'S RATIONALE FOR GM POTATOES: OVERVIEW OF THE JORDAAN AND HART STUDIES

The Jordaan Study

ARC included the socio-economic study concerned with commercial farmers in South Africa. This study was conducted by Jordaan, AJ and Carstens J.P. assisted by Jordaan, AD, Swanepoel, K and Sissons, D, and is titled 'Potential Economic Benefits of a Genetically Modified (GM) Tubermoth-Resistant Potato Variety in South Africa: An Ex-Ante Socio-Economic Evaluation For Commercial Producers' April 2007.

For ease of reference, we refer to this study as the 'Jordaan study'

The Jordaan study disputes the ABSP report of 2005 that apparently states that the GM potato will bring about an input cost reduction of 8% for commercial farmers. Based on its research and interviews with commercial potato farmers in South Africa, the Jordaan study found that farmers could save only between 1.3 and 1.7% in inputs costs, if the prices of seeds remained the same as at 2007. This percentage is likely to be even lower in the light of the current global food crises, precipitated by the soaring price of off farm agricultural inputs, including seeds-GM and non-GM.

According to the Jordaan study, the average saving that can be expected by potato producers is R610 per farm, only on those farms actually experiencing tuber moth problems. This finding does not support the ABSP report, which puts the average cost of tuber moth control at R1176 per ha.

It is extremely significant to note that the Jordaan study states that according to the farmers interviewed, they indicated that they had other more serious problems such as leafminer that they had to control as well as a range of insects, other than the PTM. Potato farmers regard leaf insects on potatoes as the most serious problem. This is followed by leaf diseases, market and price volatility, seed quality and viruses. Tuber diseases are ranked sixth, with labour problems as the seventh most serious problems (p.23).

Seed potato producers regarded viruses as their most serious problem followed by insects, market and price volatility, tuber diseases, labour, seed quality, soil insects, and weed control. (p.24). The most serious pest or disease amongst potato producers was identified as the leaf miner followed by late blight, early blight, scab and viruses, with TM as the sixth most serious problem, on the average priority list for all producers in South Africa. (p.25).

Farmers used chemicals designed for the control of leaf miner and other insects, that also control PTM. Significantly, the farmers that were interviewed also said that the GM potato would not have any significant impact on their production. That indeed, they had cultivars available to them with a higher yield potential than the GM cultivar and they did not expect a rapid adoption rate with the new potato.

The majority-67% of farmers interviewed from KZN indicated that tubermoth was not a problem in their region. 66% of the respondents interviewed in the study were of the opinion that GM potatoes would not solve the most serious problems experienced by potato producers as they felt that other insect pests and diseases posed a greater risk than the tubermoth. (p.19 of Jordaan report).

Out of the 16 regions where potatoes are cultivated in South Africa, only farmers in Ceres ranked PTM as a high priority, while in other regions it was rated low or not a problem at all.

The final findings of the study were that "The GM potato with tubermoth-resistant genes might not have the expected rapid adoption rate amongst farmers, since most farmers have tubermoth infestation under control at a reasonable cost".[ii]

According to the study, the commercial farmers interviewed were actually divided withno consensusabout the efficacy of the GM potatoes on storage-54% of the respondents said that GM potatoes would have a positive effect on their ability to store potatoes due to an improvement in the keeping quality of potatoes in the absence of tubermoth and 34% said that TM control was not relevant to their specific storage situations.

THE HART STUDY

A socio economic study was conducted titled, Smallholder potato production activities in South Africa: A socio-economic and technical assessment of five cases in three provinces 15 December 2006 by TGB Hart (HSRC) and HJ Vorster (ARC), (hereinafter referred to as 'the Hart study').

The Hart study undertook several case studies in various provinces of smallholder potato farmers. The results of these studies are summarised below.

Case Study 1-Western Cape

The Hart Study found that small-holder farmers were concerned that the PTM resistant cultivar would not really reduce inputs and associated costs. In essence, the study found that for such a cultivar to be favourable to farmers it would need to incur the same overall costs or less while simultaneously improving quality and quantity of the harvest. Farmer preferences were for a new cultivar that was drought, pest and disease tolerant and indeed, but PTM was not mentioned as a specific pest that such a variety should address.

Case Study 2-KZN (1)

The Hart study found that water was a major concern for small holder farmers and that these farmers needed assistance with current potato production practises such as the introduction of locally appropriate IMP strategies would most likely reduce the effects of pests afflicting their potato crops such as cutworm, and millipedes. Significantly, the most frequently mentioned storage problem was rodents that ate the potato tubers.

Case Study 3-KZN(2)

The study found that PTM was not identified as being a storage problem that the farmers had been encountering during the previous three years. The study thus made the following recommendation "Therefore it seems that suitable agricultural interventions would be those which are adapted to

these circumstances in conjunction with the farmers. A process of participatory action research would probably produce suitable results. By enhancing and improving some of the farmers' specific constraints this will reduce the high costs of developing new technologies. While water access remains a concern it is likely that assistance with current potato production practises such as the introduction of locally appropriate IMP strategies would most likely reduce the effects of pests. This seems most practical in light of the limited use of agrochemicals to control pests. Similarly, optimising storage practises using simple techniques might also reduce the rodent problems encountered during storage."(p.69).

These recommendations are not consistent with ARC's GM participatory trials, currently been sought under the protection of a general release permit.

Case Study 4 KZN 3

The Hart study made similar recommendations in regard to this case study:
" Farmers indicated a range of problems, many of which might be simply and cost effectively reduced by means of adopting existing technology to local conditions and practises" and that appropriate agricultural interventions would be those that which are adapted to local conditions and practises."

"A process of participatory action research would probably produce suitable results. By enhancing and improving some of the current practises and by adopting existing technology for locally appropriate solutions in light of famers' specific constraints…." (p.88).

None of these recommendations support participatory farmer research with the GM potatoes.

Case Study 5 Mpumalanga

The Hart study found that the general potato production problems that were most frequently mentioned were millipedes, moles, cutworm and input costs, including transport. It recommended that advice on IPM might reduce these pest problems. The study also found that the most frequently mentioned storage problem was rodents, which ate the potato tubers. (p. 107).

The study summarised the needs of the farmers as including the following: (p112) basic agricultural support such as soil fertilisation techniques, water harvesting, pest and disease identification and improved storage techniques.

The study thus concluded as follows: " In conclusion, the best way to address some of the production and storage problems would be to spend a few days with each of the groups at different times during the production and storage cycles, learning more about their practices and the reasons why

they follow such practices. Proposed solutions would have to be developed in conjunction with the farmers in order to determine what resources are locally available and accessible in each village and how these can help in making solutions effective and sustainable. Such a process and understanding will enable practical solutions to be developed and implemented."

This conclusion in no way supports ARC views that what small- holder farmers need are participatory trials with the GM Spunta potato.

3. BIODIVERSITY BEST PRACTISE

In 2005 potato farming received a great deal of bad press, especially around environmentally destructive farming practises happening in the Sandveld area. It is becoming increasingly necessary for farmers to change to more environmentally sound agricultural practices, both for the sustainability of our environment and to suit market demands. Woolworths and Pick n Pay have helped to develop Biodiversity Best Practice guidelines for Potato SA[iii], showing that the coming trend in the market is towards environmentally responsible production. Bt potatoes are located squarely within the environmentally destructive industrial agriculture model that is based on mechanisation and heavy reliance on fossil fuels in the form of chemical fertilisers, pesticides and herbicides. Both the Jordaan and Hart studies show that the transgenic SpuntaG2 will not reduce the use of pesticides. This technology is not bringing anything new to move us into the new agricultural practices we need to develop if we are to meet the challenges of climate change, degrading local environments and food security.

PART TWO

1. RESPONSES BY THE POTATO INDUSTRY

The ACB canvassed some of the players in the potato industry to find out how they feel about using genetically modified potatoes. Spunta is not a popular variety in South Africa-indeed, it is not in commercial production. Some of the major issues that emerged about GM potatoes in general included lack of consumer confidence, lack of segregation and labelling and lack of biosafety laws beyond South African borders. In fact, we found no enthusiasm or appetite for the GM potato, as is more fully discussed below.

Potato South Africa (PSA) told the ACB that GM potatoes would not benefit the potato industry, in fact it threatens to destabilise an already shaky potato market. The conclusions reached in the Jordaan and Hart socio-economic studies mirrored the opinion of PSA that tubermoth is not a priority threat and that the technology would not significantly reduce input costs or the amount of toxins in the environment. In addition PSA is of the opinion that the small-scale farmers affiliated with them did not want a new and controversial technology imposed on them. They also expressed the opinion that the safety testing done by ARC to date is not complete. They

found it unfortunate that this application comes in the international 'year of the potato', when they are trying to raise the profile of potatoes and said they would oppose the application[iv] [v].

McCain, which dominates the food processing industry in South Africa, has had to deal with GM potatoes in the United States and Canada. A decision has been taken by the company at Canadian headquarters not to use genetically modified potatoes and this applies to all operations internationally[vi].

McDonald's and Spur: both are supplied by McCain, as are many other fast food franchises. McDonald's has been given an assurance from McCain's Managing Director, Owen Porteus, that McCain "does not accept nor use GMO potatoes in any of its products," and although Spunta is not a part of their breeding programme, and therefore not a threat, they would continue to monitor the situation on future GM potato products[vii]. The letter from McDonalds is attached as Annex 1.

Simba: several brands fall under Simba, including Lays crisps. Simba stated that they would not consider using GM potatoes; they use a specific variety that is prized for its crisping characteristics. They stated that even the maize they use in Doritos and Frito's is GM Free.[viii] A letter from Simba is attached as annex 2.

Woolworths said that they were alive to this issue as they have had plenty of consumer requests and concerns about their position on GM potatoes in the last few months. Their current policy is to label GM where they can to keep consumers informed. Fresh produce such as potato presents a new challenge however, and they would now need to reassess how they will deal with GM produce. They will embark on reassessment within the company in the near future[ix].

Pick n Pay are embarking on a project to promote organic foods at the same prices as conventional produce. They are marketing organics as healthier than conventional produce and environmentally sound and are educating their customers about these issues. When asked how they would deal with the problem of possibly unwittingly selling GM potatoes into Namibia, Swaziland and Botswana (they have satellite stores), where they have not been approved, they said they have their own identity preservation systems in place and so would not source them[x]. Indeed what emerged from our discussions is that Pick n Pay have a very clear position that they are not willing to back publically, namely, that they source only non GM products for their shelves.

Shoprite are becoming a well-established chain store throughout Africa. Shoprite did not foresee a problem with the possibility of GM potatoes being sold into Africa, saying that no one checks because there is no legislation in place[xi]. This is exactly the kind of cavalier attitude that is of concern to the ACB. The transboundary movement of GMOs without prior informed consent is in contravention of the Cartagena Protocol. With no labelling and

segregation in place for GM potatoes, this would be inevitable. Interviews with the National Biosafety Focal Point in Botswana confirmed that this is in fact currently the case with produce coming from South Africa.

Fruit and Veg City supplies both the lower end of the market with low priced vegetables and the higher end with their gourmet stores. They are opposed to genetically modified produce, saying "*We at Fruit and Veg City are of the opinion that the availability and sale of genetically modified fruits or vegetables should be treated with caution, and we do not support the current application process to sell these products in South Africa. It is a cause for concern that there is only limited knowledge of the implications of this technology being applied, and the long term effects on the environment and on human health has not been fully established. Just because there has not been any significant scientific proof to date that GMO's pose any serious problems, it does not mean that it is not a possibility. ..... Responsible companies must take into account not only the technological feasibility but also the possible effect on human or animal health, financial benefits (which are debated) and environmental issues that may arise*"[xii]. Fruit and Veg City's letter is attached as annex 3.

2. PETITION SIGNED BY CONSUMERS AND CIVIL SOCIETY

The ACB has alerted consumers and civil society to the fact that the commercialisation of GM potatoes would be considered in South Africa, through a web based sign-on petition. One of the comments on the site was "Thank you for giving us a voice.[xiii]" It has to be said that this is a very limited voice – only available to that section of society that has access to the internet, is literate and English speaking. Unfortunately the mechanisms for public participation under the GMO Act allow for very limited consultation and informed participation – a study commissioned by the National Environmental Advisory Forum (NEAF) into public participation in GMO decision-making highlighted a number of shortfalls here, including inadequate public notification, obstacles to accessing relevant information on which to make meaningful input and short window periods to make comment.[xiv] Over 2000 individuals and organisations pledged their support for the petition. All those who signed were in support of the petition text drafted by the ACB, attached as annex 4, and were given a space to raise their own issues. The comments show a general sense of outrage at not being consulted about the food they eat and being given no choice through labelling. Concerns raised by the public varied – many were concerned by:

- the lack of independent scientific evidence of the long-term safety of genetically modified foods for human health,
- the lack of labelling and consumer choice,
- Continued government support for industrial agriculture models that are environmentally destructive and undermine food sovereignty in favour of corporate interests

Civil society from South Africa and all over the world also signed on. Comments from NGO, The Grail, sum up the gist of many of the comments received from the NGO sector:
"*As a movement with strong membership in many different African countries we strongly object to the introduction of GM potatoes into South Africa and then into the rest of Africa. Agribusiness has intensified not solved the problem of hunger in Africa and we believe it is unethical to impose a technology on Africa, which will reduce the capacity of local farmers to ensure local food self-sufficiency. Sincerely, Anne Hope. The Grail.*"

NGO's from countries where GM Potatoes were subject to field trials but never made it to market also sent information as to why they were rejected in their countries. In this regard, we attach, marked annexure "5", a letter from the Canadian Biodiversity Action Network, outlining their experience with GM Potato. Although a variety of Bt potatoes were approved in Canada between 1995 and 2001, they were subsequently taken off the market by Monsanto in 2001 due to lack of markets. Markets were dampened by lack of consumer confidence, fuelled by concerns about the health implications and environmental management and the extremely poor science that was submitted as safety data around these issues[xv].

3. SADC

South Africa exports over 90% of its export potato crop to several countries in SADC. The ACB has alerted the National Biosafety Focal Points of all countries that are members of SADC of the application by the ARC to commercialise GM potatoes in South Africa by posting information packages and following up with phone calls. The majority of SADC countries are still in the process of developing their biosafety legal frameworks and are thus not in a position to import genetically modified fresh produce in compliance with their obligations under the Cartagena Protocol on Biosafety, such as undertaking biosafety assessments, evaluations, studies, public consultations and so forth. Telephone interviews were held with representatives from Namibia, Angola, Botswana and Lesotho to confirm this position. This situation makes the ARC application excessively, disingenuously premature and extremely dubious in the sense that it exposes SADC to the spectre of being force fed on GM potatoes! And is in violation of international law. Responsible action by these countries would be to limit the importation of South African potatoes, seriously impacting on South Africa's export trade.

PART TWO

1.SCIENTIFIC ASSESSMENT

<u>1.1. Molecular characterisation of the SpuntaG2 event</u>

The SpuntaG2 contains the Cry1Ia1 transgene under control of the 35S CaMV promoter and the npt11 antibiotic resistance marker (kanamycin resistance). The data presented in Appendix VII-X by the applicant provides evidence of one copy of the cassette that had been integrated into the genome. The restriction digests indicate that there is probably one copy present in the genome, but there is no evidence of quantification of the Southern blots that should have been carried out to clearly demonstrate this. Appendix IX.7 states that the "intensity of bands in the lanes with G2 genomic DNA is 2-3 times the intensity of the bands in the lanes with SpuntaG2 genomic DNA, consistent with the results of experiment 1 that indicate that G2 has three T-DNA copies". The use of Spunta G3 as the standard is inappropriate since there is no evidence presented (or in the published literature) that Spunta G3 does indeed contain three copies. The basic experiment using the plasmid used for transformation (pSPUD5) at different copies (1-5) alongside the SpuntaG2 transgenic digested with 3-4 different restriction enzymes needs to be conducted so that subsequent analysis of the images can be carried out in a quantitative way to demonstrate the copy number. Furthermore, there should be more than one probe used in the experiment since the transgenes may have fragmented and integrated elsewhere in the genome (i.e. not only Cry1Ia1 but also npt11 and 35SCamV).

The applicant provides the sequence for the site of integration of the transgene, and demonstrates that no unexpected additional recombination events had occurred at the border sequences (Appendix IX). However, it is unclear if the insertion event has resulted in the interruption of a host gene. Presumably, the potato genome is incompletely annotated so that the site of insertion is not clearly annotated as a gene. The ACB has not been afforded the opportunity to independently repeat this BLAST search due to the short period of time the public is given to comment on GMO applications. Nevertheless, the applicant translated this region in all six reading frames and used this to search BLASTP for sequence similarities (the date that this search was carried out is not given). The results indicate that the transgene inserted into a host patatin gene (Appendix X1), but this is not referred to in the underlying documents. The biosafety risks associated with such an insertion event are uncertain, but they should inform further analysis. A proteomics study to determine the protein expression profiles for SpuntaG2 compared to Spunta should be carried out. This integration site is of concern since the patatin genes in potato encode for proteins that comprise up to 40% of the soluble protein in the tubers and are a critical nutritional component (Prat et al. 1990).

There is also great concern that no evidence is provided that there is genome stability over several generations. Molecular tools (PCR and sequencing of the amplicons from plants grown in field trials or pot trials for several generations) need to be used to address this issue. The applicant has established the appropriate PCR methods to amplify the transgene (Appendix VII) as well as individual transgene elements such as Cry1Ia1, but did not use these tools to monitor transgenic stability in the field. This is particularly pertinent to potato cultivation since there is the established

practice of propagating first class seed potato for 8 generations until it loses certification. Therefore the molecular analysis needs to ensure that the SpuntaG2 has genetic stability and integrity that is similar to the non-GM Spunta over several generations. These important experiments have not been carried out nor are these proposed to be part of the post-release monitoring program.

1.2 Products of the transgenic cassette

Cry1Ia1 was produced in bacteria (E.coli) and used for animal feeding studies (see below) and initial experiments were carried out to determine if the Cry1Ia1 protein expressed in E.coli and in SpuntaG2 are same. Western blots (Appendix XIV) using the antibody (from Dr Dilip Dias) lacks the required specificity for Cry1Ia1 because according to the figures XIV.2 reacts with the same 3 bands (79 kDa and 2 lower molecular weight bands) in non-GM Spunta as well as the SpuntaG2. However, it can be seen from the Cry1Ia1 purified from E.coli (the positive control) that there are proteolytic breakdown products of Cry1Ia1 that result in bands of lower molecular mass that co-migrate with these lower molecular weight bands (this is lane 12 on the Figure XIV.2, but the figure has been incorrectly annotated as having 13 lanes- there are only 12 lanes and the legend confirms this!). Therefore, the assertion that the 81.2 kDa band alone represents Cry1Ia1 is unfounded and this assay cannot be used with confidence to detect Cry1Ia1. The applicant also carried out experiments to test bioactivity of the bacterially expressed Cry1Ia1. However, these results are meaningless since:

- Manduca sexta (hookworm) was used as the target not the problem pest, Phtorimea operculata (potato tuber moth);
- The numbers are too low to be confident in any differences (starting with two hookworms) and looking for dose-dependent killing (i.e. 0 dead, 1 dead, 2 dead). The published assay for PTM uses 10 larvae with five replications (which is what is required in order to obtain reliable data).
- There is no reference for comparison. The extracts from Spunta G2 and Spunta potato should be used as controls since the aim of the experiment is to show that the bacterially produced Cry1Ia1 is the same in character and effect as that which is produced in the transgenic potato.

Experiments were also carried out to quantify the levels of npt11 as well as Cry1Ia1 in the SpuntaG2. Unfortunately, in both cases the analysis was only carried out on the leaf tissue and not the tubers (Appendix V). Obviously, the levels in both the leaves and tubers needs to be analysed, since the claimed benefit of this GM event is the protection of potato tubers during storage. The levels of Bt toxin need to be assayed in the tubers during the storage period (in addition to levels in other parts of the plant. Furthermore, the results presented for the levels in leaves (Figures V.1 and V.2) are inconclusive since only 1, 1.5 and 2 ug Cry1Ia1 was used as the standard and this produced a (saturating) signal that cannot be accurately quantified (Figure V.2) against the amounts in SpuntaG2. Of particular note

is the poor specificity of the antibody used and the cross reactivity of a band immediately below the Cry1Ia1 band of 82.1 kDa and the fact that the standard also shows a band immediately below the 82.1 kDa Cry1Ia1 but this is barely discernible due to the saturating signal of the standards (V.2). The use of this antibody for quantification is therefore unreliable. The data is also of poor scientific quality since the results show no replication and standard errors for these determinations that need to be quantitative. Nonetheless, the value they did obtain from these studies is 23 ug/g fresh weight. A similar approach was used for determining the NptII levels in potato and the reliable results (commercial ELISA kit) demonstrate that the levels of npt11 are 11.34 ug/g fresh weight (Appendix V1). It is peculiar that the levels of npt11 are half that reported for Cry1Ia1 since they are part of the same transgenic cassette. What is the implication of this? Does it show up a mistake in the experiments?

1.3 Food safety: Compositional analysis, toxicology and allergenicity.

The levels of Bt in the potato tubers and the effect of storage age on these levels have not been addressed by the applicant. The estimates of exposure are presumptions on the levels that may be in the tubers estimated at 10 fold less than the leaves. The risks to human health are therefore uncertain based on the fact that this Bt toxin is a novel genetic variant that may have different biochemical properties from the Bt toxin found in nature. The sequence of Cry1Ia1 represents the active, processed form of the toxin and not the pre-toxin found in nature. This is very important from an ecological perspective since the naturally occurring toxin from the soil bacteria Bacillus thuringiensis is linked to the target insect it infects since the Cry1Ia1 requires activation by proteolysis that only occurs in the guts of certain insects. Therefore, many organisms may never have been subjected to the active Cry1Ia1 variant toxin that is expressed continuously in the transgenic SpuntaG2 potato in the field as well as being present in the human food chain.

The allergenic assessment was limited to the in silico bioinformatics whereby the sequence of Cry1Ia1 I was compared to the database using BLASTP which searches for toxins and allergenic proteins. For the allergenic search, the search for possible allergens (Appendix XV) identified the latex patatin homolog (Heveae Brasiliensis) that shares 30.4% identity (57.9% similar) (gi|1916805). Despite the high sequence similarity with a known allergen, the applicant made no comment on this in the documents because it is outside one threshold decided by the applicant (>35% over 80 amino acids). This is unfounded, since Cry1Ia1 fulfils the other criteria for a probable antigen in that it contains a potential epitope within the match i.e. 'correspondence of four to eight consecutive amino acids (http://www.gmo-compass.org/eng/safety/human_health/44.food_safety_evaluation_allergy_check_gmos.html http://dmd.nihs.go.jp/latex/allergen-e.html. This is important given the documented cross-reactivity between latex and food allergens (http://dx.doi.org/10.1016/S1382-6689(97)10059-X).

To determine if the Bt toxin was completely digested an in vitro (test-tube) study using simulated gastric fluid was used to determine that Cry1Ia1 is degraded in less than 0.5 min (Table 10.1)>. However, the relevance of these to real-life situations with complex food sources was not tested; despite the opportunity for doing so (the applicant carried out a toxicological test using a rat feeding study and could have incorporated this into the study). Tests were also carried out to determine if the Cry1Ia1 was heat inactivated and concluded that heat inactivation occurred in < 3min However, this experiment was not done with SpuntaG2 potatoes, but the purified recombinant protein in a solution expressed from the bacteria, containing the expressed in E.coli (Appendix XVII) One cannot draw valid conclusions from the inactivation patterns of a protein in aqueous solution to that of cooking whole potatoes.

The Appendix XX detailed the compositional analysis of SpuntaG2 compared to the non-GM Spunta and incorrectly concluded that there were no significant differences observed. The data (Table XX.4) reveals that energy content (Petrus Steyn location) and potassium (all locations) were statistically significant. The applicant argues that since the energy content was not different at all locations this is not important. Similarly, the inconsistent variation in potassium is used to dismiss the significant potassium differenced observed. This interpretation is highly questionable and scientifically flawed. In terms of anti-nutrients, only the glycoalkaloids have been measured. A major omission to these studies is that the levels of antinutrients, trypsin inhibitors and potato lectin have not been measured. The data presented of the total glycoalkaloid levels in the replicates showed too much variability to be certain that the differences between Spunta and SpuntaG2 were not significant (freeze dried samples from 2007- the standard deviations, SD, must be shown for these values so that the validity of the data can be assessed. (Table XX.2 on page XX.7 Note there are two tables labelled XX.2, the other is on page XX.3). In the general chemical analysis, it was not explained why the analyses had to be repeated and amended. Also it was not clear how the analysed samples in the three sets of analyses were related to each other.

The food safety testing of SpuntaG2 was limited to acute toxicological testing in a rat feeding study (Appendix XXI). There is no information on the detailed composition of the standard commercial rodent pellet, and whether it contained other GM material (e.g. soya) and the details of the cooking procedures have been omitted. In this feeding study, only means of starting weights of the rats are given. The high variation (SD values) indicate that there were major differences in the weights of the selected rats at the beginning of the experiment and this extended weight range can hide the growth and developmental changes. Additionally, the potato only made up 30% of the rat's total diet, and it is peculiar why the standard food used in the study contained 20% more protein and correspondingly less energy (starch) than the SpuntaG2 diet (Appendix XXI, table 1, page 7). Despite this fact, the male rats grew to a greater size when fed SpuntaG2 compared to the controls (Appendix XXI, table 2), but this was dismissed by

the applicant since both males and females were not similarly affected. The clinical chemistry parameters that were measured have unacceptably high variability; some had SD values of +/- 30% or more (e.g. Ab lymphocytes). Such a high intrasample variability will mask any differences between groups and this can be seen if a two- way analysis of variance of the results in Table 4 is carried out. In essence it makes the comparison between SpuntaG2 and Spunta invalid or meaningless.

The acute toxicology of Cry1Ia1 protein was also carried out. However, this used the Cry1Ia1 expressed from the bacteria, E.coli, and the biochemical characteristics of this Cry1Ia1 compared to that expressed in planta (i.e. in Spunta G2) has not been firmly established (see above and Appendix XIV).

1.4 Environmental effects

1.4.1 Agronomic performance

The PTM does not seem to be a prevalent pest in South Africa. Of all the field trials documented to date, many failed simply because there was poor infestation of PTM at that location. Of all the trials conducted at various locations since 2001 (approx 20) only 4 delivered results that were convincing as to the benefits of SpuntaG2 in controlling PTM. Many of the others had no data on efficacy because the natural infestation of PTM was too low. In one case the applicant irresponsibly released PTM at a location in an attempt to get infestation (Report 2002/3, page 12), but still failed - "Despite release of 30,000 moths level of infestation was low".

In general, the yields of SpuntaG2 and Spunta at various locations were no different (Appendix III) and the SpuntaG2 only offers benefits during storage. Interestingly, in some locations yields for the transgenic potatoes SpuntaG2 are 10-15 tons/ha less than the non-transgenic controls when insecticidal sprays were not used (Table III.1 Dendron), but this was not commented upon by the applicant.

The data also clearly shows that there is often no additional benefit of SpuntaG2 when Aldicarb is used (Appendix II.1- II.5). Aldicarb is often applied to control more prevalent pests that affect potato yields (namely nematodes, mites and aphids; the latter also greatly contributing to transmission of potato viruses). Since most farmers will normally spray Aldicarb for the control of these pests, the introduction of SpuntaG2 will have little effect on the level of insecticide used and will introduce new risks to the environment.

In their efficacy trials to show the effect of PTM they did not measure the effect on the PTM per se. They measured the effect on the plants by observing the tunnels in leaves and infer that low tunnelling means high mortality of the pest PTM. However, there is no data to determine if the effects seen in the field are due to PTM mortality or other effects (such as migration to the border rows or changes to PTM reproduction. In fact there were flaws in experimental design of some field trials in 2002/2003 where all borders were non-GM and blocks were incompletely randomised so that

the outside rows/areas of the plots were more likely to become infested with PTM. Furthermore, there is no clear way that the in vitro bioassays showing efficacy against the hookworm can be related to effects in the field on the potato tuber moth. Experiments need to be carried out with the transgenic potato tuber (not the leaves) to determine the levels of Bt in the potato grown during the field trials (from several plants at the various locations) and the efficacy in killing PTM and to relate this to an in vitro assay using the SpuntaG2 potato extract on PTM. This can answer important questions regarding efficacy and reliability of the transgenic line.

1.4.2 Effect on non-targets

There were field trials carried out by the applicant to measure the effect on biodiversity and non-target insects (Appendix XXII). The studies were carried out at only 3 of the locations studied (Table XXII.1)- what became of the data from Patensie and Kokstad? Evidence from the literature has shown that lacewings fed on aphid pests that had eaten Bt-maize took longer to develop and were two to three times more likely to die. Earthworms have been shown to be affected and significant reductions in populations of the beneficial parasites Microplitis sp. (88.9% reduction) and Campoletis chloridae (79.2% reduction) were detected in Bt cotton fields (Birch, et al. 1997, Marvier, M. 2001). The effects of Bt may be considerable since transgenic plants release Bt into the soil where it can remain for up to 234 days (Koskella, J. and G. Stotzky. 1997, Tapp, H. and G. Stotzky. 1998).

The design of the study is limited and flawed so that the statistical comparison is meaningless (i.e. mean numbers of roundworms measured ranges from 0.5 to 2.8). The sampling strategy and/or size will need to be adjusted for measuring the specific non-target, but the design took a general approach that resulted in too small a sample size in many cases. The approach is very general with the aggregation of whole orders (e.g. Hymenoptera) that contain many species. Further, the details of the traps (pitfalls and sweep nets) are not given and it appears that the frequency, number or layout of the traps is insufficient. Most evident is the low frequency of trapping that was used- the monitoring of non-target effects amounts to 4 - 6 days in a period of 3 years, which will only provide a snapshot in time. The considerable intrasampling variability observed may obscure real differences between samples and a two way ANOVA needs to be presented.

Despite these limitations, the comparison of the SpuntaG2 with the non-GM Spunta for effects on non-target anthropods, did reveal differences: in Hemipptera and Diptera at Roodeplaaat (Table XXII.20 and Table XXII.21); Hymenoptera at Ceres (Table XXII.23) and thrips and Aphids at Perys Steyn (Table XXII.25 and Table XXII.26) . These differences were all significant, however the applicant chooses to use non-applicable controls (Spunta and SpuntaG2 grown at different localities) to conclude that there are no differences: “For any treatment to have a significant and stable effect on any organism the effect has to be present over time and repeated under different environmental conditions. We could not prove any of the

aforementioned in trials...” (pg 29, Appendix XXII). This approach of using inappropriate controls is either a deliberate attempt to obfuscate the data or the aims have clearly been lost; what would be the point of choosing different locations if one would suffice?

The numbers of parasitoids and predators were also studied (Table XXII.2), but the intrasampling variation appears to be too great to identify differences between samples (e.g. the number of mites on Spunta was 22.5 compared to 41.3 on SpuntaG2 but this was found not to be significant due to high intrasample variation). Furthermore, the experiment involved placing PTM larvae or eggs in the field and observations for predation within a 24-48 hr period was repeated once, and only represents a small snapshot of the changing predator-pest relationships throughout the potato's growing season. This cannot be considered reliable data. Additionally, the approach also only observed single trophic events and the observation of other pests en passant in a qualitative manner.

A study was carried out to assess changes in soil microbiology (Appendix XXIV). The data presented and evidence cited from the literature deliberately compounds the variables of location, soil type and seasonality that have been shown to have a greater overall effect on the microbial community compared to the difference observed between transgenic and non-transgenic crop lines. The ecological relevance as to the degree of microbial changes occurring and consequences are unknown and small changes in microbial communities can obviously have gross consequences for soil ecology- it depends what these difference are. The study carried out by the applicant using t-RFLP compounds the variables of different treatments, sampling times and storage regimes when comparing SpuntaG2 to Spunta. This obscures real differences observed in the comparison and is highly questionable. The true comparisons are the SpuntaG2 compared to the Spunta (other variables constant- i.e. same sampling time, storage regime and treatment). Even with this obfuscation of data, some differences are noted (although this is really difficult to see from the graph since it was presented in colour and ACB was provided with a black and white copy that made interpretation difficult). A more appropriate method is DGGE/TGGE that can be used to gain a visual profile of the microbial communities with the excision and DNA sequencing of bands (Muyzer et al. 1993) that are different between the profiles of Spunta and SpuntaG2. This enables the identity of these micro-organims to be attained and this can inform the risk assessment more accurately. There are also no measurements of the Cry1Ia1 in the soil during the field trials. This is important since studies have shown that Cry proteins can persist in the soil for months (Tapp and Stotsky 1998) and the Cry1Ia1 gene used in SpuntaG2 is a variant not found in nature that may have an altered degradation rate.

1.5 Other environmental problems

1.5.1 Spread of antibiotic resistance

Current evidence shows that horizontal gene transfer (HGT) to bacteria does occur and is significant. Horizontal transfer of DNA occurs at a very low

frequency under laboratory conditions, for example Acinetobacter, a soil- and water-borne bacterium (Gebhard and Smalla, 1998), Streptococcus gordonii, a cause of dental cavities and heart valve infection (Mercer et al., 1999), and Aspergillus niger, a fungus harnessed to produce citric acid for soft drinks (Hoffmann et al., 1994). Crucial to the detection of HGT is the use of assay systems that are sensitive enough to detect even very rare events. The detection limits of some culture-based methods (typical detection limit of 10^{-8}–10^{-11} HGT events per bacterium) can exceed expected rates of HGT (10^{-16}–10^{-17}) by several orders of magnitude. A sensitive marker assisted transformation study with bacteria harbouring a plasmid with an nptII gene containing a small deletion (hence non-functional) was used to detect the frequency of HGT from plants containing transgenic DNA. The nptII gene in transgenic potato plants coding for kanamycin resistance, transforms naturally competent cells of the soil bacteria Pseudomonas stutzeri and Acinetobacter BD413 with the same high efficiency as nptII genes on plasmid DNA ($3x10^{-5}$ -$1x10^{-4}$) despite the presence of a more than 106 fold excess of plant DNA. However, in the absence of homologous sequences in the recipient cells the transformation dropped by at least about 10^{8} fold - 10^{9} fold. This indicates that recombination in bacteria is most efficient where sequence homology is present (de Vries J, Wackernagel W 1998). The npt11 gene has many gene homologs in soil bacteria indicating an increased risk for horizontal gene transfer. Furthermore a study carried out by the British Food Standards agency to determine if transgenic DNA transferred to bacteria of the human gut by HGT, found that this did indeed occur (Netherwood 1990).

The main concerns are that GMOs containing antibiotic resistance marker genes will spread antibiotic resistance amongst pathogens through HGT. As regards to selection or selective pressure, the use of antibiotics such as kanamycin (and related B-aminoglycoside antibiotics such as spectromycin since there is cross- resistance – Onaolapo J. 1994, and Mikkelson et al 1999) will place a selective pressure on selection of transgenic constructs that have transferred to the intestinal bacteria. Kanamycin is still used in operative procedures of colon and rectum and to treat ear infections and has also been found to be effective against E coli 0157 as well as being valuable in developing countries (but not in the EU- see below) for the treatment of multi-drug resistance tuberculosis (WHO Essential Medicines Library http://www.who.int/emlib, Ishikawa et al., 1999, 5, 86-90, Hehl et al. 1999, Yelon J, et al. 1996, Ito et al. 1997).

The selective pressures that would confer advantage to soil bacteria are poorly studied but may include stresses such as soil tilling or application of agrochemicals. Current evidence suggests that a stress response facilitates the HGT and spread of antibiotic resistance genes. For example, the SOS response—induction of specific genes in response to DNA damage—alleviates the repression of genes necessary for horizontal transfer of the mobile integrating conjugative element SXT. This is a ~100 kb plasmid derived from Vibrio cholerae that confers resistance to the antibiotics chloramphenicol, trimethoprim, streptomycin, and methoxazole. (Beaber et al., 2003). The emergence of bacterial antibiotic resistances as a consequence of the wide-

scale use of antibiotics has resulted in a rapid evolution of bacterial genomes. Mobile genetic elements have played a key role in the spreading of antibiotic resistance genes amongst bacterial populations and contributes to the multiple antibiotic resistance by bacterial pathogens (Salyers and Shoemaker, 1994; and Witte.,1997). Therefore there are risks associated with the spread of antibiotic resistance genes amongst soil bacteria or to the human gut bacteria, even when there is no selection for the transgenic construct per se (such as selection for kanamycin resistance).

Practically every medical organization that has looked at GMO crop safety has expressed concern about antibiotic resistance marker genes, including the American Medical Association, World Health Organization, UK Royal Society, United Nations Food and Agriculture Organization, Pasteur Institute, European Food Safety Authority, and the British Medical Association. Alerted to these risks, the EU Deliberate Release Directive, which has been in effect since 2002, requires "the phasing out of the use of antibiotic-resistance markers in GMOs which may have a harmful impact on human health or the environment" from autumn 2002 (http://www.efsa.europa.eu/EFSA and also (directive 2001/18EC and Revising Directive 90/220/CEE). The European Food Standards Agency, EFSA, adopted a pragmatic approach to deal with the issue of antibiotic resistance marker (ARM) genes in transgenic crops that recognises the fact that many GM crops already on the market contain ARMs and that some antibiotics are infrequently used to treat diseases in the EU. For this reason they categorise npt11 (kanamycin resistance) into 'class 1: can be used', while bla (ampicillin) is 'class 2: limited to contained use and field trials only' and tetA (tetracycline resistance) in 'class3: should not be used'. There is, however, a general consensus within the scientific community that antibiotic markers pose risks that are unnecessary. It is noted that the applicant aims to remove these unwanted markers through the use of an alternate vector system pSPUD 80 (http://www.potatocongress.org/wpc/David-Douches.pdf), but is prematurely applying for a general release permit prior to doing so with their current product.

1.5.2 Viral recombination

The risks of the HGT and the spread of antibiotic resistance are greater since the CaMV viral promoter was used to drive expression of the Bt transgene. The 35S CaMV (cauliflower mosaic virus promoter) is fused to bacterial genes (cry1Ia1 and npt11) and present in every cell of the transgenic plant where it is integrated into the genome. Studies have shown transgenic instability (rearrangements, deletions, insertions, and truncation) due to 35S CaMV and explained this by the cruciform secondary structure that makes it susceptible to a double stranded DNA break and recombination (Vaden et al. 1990 and Koholi et al. 1999). The effects of this recombination are increased gene flow and unpredictable genotypic changes. It is therefore required to assess the gene flow from the transgenic plant to other organisms interacting with the plant (including, but not limited to, soil microbiota, and feeding and pollinating insects,

reptiles, and mammals). These experiments have not been done despite the sensitive detection methods being available (Appendix VII). This important aspect of the risk assessment has been largely overlooked since there is evidence that 35S-CaMV causes increased rearrangements/ deletions affecting genome integrity and stability in evidence from both the laboratory (Koholi et al. 1998 and 2003) and field studies (Quist and Chapela 2001, Collonier et al. 2000, Ho et al. 2000).

There are other risks associated with increased recombination of 35S-CaMV with other viral elements that may result in the creation of new viruses that may be plant or animal pathogens (Falk et al 1994; Wintermantel et al. 1996, Vaden and Melcher 1990, Greene et al. 1994; Ho and Cummins 2000). New and successful variants of viruses do arise naturally by recombination with a frequency that varies depending on the virus family (e.g. Chenault and Melcher 1994; Revers et al 1996; Padidam et al 1999). Several experiments have shown that this does indeed occur (Greene, and Allison, 1994, Wintermantel, and Schoelz, 1996). Interestingly, results of the applicant's previous trials (Original Application Report 2002/3) have indicated an increased viral infection of some transgenic lines and this was previously commented upon. This urgently requires further investigation with larger sample sizes (5 sampled from 30 plants would be insufficient for statistical analysis).

1.5.3 Emergence of insecticide resistance

The applicant supposes that there are sufficiently large refugia of non-GMO potato and other Solanaceae that will prevent the emergence of resistance, but there is no evidence presented to support this (pg 29 section 9.2). Despite eight years of field trials, the only evidence for PTM using alternate crops is a laboratory assay (feeding study). Whether or not farmers can rely on the alternate hosts to maintain a sufficiently large pool of susceptible PTM is entirely speculative and most certainly will differ (i.e. regionally depending on frequency abundance, distribution and phenology of the alternate hosts) and requires careful research and knowledge. The applicant argues that the SpuntaG2 will not be a significant potato on the market and will be slowly introduced and backcrossed with local varieties so that the levels of Bt in the potato fields will be gradual. While it is true that a gradual introduction is likely to result in the gradual development of resistance; this risk assessment cannot rely on the applicant's claims about the degree of market penetration and dominance (pg 29 section 9.2). Furthermore, the ability of PTM to quickly develop resistance to pesticides has been proven in many countries, and South African farmers are warned that different types of insecticides must be used alternately and only when necessary to prevent resistance from developing.[xvi] It is therefore likely that the PTM will rapidly develop resistance to the BT toxin given the uncontrollable but permanent release of the Bt toxin into the environment through GM potato plants. The applicant avoids the responsibility of monitoring and will rely on the feedback from farmers to initiate farmer education on resistance management. This does not constitute a monitoring program and there is no proposal to observe the emergence of resistance

before it becomes an unmanageable problem. This is a precarious situation because reaching such a point will necessitate the use of additional insecticides or switching to another GM event. A true resistance monitoring program always aims at detecting increases in resistance allele frequencies at a stage before the resistance emerges as a problem so that there are opportunities for mitigation. In this case the applicant will rely on feedback from farmers to determine if resistance has developed and, if so, simply withdraw the product! There is clearly no intention to observe the emergence of resistance since the opportunities to do so during the field trials were not taken- for example, the applicant did not continue to look at efficacy (2006/2007) because it was "judged no longer necessary" (Appendix II.3).

To determine if SpuntaG2 (compared to Spunta) could become weedy, only two experiments were carried out looking at emergence in the field (Appendix IV, Table IV.1 and IV.2). The locations are omitted for these studies and the sample sizes questionably small. In addition to asexual reproduction and the emergence of these volunteers, other factors that can contribute to weediness have not been studied:- such as the degree of predation of the tubers and the number, viability and dormancy of seed (sexual reproduction). Although the applicants claim that Spunta produces little true seed for reproduction, this may not necessarily be the case with the commercial cultivars that the ARC intend to transform in future should they be granted this permit.

1.5.4 Environmental monitoring

It is unclear from the notification if any environmental monitoring or assessment will take place, as is required by international obligations (Cartagena Protocol on Biosafety) and local legislation (National Environmental Management Act of 1998 and the Biosafety Bill, 1576). In fact, there is no method established for the detection of the SpuntaG2 event that is proposed to be used for monitoring, despite the fact that a PCR method was developed (Appendix VII) and there is an immunological test under development (pg 60 Section 24 " an immunological strip test is under development"). The monitoring program needs to include hybridisation and introgression into other potato varieties, horizontal gene transfer and gene flow to other organisms, as well as the commodity tracking of transboundary SpuntaG2 potato and potato products.

CONCLUSION

Potato farming is a high-yield high-risk enterprise. Emerging farmers do not feel ready to experiment with new and controversial technology. They would prefer their commercial mentors to become familiar with the terrain while they gain experience with conventional varieties[xvii]. Lack of consumer confidence in the product brings in yet another possible uncertainty.

Some of the characteristics of smallholder farmers are access to small pieces of land for farming, limited access to markets and low annual incomes supporting big households[xviii]. These are the people in our society with the smallest margins for risk-taking, since failure in any aspect of the production process means a real threat to survival. These farmers spread their risks by planting small diverse crops to substitute their household food and to sell surplus; if one crop fails they can fall back on others that have succeeded. They use local resources and intercropping techniques to create soil fertility and control pests where possible. They have little access to tractors or the other trappings of industrial agricultural systems. They are risk averting and opportunistic, their greatest asset being adaptability. The average household income of the farmers researched by the Hart study on smallholder farmers was between R8000 and R31 000 per year. A very low percentage of that income can be available for farming inputs. Encouraging these farmers to switch from their diverse and risk averting farming systems in favour of costly and high input methods is asking them to risk too much. If the crop fails they are not able to pay back loans, even if the crop is successful a lack of access to markets may mean small or no profits. The study recommended that "adapting current technologies to local conditions tends to be more cost effective than developing new technologies, which, due to their generic nature, are not adapted to local conditions and might not be adopted as a result".[xix]

It is shameful that the most vulnerable people in our society are being asked to take on the burden of experimenting with new and very expensive technology that does not address their needs and that they have not asked for.

The tuber-moth resistant potato was not developed in answer to pressing problems faced by South African farmers, industry or consumers. It is a solution developed in a foreign laboratory in search of a problem. The socio-economic studies commissioned by the Agricultural Research Council clearly showed that neither commercial nor small-holder farmers will benefit from the technology.

The product also has no benefit for consumers, who feel that they should not have to take the risk of eating a controversial product. The lack of labelling and segregation systems also robs them of their right to choose not to eat GM if they so choose. The potato industry is left with the problem of what to do with these potatoes and how to answer to their clientele.

Over 90% of South Africa's export potato crop is sold in the SADC region. The SADC community is largely unprepared to receive genetically modified fresh produce into their countries as their Biosafety Frameworks and legislation is still in process of being put in place. The transboundary movement of GM potatoes without the consent of these governments would constitute a breach in international law. The rejection of GM potato imports by these countries would mean a loss of markets for farmers in an already unstable environment.

Our scientific evaluation of ARC's dossier has shown up the numerous flaws in the design and interpretation of experiments as well as gross omissions in the biosafety tests carried out to date. In the light of current scientific evidence that SpuntaG2 poses unacceptable risks for the human health and the environment, it should not be approved for general release.

Endnotes

[i] **Media Release 07 July 2008 'Finally, GM potatoes'. Dr. Kobie de Ronde, ARC-VOPI**

[ii] Potential Economic Benefits of a Genetically Modified (GM) Tubermoth-Resistant Potato Variety in South Africa: An Ex-Ante Socio-Economic Evaluation for Commercial Producers. Jordaan, A.J. et al. ARC and University of the Free State. April 2007

[iii] Biodiversity Champions of the Sandveld. Sonja Burger. Farmers Weekly 22 August 2008

[iv] Meeting with Transformation Manager Diale Nokgojwa and Ben Pieterse, Manager for Research and Development

[v] See also, 'No GM potatoes yet!' PSA protests
Wouter Kriel, Farmer's Weekly (South Africa), 25 July 2008.

[vi] Telephone communication – Stuart Wertley, fresh produce McCain

[vii] Letter from McDonald's Managing Director Darren Hall (attached)

[viii] E-mail correspondence – Simba agronomy manager Peter Mulder

[ix] Meeting – Leon Grundlingh, Woolworths Food Technologist

[x] Meeting – Warren Lipke, Pick n Pay Fresh Produce

[xi] Telephone conversation – Natasha Nell – Food Safety, Freshmark

[xii] Letter from Fruit n Veg City Managing Director Brian Coppin (attached) as annexure to these objections.

[xiii] List of signatories and comments attached as annexure to these objections.

[xiv] Public Participation in the Context of the Regulation of Genetically Modified Organisms in South Africa. A study prepared for National Environmental Advisory Forum. A. Pole. November 2007

[xv] Letter from Lucy Sharrat, Coordinator Canadian Biotechnology Action Network, August 2008. (attached)

[xvi] Le Roux, S.M., Steyn P.J. and Visser, D. 2003. Occurrence and control of pests. In J.G. Niederwiesser (Ed). **Guide to potato production in South Africa**. ARC-Roodeplaat Vegetable and Ornamental Plant Institute (pp. 156, 170-171).

[xvii] Personal communication with Potato SA BEE Transformation Manager, Diale Mokgojwa.

[xviii] Smallholder Potato Production Activities in South Africa: A Socio-Economic and Technical Assessment of Five Cases in Three Provinces. TGB Hart (HSRC) and HJ Vorster (ARC). December 2006

[xix] ibid

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