AFRICAN CENTRE FOR BIOSAFETY

OBJECTIONS TO THE APPLICATION MADE BY SYNGENTA SEEDCO

IN RESPECT OF EVENT GA21

TO THE NATIONAL DEPARTMENT OF AGRICULTURE, SOUTH AFRICA

PREPARED BY MARIAM MAYET AND SHENAZ MOOLA

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1 SUMMARY OF GROUNDS FOR REJECTION OF SYNGENTA SEEDCO'S APPLICATION

"We humans have never excelled in planning the path of progress. We tend to adopt new technology as soon as it comes along, then wait to discover the consequences."[1]

1.1 SCIENTIFIC OBJECTIONS

A scientific assessment was made of the available information. The main findings of this assessment, which are discussed in greater detail later in the document, are:

- A full assessment of the scientific data could not be made because of the designation of sections of the application as Confidential Business Information
- Genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed
- The molecular characterisation information provided by the notifier indicates several irregularities including open reading frames and a truncated constructs which could give rise to unintended gene effects
- The transfer of the herbicide-tolerant trait to weeds could result in increased herbicide application. The potential for economically important weeds developing herbicide tolerance is a cause for concern
- Glyphosate use has resulted in several unwanted effects on aquatic systems and terrestrial organisms and ecosystems
- The US experience of Roundup Ready field trials has shown a marked increase in herbicide usage, particularly glyphosate
- In the Argentinean experience, the large scale uptake of Roundup Ready Soya has had devastating impacts on food security and the environment

1.2 SUMMARY OF PRELIMINARY AND LEGAL ISSUES

1.2.1 Non Compliance with PAJA - EC has No Authority to Take Decisions

Administrative action on the part of the Executive Council (EC) established under the Genetically Modified Organisms Act ("GMO Act"), more particularly, decisions taken by it approving applications for the import, release and marketing of genetically modified organisms (GMOs) adversely affect the fundamental human rights of the public.

Decision-making on the part of the EC established under the GMO Act concerning GMOs fall within the purview especially of section 4(1)(a) and (b) of Promotion of Administrative Justice Act No 3 of 2000 ("PAJA").

Regulation 6 of the Regulations made under the GMO Act is inconsistent with the provisions of PAJA. In terms of the judgment of the judgement of Wills J, in an unreported judgment in the matter of Sasol Oil (Pty) Ltd and Bright Sun Developments CC v Mary Metcalfe NO Case No 17363/03, High Court of South Africa (Witwatersrand Local Division) PAJA triumphs the said Regulations made under the GMO Act.

In any event, Regulation 6 dealing with an invitation by an applicant to members of the public in the area where a release is intended to take place is not within the contemplation of sections 3 and 4(1) of PAJA. Both section 3 and 4(1) of PAJA deal with administrative action. It is clearly the intention of the legislature that PAJA should apply to the duty on the part of the administrator regarding administrative actions vis-à-vis the public, in ensuring fair administrative justice.

1. In the light of there having been a failure on the part of the EC to comply with sections 3 and 4(1) of PAJA, read together with the said PAJA Regulations, we believe that decision-making on the part of the EC will be ultra vires and therefore null and void.

2. We therefore call upon the EC to desist from making any decision and comply with the said provisions of PAJA.

1.2.2 EC has a Constitutional and Statutory Duty to Protect the Environment and not Further Commercial Interest of Gene Giants

It is our respectful submission 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, 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 environmental impacts of the proposed activities and to have regard to the cumulative potential impacts of such activities on the environment.

Regard must be had in particular, to the explicit purpose of the field trial, namely to

evaluate the efficacy of GA21 GM maize, increase seed production for the purpose of exporting seed to the US for additional trials, and support the global evaluation of the GA21. In other words, to use the land of South Africa, as a nursery for the production of seeds to assist and to support applicants for approvals elsewhere in the world. This is particularly pertinent, given that GA21 is key to Syngenta gaining access to the global seed market, as is borne out by the litigation pending in the US courts between Syngenta and Monsanto. It is not the role of the EC, to become embroiled in the bitter fight between these two multinational gene giants for control over the global seed market.

1.2.3 South African Government makes a Mockery of Biosafety

The National Environmental Management Biodiversity Act, 2004 (NEMBA) came into effect on the 1 September 2004. Section 78 of NEMBA creates the possibility that where the Minister is of the belief that the release of a GMO may pose risks to the

environment, and therefore, an environmental assessment is required to be conducted in terms of Chapter 5 of NEMA, then such intended release, will in terms of section 78, be deemed to be a listed activity in terms of Chapter 5 of NEMA. Environmental assessments of listed activities is to be regulated through a series of Regulations to be promulgated in terms of section 24(5) of NEMA, using powers that have been created by Act No. 8 of 2004. It stands to reason therefore, that such Regulations must be drafted in a way, so that section 78 is itself operationlised. However, the draft Regulations issued under government notice 764 in Government Gazette26503 of 25 June 2004, have been drafted in a way that completely ignores section 78 of NEMBA. As it currently stands, these Regulations do not apply to GMOs. This means that section 78 has potentially been rendered unimplementable.

It is our belief that that these Regulations were never intended to apply to GMOs, because the DEAT does not take biosafety seriously. As the situation currently stands, we have no alternative but to conclude that the South Africa government makes a mockery of biosafety.

2 SCIENTIFIC ASSESSMENT

> *"The debate over genetically modified crops was not about an existing technology, but one that agribiotech companies wanted to introduce and governments seemed happy to nod through. But before that could happen, environmental groups asked new questions: what are the health and environmental risks likely to be, and what are the likely benefits for consumers? This caught both companies and governments on the wrong foot. The answers did not exist because no one had done the research. Only after a public outcry did anyone get around to it – only to discover that existing GM crops had no great benefit to consumers, were economically suspect and that their environmental impacts were mixed."*[1]

2.1 TRIAL RELEASE OF GA21: APPLICATION AND AVAILABLE INFORMATION

For the purposes of this discussion references in parentheses of the format '(x.x, x)' refer to the question number and page number respectively of the notifier response in the application to the Department of Agriculture, South Africa (CBI deleted version). A copy of the application submitted by Syngenta SeedCo (the Notifier) for field trials of GA21, excluding confidential business information has been furnished to us. According to this application, a brief description, objectives and questions related to a general trial release, crop or pasture plants, monitoring and accidents and pathogenic and ecological impacts have been completed. Additionally, the risk assessment has been provided. Appendix A detailing location descriptions and maps and Appendix B has not been provided. The main aim of the trial is study of the efficacy and agronomic characteristics of GA21 in South Africa (2, 1).

Both the application and risk assessment make reference to http://gmoinfo.jrc.it/csnifs/C-ES-98-01.pdf which is a Summary Notification Information Format (SNIF) for Roundup Ready Maize Line GA21 by Monsanto, as

listed on a website (http://gmoinfo.jrc.it) managed by the Joint Research Centre of the European Commission on behalf of the Directorate General of the Environment. The purpose of the website is to publish information and receive comments from the public regarding notifications about deliberate field trials and placing on the market of genetically modified organisms in accordance with Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001. The current status of the application is listed as "Withdrawn".

2.2 THE HOST PLANT AND GA21: BRIEF DESCRIPTION

Maize or corn (*Zea mays* L.) is grown commercially in over 100 countries primarily for the kernel, which is processed into a wide range of food and industrial goods[2]. The greater proportion of maize produced is used for animal feed with under 10% of the maize used as human food products. Starch produced from maize is converted into sweeteners, syrups and fermentation products[2,3]. *Zea mays* L. was subjected to biolistic transformation (particle acceleration) to yield GA21, a glyphosate-tolerant (Roundup Ready) maize line.

2.3 GENETIC MODIFICATIONS AND MOLECULAR CHARACTERISATION

2.3.1 Sequence Information

The bacterial gene (*aroA*) that encodes 5-enol-pyruvyl-shikimate-3-phosphate-synthase (EPSPS) is inserted into transgenic plants to confer glyphosate resistance[14]. Monsanto maize line GA21 is glyphosate tolerant due to the insertion of a plant gene encoding a modified version of the EPSPS protein. The wild type *epsps* gene cloned from maize was subjected to *in vitro* mutagenesis to produce the modified *epsps*, designated *mepsps*.

A 3.4Kb agarose gel-isolated *Not1* restriction fragment of the plasmid pDPG434 containing the modified maize *epsps* gene expression cassette was introduced by particle acceleration into embryogenic corn cells (4.3, 4). The promoter sequence was derived from the 5' region of the rice actin gene (4.3, 4) and the nopaline synthase gene derived from the Ti plasmid of *Agrobacterium tumefaciens* served as terminator sequence (4.3, 5).

The SNIF[4] states that 'three internal *mepsps* cassettes are estimated to be present'. In addition, a partial *mepsps* cassette, containing the full length rice actin promoter and intron, the optimised transit peptide, a truncated *mepsps* gene containing the first 289 nucleotides of the *mepsps* coding sequence and terminating in a stop codon, is present. At the 3' end of the inserted genetic elements, there is a partial *mepsps* cassette containing only the rice actin promoter and 5' mRNA leader sequence but truncating before the start of the rice actin intron[4].

2.3.2 Possible unintended effects of the non-functional DNA fragments in GA21

The estimate of the number of complete copies of the internal *mepsps* cassette is considered by the European Commission Scientific Committee on Food to be an underestimate due to an inaccuracy in the interpretation of the data as the relationship

between DNA fragment size and signal transfer in the Southern transfer and hybridisation experiments has not been taken into consideration[8].

Despite the expression of the introduced gene sequences having been confirmed by molecular characterisation, unintended effects that are not detected in the lab and that may only become apparent in the long term, cannot be ruled out. Transformation by particle acceleration is associated with multiple fragments and gene rearrangements[5,6]. That this has happened in the development of GA21 is not in question. The DNA sequence data shows the presence of two open reading frames[4] i.e. genes without a stop codon. What is of concern here is the possible production of novel proteins from the transcription of these unintended GA21 fragments. According to Monsanto, these are not transcribed[7] and hence do not produce protein. The European Commission Scientific Committee on Food[8] has stated that the lack of transcription or translation signals from Northern and Western blots, does not 'preclude absolutely the possibility that the truncated gene is expressed but the possibility that this is the case will be extremely remote'[8]. Inserted gene sequences may interrupt native gene sequences and/or their promoters and additional code fragments are not necessarily non-functional and may be transcribed. Extra gene fragments in Monsanto's Roundup Ready Soya were also claimed to be non-functional and not-transcribed[9], but were later found to be transcribed to produce RNA[10,11].

Further, it is not clear if the insert or fragments thereof lie on any maize transposons and what the impact of the DNA insert is on flanking sequences. The lack of sophisticated methods for targeted insertion, especially in higher organisms[6] necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment. Further, if transgenes behave just like naturally occurring genes, then they have the potential to be inherited in the same way and persist indefinitely in cultivated or free-living populations. Any mixing of native and transgenic plants whether by dispersal, improper handling etc., can result in the spread of transgenes. The consequences, both ecological and evolutionary of crop-to-crop gene flow are only now beginning to be investigated in any meaningful way and the possible exposure of non-target organisms, including humans to novel proteins cannot be discounted[6].

The response to the question regarding frequency of reversion, appeals to 'Public information' (4.4, 7) and refers to the SNIF by Monsanto[4] and is not a reference to any independent, objective source.

2.3.3 Genetic modification: degree of certainty

In general, genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed[12]. Additionally, the gaps in the knowledge regarding composition and functioning of the genomes that are often subjected to genetic manipulation and ill-designed experiments compound such scientific uncertainty[12].

Uncertainty is a key element of the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity[13]. The lack of sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects allows the Precautionary Principle referenced in the Biosafety Protocol to be triggered. The precautionary principle states "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". The discussions above have identified potentially dangerous effects from the use of GA21. Further the available scientific information, as provided by the notifier, does not allow for a full evaluation or determination of the associated risks of the use of the said transgenic line.

2.4 HERBICIDE TOLERANCE AND USE

2.4.1 Mechanism of Glyphosate Tolerance

EPSPS plays a role in chloroplast amino acids synthesis, particularly tyrosine, phenylalanine and tryptophan and the naturally occurring plant form is inhibited by glyphosate. The modified plant EPSPS enzyme as found in GA21 has reduced affinity to glyphosate and hence confers tolerance[14] by allowing the plant to function normally in the presence of the herbicide.

2.4.2 Herbicide Tolerance and Effects on Non-Target Species

The main environmental concern related to introducing herbicide resistance into transgenic plants is the development of weed populations that are resistant to particular herbicides, the so-called superweeds[15]. These weeds may then be able to successfully outcompete other non-herbicide–resistant weeds[16]. This may result in increased use of herbicides in greater volumes and varieties with possible negative impacts on soil and groundwater[17]. Increased herbicide use may also result from less restrained herbicide application arising from producer confidence that the desirable plant will be unaffected.

2.4.3 Herbicide use and GM crops

One of the draw cards, as claimed by seed companies for the use of GM seed is the benefit of reduced herbicide use. Research in support of this claim is by and large carried out by the developers of GM seeds in field scale evaluations.

Trends in the degree and extent of herbicide applications with the advent of GM crops are only now emerging. In the USA, planting of GM crops has led to a substantially greater use of herbicides than non-GM crops with significant year on year increases particularly for GM soya and maize. Between 2001 and 2003, the planting of GM crops resulted in 73 million pounds more agrochemicals being applied in the USA[18]. Benbrook examined agrochemical use on GM crops[18], including most recent impacts (since 2002). His data is in agreement with USDA estimates for earlier years. He observed that 'proponents of biotechnology claim that GE varieties substantially reduce pesticide use. While true in the first few years of widespread planting it is clearly not the case now'. Further he found that there is now 'clear evidence that the average pounds of herbicides

applied per acre planted to herbicide tolerant (HT) varieties have increased compared to the first few years of adoption.

The notifier states that the field will be monitored after trial harvest and throughout the following growing season (5.10, 14), which seems to suggest that the trial will be conducted for a single season. The practice of examining herbicide use for a single season, as typically occurs with most field trials, and as is proposed for this application is not sound. Examination of agrochemical usage for GM crops suggest that for a full assessment of the extent of herbicide use, changes in herbicide use need to be monitored over full crop rotation cycles, not just a single harvest as is typical of a number of field scale evaluations[18,19].

2.4.4 Increased Glyphosate Use Impacts on other Plant Species

The dramatic increase in the use of glyphosate over the past decade has resulted in weedy morning glories in the South-eastern United States developing tolerance to glyphosate. The repeated use of herbicides exerting strong selection pressure on crop weeds has led to more than 250 documented cases of herbicide resistance, a process that is 'likely to accelerate with increased reliance on herbicides'[20]. A strong positive directional selection in the presence of glyphosate and strong negative directional selection in its absence was observed[21].

Common ragweed found in a 22 acre patch of north-central Arkansas dryland has survived heavy, and repeated, shots of Roundup[22]. Laboratory studies are still in progress, but preliminary indications are that resistance to glyphosate (Roundup) has developed in these plants. The presence of resistant ragweed is unlikely to cause major waves amongst agriculturalists as ragweed is not a threat to any major crop and there are herbicides besides Roundup to control the weed. The larger issue is the potential for agriculturally important weeds such as pigweed, tall waterhemp or lambsquarter to develop resistance. Monsanto is well aware of the problem ragweed and is evaluating sample plants in St. Louis[22]. Developing weed resistance is a growing concern amongst farmers and Syngenta have acknowledged that 'many of these concerns with resistant weeds are realistic'[23].

2.4.5 Health and Environmental Effects of Glyphosate and Glyphosate-tolerant GMOs

There is a paucity of experimental studies devoted to health or environmental effects of glyphosate-tolerant GMOs or glyphosate itself. Glyphosate is a broad spectrum herbicide and its usage may result in harmless plant species being destroyed. The large scale cultivation of glyphosate resistant crops will result in an increase in the use of glyphosate with concomitant negative environmental impacts. The full impact of glyphosate on groundwater can only really be determined by long-term monitoring programmes. In terms of impacts on human health, glyphosate is acutely toxic to humans and in California has been reported to be the third most commonly reported pesticide related illness amongst agricultural workers[24]. A study on mice fed GM soybean suggested that *epsps*-transgenic soybean intake was impacting on the morphology, particularly the nuclear features of liver cells, in both adult and young mice[25]. The mechanism for this effect is still to be determined[26]. Glyphosate use, an integral part of planting Roundup

Ready crops, has indicated several unwanted effects on aquatic[27] systems, terrestrial [28] organisms and ecosystems[29]. Negative impacts on human [30,31], rodent [32] and fish [33] health have also been observed.

2.4.6 Experience of other GM Crops: Roundup Ready Soya in the USA

More research has been carried out on the nature and extent of herbicide applications with Roundup Ready soya. Roundup Ready Soya bean went from comprising only a small fraction of soya bean planted in the USA in 1996 to more than half of all soya bean planted in 1999, an uptake all the more remarkable given the yield-drag associated with engineered varieties[34]. In a report reviewing the results of 8200 university-based soybean varietal trials it was found that RR soybean yield drag could result in perhaps a 2.0 to 2.5 percent reduction in national average soybean yields compared to what they might have been had seed companies not forced crop production focus on herbicide tolerance. Further, the dependence of RR systems on herbicides resulted in 2 to 5 times more herbicide being applied compared to other popular weed management systems[34].

2.4.7 Roundup Ready Crops: The Argentinean Experience

Argentina was one of the first countries to authorise GM crops with the cultivation of Monsanto's Roundup Ready soya in 1997[38,35]. Large areas of Argentina's most fertile farming region in the Pampas had been suffering from serious soil erosion. Farmers experimenting with a no-tilling approach to alleviate the problem saw the introduction of a herbicide tolerant crop as a heaven-sent solution[35]. Impoverished smallholders, largely peasant farmers, leased their land out to soya farmers and by 2002 almost half of Argentina's arable land -11.6 million hectares was planted with soya, almost all of it GM, compared with just 37,700 hectares of soya in 1971[35,36].

The demand for arable land for planting soya saw cultivation extending into more environmentally fragile areas; Argentina has lost three-quarters of its native forest to farming over the past century[37]. In 2001, Benbrook reported that Argentinean Roundup Ready soya growers were using more than twice as much herbicide as conventional soya farmers, largely because of unexpected problems with tolerant weeds[35,36]. His warning of shifts in the composition of weed species, the emergence of resistant superweeds, and changes in soil microbiology under the existing herbicide application regime went unheeded. The outcome is the emergence of several previously uncommon species of glyphosate tolerant weed, a decline in soil bacteria, changes in soil structure and fitness with soil becoming inert thereby inhibiting the usual process of decomposition[35]. On top of all of this is a proliferation of volunteer soya. Rival's to Monsanto in the agrochemical industry are promoting their products to eradicate these volunteers with Syngenta advocating the use of Paraquat and atrazine[35,38] and Dow AgroSciences recommending a mixture of glyphosate with metsulfuron and clopyralid[35, 38].

Spraying of RR soya crops has resulted in devastating impacts on the health of local populations and on their environment, livestock and food crops. Studies carried out by the University of Formosa Province reported serious health problems in peasant communities arising from such fumigation on RR soya fields[38,35]. The Argentinean experience also raises issues of food security. Argentina has gone from being known as

one of the world's best beef producer and the breadbasket of the world to an economy dependent on near monoculture[36]. The proliferation of soya has provoked an exodus of people from the rural areas to the cities and into extreme poverty since they cannot produce their own food[35,36]. RR soya has also won out against traditionally grown crops such as sweet potatoes, sweet maize, lentils (a staple), peas and cotton. Argentina used to produce food sufficient to feed eight times its population, now it imports milk. 'Now, in beef country, the poor are being fed with crops used for animal feed in the first world'[36].

2.5 TRIAL RELEASE: GENERAL

This section details our responses to the notifier application responses under the heading in the application form; 'Trial Release: General' (5, 8).

Responses to 5.1 (page 8) refer to an Appendix A, a copy of which has not been furnished to us. Supervision of the trial site will be carried out by Syngenta (5.1.5, 9). More detail needs to be provided on monitoring of the site e.g. how often will the visits occur. What sort of monitoring will take place? A comprehensive monitoring plan needs to be put into place to assess weediness, contamination of groundwater (if there are water bodies/aquifers nearby – this information has been designated CBI), and environmental monitoring for volunteers.

The response to 5.1.6 (page 9) makes no mention of the measures that will be employed in the event of storms, floods and bush fires, however unlikely the notifier considers such eventualities. What contingency measures will be put in place by the Syngenta employees during the growing period should such conditions arise? In the event of storms or floods, what additional measures will be taken to monitor the surrounding areas as surely water dispersal will greatly increase the required monitoring area? What other measures can be considered during floods/storms to contain the release area? Will the use of herbicides (not glyphosate) be considered at all as part of the contingency measures strategy? In the event of heavy rains and floods the potential for transport of transgenic plants or pollen will be greatly increased. What other measures can be considered during floods/storms to contain the release area - the use of herbicides under such circumstances does not appear to be a safe and environmentally sound option.

At the end of the field trial, the plants will be destroyed by dicing/ploughing (5.1.7, 9) and herbicide application. No detail is provided of the proposed herbicides to this end. The previous issuing of trial permits for GA21 is not to be taken as proof of 'no potential hazardous or deleterious effects' as suggested by the notifier (5.2, 10). This response suggests a static body of knowledge relating to the transgene and begs the question of the need for another field trial to test 'efficacy' and 'agronomic' characteristics' (2, 1). A cursory study of the literature reveals possible negative effects including the very real potential for spread of the transgene and impacts on non-target organisms, none of which have been raised by the notifier. The response to these questions is considered by us to be incomplete.

It is not clear from the questionnaire what the release of **similar** GMOs might refer to (5.3, 10) – is it a reference to (a) genetically modified higher plants, (b) all plants which

have been engineered to be Roundup ready which would then include maize, Soya and cotton amongst others, (c) all glyphosate tolerant maize, which would then include NK603 or (d) all herbicide tolerant maize, taking into consideration other herbicides. The trials in question are not detailed, nor is the trial data available for independent scrutiny. The stated beneficial consequences are the same as those identified by the developer of the technology (Monsanto) and not necessarily based on actual release data.

The reference to the Monsanto SNIF (5.3.2, 11)[4] is not proof of any lack of adverse effects as the information contained in the SNIF is provided by the developer Monsanto and not independently verified. The body of research relating to GE crops is growing and several studies report results that do not bear out the notifier's claim. For example, it has been reported that people with ileostomies (i.e. who make use of a colostomy bag) are capable of acquiring and harbouring DNA sequences from GM plants in the small intestine[39].

Question 5.5 deals with the issue of gene transfer. The notifier discusses the possible transfer of the genetic trait by pollen from transgenic plants. Whilst it is true that the maize pollen grains are round and heavy with a high water content, which limits their dispersal range, small amounts of pollen can travel 400m or more and remain viable[40]. It is prudent to make allowance for such an eventuality especially in a field trial, which has the stated aim of evaluating the efficacy of the transgenic plant. It cannot be conclusively stated that no gene transfer occurs. It has only been recently reported that transgene fragments have been detected in mammals[39,41]. There is still much work that needs to be done to determine behaviour of these fragments.

No real risks have been identified by the notifier (5.9, 13). The field trials are not designed to monitor low probability risks, such as gene transfer. There are no plans to monitor impacts on non-target organisms despite the various papers that have been published on the subject.

2.6 CROP OR PASTURE PLANTS

Notifier responses to the questions in the application under **Crop or Pasture Plants** (12, 20) makes the same claims as previously (Trial Release: General) that no adverse effects have been observed, that there is no evidence of gene transfer (12.12, 23), toxicity effects have not been observed (12.10, 22) and that there are no impacts on non-target organisms (12.16, 23). These claims have been responded to above.

2.7 MONITORING AND ACCIDENTS AND PATHOGENIC AND ECOLOGICAL IMPACTS

More detail needs to be provided on monitoring of the site e.g. how often will the visits occur. What sort of monitoring will take place? Our concerns regarding the accident response measures have been detailed above. The results obtained from the numerous field trials (5.3, 10) carried out in South Africa, the EU, Canada and the USA cannot be assessed as no details of these trials have been provided. It is usually necessary to be able to assess experimental data so as to make an assessment of research design and relevance. Experiments are often poorly designed or conducted under very controlled

and artificial conditions that make meaningful extrapolation to full scale conditions meaningless if not impossible.

2.8 RISK ASSESSMENT

Syngenta SeedCo has certain obligations in terms of the Cartagena Protocol on Biosafety. Article 15 states that Risk Assessments undertaken pursuant to the Biosafety Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III, taking into account recognised risk assessment techniques.

The risk assessment (26) states that wild populations with which maize could cross-pollinate are 'uncommon'. Despite the possibility of cross-pollination, however rare, the risk assessment does detail any course of action should the GE maize be accidentally released to the environment. It is not expected that the GE maize will become a persistent or invasive weed, should a seed spill or inadvertent planting occur, However, maize plants have been shown to survive over a growing season, under comparatively colder conditions[42] than found in South Africa. Should any volunteers arise, the resulting pollen could cross-pollinate with maize in fields, producing genetic contamination. The chances of cross pollination with other maize crops is described as a "medium to high risk" [43].

2.9 ADDITIONAL COMMENTS REGARDING THE NOTIFIER APPLICATION

In light of the responses by the notifier to question regarding the field trial, it is our contention that this application cannot be adequately assessed. The information provided is sketchy at best and several application questions appear to have been misinterpreted. Claims are made regarding gene stability and behaviour by reference to information provided by the developer of the GMO and not to any independent objective source. The basis of these claims is therefore in question. The impression gained from the notifiers responses is that any possible impacts of the release of the transgene are negligible and that the transgenic line is equivalent to the conventional type – this is a view not supported by the published literature. At a minimum, the literature indicates that a great deal more investigation has to be carried out on the impacts of transgenes before their release into the environment. The long review process of similar applications by the EU bear out these concerns.

It is of concern that in several instances where claims are made by the notifier of no adverse effects to human and animal health and the environment from release of the transgenic organism that no supporting literature is cited (5.3, 5.8, 12.3). Are we to assume that these conclusions are based on research conducted by the notifier and if so, have any independent assessments been made of this research?

The notifier makes the claim that the genetic modification does not introduce any new category of risk as compared to risks from conventional breeding. This is not to be taken as an apparent truth. The ability of ecosystems to develop gradually, the ability to anticipate environmental health effects and very importantly, the establishment of regulatory mechanisms that can effectively, efficiently and credibly manage risks

associated with the use of GMOs has not kept apace with the rapid introduction of GMOs. Traditional breeding practices have an established history of safe use dating back several years as opposed to the application of recombinant DNA technology for human use, which is as young as 22 years when genetically modified bacteria-produced insulin was first introduced and even younger for genetically modified plants at ten years[12].

3 PRELIMINARY ISSUES: DETAILED DISCUSSION

3.1 FAILURE BY EC TO COMPLY WITH PROVISIONS OF PAJA-NO AUTHORITY TO TAKE DECISIONS

Administrative action on the part of the EC, more particularly, decisions taken by it approving applications for the import, release and marketing of GMOs adversely affect the fundamental human rights of the public. These rights include inter alia, the right to nutritious, safe and culturally acceptable food, the right to informed choice, the right to fair administrative decision-making, the right to democratic participation, the right to save and exchange seeds, and the right to a safe and healthy environment. It also raises far-reaching ethical concerns for those that adhere to ethical and value systems underpinned by African communal spirituality concerning life and food.

It is our belief that administrative decision-making on the part of the EC established under the GMO Act concerning GMOs fall within the purview especially of section 4(1)(a) and (b) of Promotion of Administrative Justice Act No 3 of 2000 ("PAJA"). In terms of section 4(1) of PAJA, the EC must, in order to give effect to the right to procedurally fair administrative action, decide whether-

> " (a) to hold a public enquiry;
> (b) to follow a notice and comment procedure in terms of subsection (3);
> (c) to follow the procedures in both subsections (2) and (3);
> (d) where the administrator is empowered by an empowering provision to follow a procedure which is fair but different, to follow that procedure; or
> (e) to follow another appropriate procedure which gives effect to section 3."

We strenuously dispute the Registrar's contention contained in his letter of 16 August 2004, that regulation 6 of the Regulations dated 1 December 1999 made under the GMO Act, is a fair procedure, as contemplated by the objections and provisions of section 3(5) the PAJA. It is our view that regulation 6 of the Regulations made under the GMO Act is not in compliance with sections 3 and 4(1) of PAJA. We refer the EC to our numerous objections submitted to the EC over the last few months, to various applications for GM imports and releases, as well as to numerous correspondence wherein we have illustrated amply and clearly to the EC and the Registrar, that regulation 6 of the said GMO Regulations is inherently unfair, prejudicial and obstructs the administration of justice.

In this regard, we bring to your attention the judgement of Wills J, in an unreported judgment in the matter of Sasol Oil (Pty) Ltd and Bright Sun Developments CC v Mary

Metcalfe NO Case No 17363/03, High Court of South Africa (Witwatersrand Local Division) when the learned Judge stated that:

" It is trite that in the interpretation of ordinary statutes, to the extent that there is inconsistency between earlier and subsequent legislation, the provisions of subsequent legislation will ordinarily prevail….The purpose of PAJA is plainly to give effect to the rights, constitutionally enshrined in the Bill of Rights of the Constitution, to just administrative action. It is constitutional legislation. It is triumphal legislation…We have resolved, almost unanimously, that never again must such injustices as had been experienced under apartheid and in other parts of the world prevail in our own country…[PAJA] confers rights upon all who lives in South Africa in so far as their dealings with organs of State are concerned. To the extent that earlier legislation is inconsistent with PAJA, PAJA must prevail."

It is our contention that regulation 6 of the Regulations made under the GMO Act is inconsistent with the provisions of PAJA. In terms of the above judgment, PAJA triumphs the said Regulations made under the GMO Act; whereas the Regulations of the GMO Act came into effect on the 1 December 1999, PAJA came into effect on the 3 February 2000. The Regulations made under the GMO Act are in any event, subordinate legislation and can in no way be said to be equivalent to constitutional legislation such as PAJA.

In any event, we are of the belief that the said regulation 6 which deals with an invitation by an applicant to members of the public in the area where a release is intended to take place, is not within the contemplation of sections 3 and 4(1) of PAJA. Both section 3 and 4(1) of PAJA deal with administrative action. It is clearly the intention of the legislature that PAJA should apply to the duty on the part of the administrator regarding administrative actions vis-à-vis the public, in ensuring fair administrative justice.

Since regulation 6 of Regulations of the GMO Act deals with a notice and comment procedure (between an applicant and members of the public where the release is intended to take place), we illustrate below, for your convenience, the marked difference between regulation 6 and the Regulations promulgated in terms of PAJA (Government Gazette Vol. 446. No 23710, 31 July 2002.

In this regard, please take note special note that Chapter 2 of the latter Regulations (PAJA Regulations) deals with the Notice and Comment Procedure on the part of the administrator, regarding administrative action as is required by section 4(1) of PAJA and not, notices by the applicant, as is required by regulation 6 of the GMO Regulations, for comments by the public.

"18.

1. Information concerning the proposed administrative action must be published by way of notice-

(a) if the administrative action affects the rights of the public throughout the Republic, in the Government Gazette and a newspaper which is distributed, or in newspapers which collectively are distributed, throughout the Republic;

2. A notice published in terms of subregulation (1) must include-

(a) an invitation to members of the public to submit comments in connection with the proposed administrative action to the administrator concerned on or before a date specified in the notice, which date may not be earlier than 30 days from the date of publication of the notice;
(b) a caution that comments received after the closing date may be disregarded;
(c) the name and official title of the person to whom any comments must be sent or delivered…."

3. A notice published in terms of subregulation (1) must-

(a) contain, sufficient information about the proposed administrative action to enable members of the public to submit meaningful comments…"

19. 1. A notice published in terms of regulation 18(1) must be in at least two of the official languages.

20. .1 If any proposed administrative action may materially and adversely affect the rights of members of a specific community consisting of a significant proportion of people who cannot read or write or who otherwise need special assistance-

(a) A notice must be published in the area of that community in a manner that will bring the proposed action to the attention of community at large; and
(b) The Administrator must take special steps to solicit the views of the members of the community.

2. Special steps in terms of subregulation (1)(b) may include-

(a) the holding of public or group meetings where the proposed action is explained, questions are answered and views from the audience is minuted;
(b) a survey of public opinion in the community on the proposed action; or
(c) provision of a secretarial facility in the community where members of the community can state their views on the proposed action."

In the light of there having been a failure on the part of the EC to comply with sections 3 and 4(1) of PAJA, read together with the said PAJA Regulations, we believe that decision-making on the part of the EC will be ultra vires and therefore null and void.

We therefore call upon the EC to desist from making any decision and comply with the said provisions of PAJA.

3.2 SOUTH AFRICA: A PAWN OF SYNGENTA TO PENETRATE GLOBAL SEED MARKET?

The view of the EC regarding field trials as expressed in the extract of the minutes of its meeting of 8 July 2004 is that "biosafety information cannot be obtained without trials being conducted." However, we point out, that according to Syngenta, the objectives of the field trials are not to generate biosafety information, but to evaluate the efficacy of GA21 GM maize and to increase seed production for the purpose of exporting seed to the US for additional trials. In other words, to use the land of South Africa, as a nursery for the production of seeds (because of favourable weather conditions prevailing in South Africa at this time?). It is thus Syngenta's intention to export such seeds to the US for further growing there.

Syngenta also plainly states that the field trials are meant to support the global evaluation of GA21, in other words, to support it in winning approvals for field trials and commercial releases elsewhere in the world. This is pertinent, given two important factors. First, GA21 is viewed as Syngenta's top weapon that would compete directly with Monsanto's 'Roundup Ready' maize (NK 603). Second, Monsanto and Syngenta are embroiled in bitter legal battles in the United States.[44] Syngenta is challenging Monsanto's market domination in the U.S District Court in Delaware[45] and Monsanto in turn, has initiated a patent infringement lawsuit in Illinois Federal court to stop Syngenta Seeds Inc from developing, using and selling herbicide tolerant maize seed, including GA21. [46]

It is not the role of the National Department of Agriculture (NDA) and the EC, to become embroiled in the fight between two multinational gene giants for control over the global seed market. Indeed, it is incumbent upon the NDA and the EC, to ensure food and seed security in South Africa and ensure biosafety, and not to misuse its powers to further the commercial interests of multinational seed and agrochemical companies that have little interest in biosafety or poverty alleviation in South Africa.

3.3 SOUTH AFRICAN GOVERNMENT MAKES A MOCKERY OF BIOSAFETY

1. There has been an absence of independent and on-going monitoring and testing (in the fields) in South Africa. This makes it extremely difficult for the EC, to reliably assess the degree of environmental risks posed by transgenic crops already released into the South African environment over the past 15 years[47]and hence, to make any findings, regarding the environmental safety of GM crops.

2. The EC acting in consultation with the Advisory Committee established in terms of section 10 of the GMO Act is responsible for conducting biosafety assessments (desk top evaluations only). These institutions have to date, applied the "substantial equivalence" principle, which relies on the concept of "familiarity" with conventional varieties of especially genetically engineered crop plants, to judge whether a transgenic plant requires a full environmental assessment. The principle assumes the validity of the simple linear model of "precise" single gene modifications that do not significantly alter other plant processes. This may explain why, to date, not a single independent environmental assessment (in the fields) has ever been conducted in South Africa in respect of GMOs released into the environment.

3. There has thus been no thought given by the EC to unanticipated changes that can be induced by expression of a novel gene (and indeed parts of the genetic construct), and that phenotypic consequences need to be assessed empirically across time and environments, as is required by the Precautionary Principle.

4. On the 1 September 2004, the National Environmental Management Biodiversity Act 2004 came into effect (NEMBA). Section 78 of NEMBA provides as follows:

> " 78. (1) If the Minister has reason to believe that the release of a genetically modified organism into the environment under a permit applied for in terms of the Genetically Modified Organisms Act, 1997 (Act No.15 of 1997), may pose a threat to any indigenous species or the environment, no permit for such release may be issued in terms of this Act unless an environmental assessment has been conducted in accordance with Chapter 5 of the National Environmental Management Act as if such release were a listed activity contemplated in that Chapter.
>
> (2) The Minister must convey his or her belief referred to in subsection (1) to the authority issuing permits in terms of the Genetically Modified Organisms Act, 1997, before the application for the relevant permit is decided.
>
> (3) For the purposes of subsection (1) "release" means trial release or general release as defined in section 1 of the Genetically Modified Organisms Act, 1997."

5. Thus, section 78 creates the potential for the Department of Environmental Affairs and Tourism (DEAT) to address the serious shortcomings inherent in the current requirements for risk assessment. Currently, an Applicant who wishes to release GMOs into the environment is required to furnish the Executive Council only with the information required in terms of Guidelines published by the National Department of Agriculture, Genetically Modified Organisms, Revised Procedures.48It is on the basis of this information, that a risk evaluation or assessment (desk top only) is carried out, of the potential risks posed by the GMO in question. These guidelines (Application for General Release; Application for Intentional Release) do not constitute an adequate framework for conducting an initial environmental assessment and it is therefore not possible, on the basis of these guidelines, for proper and reliable conclusions to be drawn on the potential environmental impact the release into the environment, GMOs are likely to pose.

6. Section 78 creates the possibility that where the Minister is of the belief for instance, that the release of a GMO may pose risks to the environment, and therefore, an environmental assessment is required to be conducted in terms of Chapter 5 of NEMA, then such intended release, will in terms of section 78, be deemed to be a listed activity in terms of Chapter 5 of NEMA. Environmental assessments of listed activities is to be regulated through a series of Regulations to be promulgated in terms of section 24(5) of NEMA, using powers that have been created by Act No. 8 of 2004. It stands to reason therefore, that such Regulations must be drafted in a way, so that section 78 is itself operationlised. However, the draft Regulations issued under government notice 764 in Government Gazette26503 of 25 June 2004, have been drafted in a way that completely ignores section 78 of NEMBA. As it currently stands,

these Regulations do not apply to GMOs. This means that section 78 has potentially been rendered unimplementable.

It is our belief that that these Regulations were never intended to apply to GMOs, because the DEAT does not take biosafety seriously.

4 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 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.

4.1 THE CONSTITUTION

The Constitution of the Republic of South Africa 108 of 1996 is the highest 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.

4.2 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, the employment of an independent consultant; identification of environmental issues and full details regarding alternatives, in the said Scoping Report, as required by the ECA Regulations.

It is our contention that if the EC is satisfied that the applicants have been able to produce a Scoping Report, (which has not been furnished to the Centre) it is our contention that the Applicant has not fully complied with the requirements of the ECA Regulations.

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

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.

It is our contention that the Applicant has failed to comply with section 3(1) of the ECA Regulations. We have thoroughly perused the information furnished to us, and have not found any evidence to show that the Applicant had complied with these provisions.

In terms of section 2(2) of the ECA Regulations, 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.

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 brief project description;

a brief description of how the environment may be affected;

a description of all alternatives; and

an appendix containing a description and public participation process followed, including a list of interested parties and their comments.

We have thoroughly perused the information furnished to us, and have not found any evidence to show that the Applicant had complied with these provisions. It is our contention that the Applicant has failed to comply with subsections (c) and (d) above

In the circumstances, the Applicant is obliged to withdraw its application.

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

The objectives contained in the preamble of the GMO Act state that the Act is intended to provide for measures to, among other things, 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 discussed in these objections, it is our contention that the proposed field trials of the GM events presents a hazard to the environment.

4.4 THE NATIONAL ENVIRONMENTAL MANAGEMENT ACT 107 OF 1998 ("NEMA")

The Preamble to NEMA has been promulgated pursuant to the environmental protections guaranteed by the Constitution. There are a number of provisions in NEMA that have 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).

It is clear from the discussion 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; and

6. The obligation to minimise negative impacts on the environment and on people's environmental rights (section 2(4)(a)(viii) 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.

It is our respectful submission that the application must be refused because the GMOs in question pose unnecessary and unacceptable risks to the environment. Indeed, as we have illustrated above, the statutory framework obliges the EC to inter alia adopt a risk adverse approach in assessing environment hazards.

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