AFRICAN CENTRE FOR BIOSAFETY

Objections to the Application made by Syngenta South Africa in Respect of the Following Events to the National Department of Agriculture, South Africa

1. Trial Release of GMO Cotton: Broadspectrum Resistance to Lepidopteran Pests (COT200-Cry1Ab) Stacked Cotton
2. Trial Release of GMO Cotton: Broadspectrum Resistance to Lepidopteran Pests (COT102-Cry1Ab) Stacked Cotton
3. Trial Release of GMO Cotton: Herbicide Tolerant
4. Fast Track Application of Trial Release with Event COT102/COT200 Cotton
5. Fast Track Application of Trial Release with Event Glyphosate Tolerant Cotton

Prepared by

Mariam Mayet and Shenaz Moola

11th July 2004

TABLE OF CONTENTS

STRUCTURE OF OBJECTIONS

This document is structured as follows:

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

SUMMARY OF GROUNDS FOR REJECTION OF SYNGENTA'S APPLICATION

1. Provision of false and misleading information material to the approvals sought

The notifier claims that there are no wild relatives of cotton in South Africa (5.5 of the application). It has come to our attention that this is not the case and we have a concern that we have been misled by the notifier's claims in this regard. There are about 39 species of *Gossypium*. They are found worldwide in the tropics and warm temperate regions with several species cultivated. There are three species in southern Africa, occurring in northern Namibia, Northern Botswana, Northern Province, Mpumulanga, Swaziland and KwaZulu-Natal[9]. These three species of *Gossypium* are *Gossypium anomalum* subsp. *anomalum* which occurs in Namibia, *Gossypium herbaceum* subsp *africanum* which occurs in Namibia, Botswana, Limpopo, Mocambique, Swaziland and KwaZulu-Natal and *Gossypium triphyllum* which occurs in Namibia and Botswana[10]. According to Cotton South Africa and contrary to the notifier claim, cotton does have a wild relative, *Gossypium herbaceum* subsp. *Africanum,* found in South Africa. The possibility for gene transfer in locations in Hawaii and Florida, where wild or feral cotton relatives exist has led to the EPA imposing stringent sales and distribution restrictions on Bt crops within these states.

2. Rights of access to information severely restricted; no meaningful public participation

In response to the Centre's application to the National Department of Agriculture (NDA) in terms of the Promotion of Access to Information Act ("PAIA") for access to information, we have received an astonishing paucity of information. We have been left with little choice, but to conclude that the NDA and the applicant have obstructed us from conducting any meaningful assessment of the application. Indeed, it is self-evident that the NDA has given the Applicant *carte blanche* to exercise an arbitrary decision regarding the information that has been withheld from us, on the grounds that such information is considered by the Applicant to be confidential business information (CBI).

This biased and grossly inequitable situation has arisen principally, because the NDA has failed to establish a proper formal process for the determination and characterisation of what constitutes CBI.

The issue of the public's right to access information concerning genetically modified organisms (GMOs) has been thoroughly canvassed in the court papers submitted by the Trustees of the Biowatch Trust ("Biowatch") in its application brought before the High Court of South Africa (Transvaal Provincial Division) Case Number 23005/2002, acting in the public interest.

The Centre associates itself with the relief sought by Biowatch, **and we expressly reserve our rights in this regard.**

We also note with extreme dissatisfaction that we have not been furnished with the results of the previous field trials the Applicant says it has conducted in South Africa, despite repeated requests for such information.

In the circumstances, we have been severely prejudiced in our abilities to meaningfully participate in this application.

3. Scientific objections

1. The assessment of the application in terms of the protocol and risk assessment was made difficult due to lack of supporting documentation and list of references cited. The data on the previous trials was not supplied to us despite an explicit request in our PAIA application.

2. It is not clear which transgenic lines will be cultivated and at which of the proposed sites. The details of the site are contained within Appendices, copies of which have not been supplied to us

3. The detail of the introduced gene sequences is not clear as several possible permutations are possible as outlined in the Syngenta patent application. None of the molecular characterisation detail has been made available and the designation of the bulk of this information as CBI has compromised our ability to assess the full impacts of the transgene.

4. Contrary to the notifier claim regarding gene stability, unintended effects that are not detected in the lab and that may only become apparent in the long term, cannot be ruled out.

5. The development of insecticide/pesticide resistance is of concern due to losses incurred by food producers, disease spread by resistant insects, the introduction of newer, stronger pesticides and the increased use of pesticides. There is a concern that the development of resistance in the target organism could result in the use of higher toxicity pesticides.

6. No reference has been made to the relatively large body of literature on the impacts of genetically engineered plants, including impacts on non-target organisms, the emergence of superweeds and persistence of the Bt toxin.

7. Several possible categories of non-target organisms, including beneficial species, such as the natural enemies of the target pests, pollinators including insects and avian species, non-target herbivores, soil organisms, endangered species and

species that contribute to local biodiversity are at risk of exposure to Bt toxins. The levels of expression of Bt toxins in pollen is much higher than in other parts of the transgenic plants and this has raised concern for the impacts on non-target organisms.

8. Gene stability is a contentious issue and the stability in particular of the CaMV promoter to drive expression of the gene has of late raised concern because of effects such as generation of novel viruses, mutagenicity and carcinogenicity.

9. 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.

4. EC has a constitutional and statutory duty to protect the environment.

We strenuously object to the environment of South Africa being exposed to risks just because the world's largest agrochemical company requires a nursery in the Southern hemisphere, for the breeding of its transgenic seeds, which it intends to export to the United States for cultivation there.

It is the Centre's respectful submission that the Executive Council is obliged to refuse the approvals sought by the Applicant because the release of the GMOs in question, poses unnecessary and unacceptable risks to the environment. Indeed, the EC has a duty to refuse the approvals in terms of section 24 of the Constitution, in order to protect the environment.

Taking into account our scientific assessment, it is our respectful submission that the EC has no choice, but to refuse the application, because the statutory framework obliges the EC to adopt a risk adverse approach in assessing environment hazards.

5. Failure to Comply with ECA and ECA Regulations

The "*genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism*" is a listed activity in terms of section 6 of Regulations GNR 1182 of 5th September 1997 read together with sections 21 and 22 of the Environment Conservation Act.

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.

An examination of the information furnished to the Centre does not reveal any evidence that the Applicant has complied with these provisions.

In the circumstances, the Applicant is obliged to withdraw its application. In fact, the EC is not authorised to grant the application sought by the Applicant, until such time as these provisions have been complied with.

6. Environmental Assessment in terms of section 78 of NEMBA

We are aware that the National Environmental Management Biodiversity Bill will come into effect on the 1 August 2004. We place on record, that we will, on the 1 August 2004, be approaching the Minister of Environmental Affairs and Tourism to act in terms of section 78 of what will then be, the National Environmental Management Biodiversity Act (NEMBA) to require an environmental assessment for all of the events the applicant seeks to test in open field trials. We believe that we have provided ample grounds in this submission for the Minister to come to the inescapable conclusion that the GM cotton events "may pose a risk to the environment" and therefore, require that environmental assessments be conducted in terms of Chapter V of NEMA, before the EC takes a decision.

PRELIMINARY ISSUES

Discrepancies in information provided

The notifier claims that there are no wild relatives of cotton in South Africa (5.5 of the application). It has come to our attention that this is not the case and we have a concern that we have been misled by the notifier claims in this regard. There are three species in southern Africa, occurring in northern Namibia, Northern Botswana, Northern Province, Mpumulanga, Swaziland and KwaZulu-Natal. Cotton also has a wild relative, *Gossypium herbaceum* subsp. *Africanum,* found in South Africa. The presence of these species has important implications for transfer of the genetic material. The possibility for gene transfer in locations in Hawaii and Florida, where wild or feral cotton relatives exist has led to the EPA imposing stringent sales and distribution restrictions on Bt crops within these states. We are also unclear about whether the herbicide tolerant line being tested has any introduced genes for insect resistance.

Credibility of Syngenta

It is evident from the above, that the Applicant has provided incorrect and misleading information to the NDA and the EC, in order to obtain approval.

The provision of false and misleading information calls into question the veracity of all information furnished by the Applicant and as such, all the information it has submitted in support of this application, should be viewed with the utmost caution.

The Centre thus respectfully requests that the EC refuse the application and conducts an investigation and independent verification of all information submitted by Syngenta in regard to the current application.

Access to information severely restricted; no meaningful public participation

The extent to which we have been severely impeded from meaningfully participating in this application is self evident from our scientific assessment below. However, we deal here with a few issues in more detail:

- On the 1 July 2004, the Centre requested access to the information in terms of PAIA, as is set out in annex I to this submission.

In response to this request, the Centre has been furnished with documents that contain so little information that we are left with no choice but to conclude that the NDA and the Applicant have obstructed us from conducting any meaningful assessment of the application. Indeed, it is self-evident from the documentation received by us, and from our scientific assessment, that the NDA has given the Applicant *carte blanche* to decide at its own discretion, what information could be withheld from us, ostensibly on the grounds that such information is CBI.

This biased and grossly inequitable situation has arisen principally, because the NDA has failed to establish a proper formal process for the determination and characterisation of constitutes CBI. The NDA has opted rather for a system whereby arbitrary decision-making takes place on the part of the Applicant.

- Examples of the information the NDA has allowed the Applicant to declare as CBI include such pertinent information as the genetic inserts and the molecular characterisations of the GMOs in question. This situation is wholly inconsistent with the rationale, spirit and principles of the Cartagena Protocol on Biosafety ("Biosafety Protocol"). In terms of Article 18 of the Biosafety Protocol, South Africa is obliged to take measures to require that living modified organisms (LMOs) that move across borders are handled, packaged and transported safely. The aim is to avoid adverse effects on biodiversity and risks to human health. At the First Meeting of the Parties (MOP) Kuala Lumpur, 23-27 February 2004, it was decided that the documentation accompanying LMOs imported for direct introduction into the environment (such as the GM seeds Syngenta is now seeking permission to import in order to conduct field trials), clearly identifies the LMOs by describing its names and traits, including transgenic traits such as transformation events and its unique identification.

We have no knowledge that the Applicant has indeed complied with these requirements. However, in the event that it has, this means that the following categories of people will have access to the information the Applicant and the NDA is now denying to us:

- Customs officers in the United States;
- The Ship's Captain;

- The forwarding agents in the United States;
- Customs officers in South Africa; and
- The importer's clearing and forwarding agents.

These people will thus have far greater rights of access to the on accompanying documentation, than we currently have.

The issue of the public's right to access information concerning GMOs has been thoroughly canvassed in the court papers submitted by the Trustees for the time being of The Biowatch Trust ("Biowatch") in its application brought before the High Court of South Africa (Transvaal Provincial Division) Case Number 23005/2002, acting in the public interest. The said court application was instituted by Biowatch, against: The Registrar; the EC; the Minister of Agriculture; Monsanto South Africa (Pty) Ltd; and Stoneville Pedigreed Seed Company.

The said application brought by Biowatch has already been argued before Dunn JA, and judgement is anticipated in early August 2004. The relief thus sought by Biowatch, regarding access to information concerning GMOs as set out fully in Biowatch's Application, is thus germane generally, to the public's right to information, and in this regard, the Centre associates itself with the relief sought by Biowatch and expressly reserves its rights in this regard.

- We have also not been furnished with the results of the previous field trials, the Applicant contends, it has conducted in South Africa, despite our repeated requests for access to such information.

We are therefore, not in a position to assess *inter alia*:

- The scientific design of the previous field trials;
- Whether the Applicant is able to answer key questions regarding the safety of the GM events in question, particularly, ecological risks;
- The justification and data used by the Applicant in obtaining the previous field trial permits;
- Whether the data produced by the Applicant from these previous field trials is able to support the claims of the Applicant in relation to the previous and proposed field trials;
- Whether the Applicant has complied with permit conditions; and
- Whether the proposed field trials will be able to provide the information necessary for the formulation of conclusions about ecological safety.

SCIENTIFIC ASSESSMENT

Applications by Syngenta South Africa

On 11th June 2004 Syngenta South Africa placed a public notice in The Beeld informing the public that authorisation was being sought to conduct field trials using genetically modified cotton. The events in question are COT102-Cry1Ab Cotton, COT200-Cry1Ab Cotton and Herbicide Tolerant Cotton.

Application for Trial Release of COT102-Cry1Ab Cotton: Available Information

A copy of the application submitted by Syngenta South Africa (the Notifier) for field trials of COT102-Cry1Ab Cotton, excluding confidential business information has been furnished to us. According to this application, a brief description, objective of the release, information on the organism and novel genetic material, questions related to a general trial release, crop or pasture plants, monitoring and accidents and pathogenic and ecological impacts have been completed. The list of cited references in response to the application questions has not been provided.

Application for Trial Release of COT200-Cry1Ab Cotton: Available Information

A copy of the application submitted by Syngenta South Africa (the Notifier) for field trials of COT200-Cry1Ab Cotton, excluding confidential business information has been furnished to us. According to this application, a brief description, objective of the release, information on the organism and novel genetic material, questions related to a general trial release, crop or pasture plants, monitoring and accidents and pathogenic and ecological impacts have been completed. The list of cited references in response to the application questions has not been provided.

Application for Trial Release of Herbicide Tolerant Cotton: Available Information

A copy of the application submitted by Syngenta South Africa (the Notifier) for field trials of Herbicide Tolerant Cotton (HTC), excluding confidential business information has been furnished to us. According to this application, a brief description, objective of the release, information on the organism and novel genetic material, questions related to a general trial release, crop or pasture plants, monitoring and accidents and pathogenic and ecological impacts have been completed. The list of cited references in response to the application questions has not been provided.

Application for Fast Track Permits for COT102/COT200 Cotton and Herbicide Tolerant Cotton

In addition, fast track permits are being sought by Syngenta South Africa for the import of the above-listed insect resistant and herbicide cotton events from the USA. It would appear that import permits for the above mentioned events have been previously granted.

Background

Bacillus thuringiensis: Mode of Insecticidal Action

Bacillus thuringiensis (Bt), a common soil bacterium produces insecticidal proteins during sporulation. Each of the several thousand strains of Bt that exist produces its own unique insecticidal crystal protein (delta endotoxin)[1], each of which displays differing insecticidal activity, but with a similar mode of action. Typically, ingested delta endotoxins are dissolved in the insect midgut liberating the protoxins of which they are comprised. These undergo proteolysis and one of the fragments binds to the cells of the insect midgut epithelium, disrupting the osmotic balance and forming pores in the cell membrane causing cell lysis, gut paralysis and death within a few hours of ingestion[1,2].

More recently, proteins produced during the vegetative stage of Bt growth, called vegetative insecticidal proteins (Vips), have been identified[3,4]. The *Vip3A* gene in particular, codes for an 88-kDa Vip3A protein that possesses insecticidal activity against a wide range of *Lepidoptera* with acute activity towards the black cutworm, the fall armyworm and beet armyworm. Vip3A ingestion, similar to the delta-endotoxins, results in cessation of feeding, loss of gut peristalsis, overall paralysis of the insect and death. The difference appears to be in manifestation of the symptoms, at 48-72 hrs for Vip3A proteins and 16-24 hrs for delta endotoxins with Vip3A producing an acute toxicity relative to that caused by delta-endotoxins[3]. The molecular target of the Vip3A protein when compared to that of the Cry1Ab delta endotoxin has been shown to be different with distinct ion channels being formed[5].

Glyphosate Tolerance

The bacterial gene (*aroA*) that encodes 5-enol-pyruvyl-shikimate-3-phosphate-synthase (EPSPS) is inserted into transgenic plants to confer glyphosate resistance[6]. Monsanto maize line GA21 is glyphosate tolerant due to the insertion of a plant gene encoding a modified version of the EPSPS protein. EPSPS plays a role in chloroplast amino acids synthesis and the naturally occurring plant form is inhibited by glyphosate unlike the bacterial or modified plant EPSPS enzyme, both of which have reduced affinity to glyphosate and hence confer tolerance[6].

The Host Plant and the Transgenic Forms: Description and Characteristics

Gossypium hirsutum is a Mexican cotton, wild populations of which are found in coastal vegetation of Central and southern North America[7]. Historical documents from 1516 show that a type of wild cotton species which exists to this day was grown in South Africa. In terms of Section 102 of the Co-operative Societies Act (Act 29 of 1929) cotton was officially declared an agricultural crop in 1939[8]. There are about 39 species of *Gossypium*. They are found worldwide in the tropics and warm temperate regions with several species cultivated. There are three species in southern Africa, occurring in northern Namibia, Northern Botswana, Northern Province, Mpumulanga, Swaziland and KwaZulu-Natal[9]. These three species of *Gossypium* are *Gossypium anomalum* subsp. *anomalum* which occurs in Namibia, *Gossypium herbaceum* subsp *africanum* which occurs in Namibia, Botswana, Limpopo, Mocambique, Swaziland and KwaZulu-Natal and *Gossypium triphyllum* which occurs in Namibia and Botswana[10].

Question 4.3 of the applications to the Department of Agriculture in South Africa for the trial release of events COT102-Cry1Ab Cotton (hereinafter designated as C1), COT200-Cry1Ab Cotton (hereinafter designated as C2) and Herbicide Tolerant Cotton (hereinafter designated as C3) requests information regarding the genetic and resultant phenotypic modifications of the GMO, including the origin of the inserted DNA, the procedure used to induce the genetic modification and the extent to which it has been characterised. For all three applications, the notifier (Syngenta) response to this question is "CBI deleted". The aim of these trials is for the "collection of additional efficacy and agronomic data"[11].

Gossypium hirsutum has been modified to yield the transgenic forms C1, C2 and C3. From the public notice (The Beeld, 11 June 2004), C1 and C2 have genes isolated from Bt that code for Vip3A (Bt strain AB88) and Cry1Ab proteins that confer control of lepidopteran pests. Additionally, COT102 has a selective marker that has been isolated

from *Escherichia coli*. A herbicide tolerant line, C3, containing the EPSPS gene derived from soybean has also been developed; it is not clear if this is in combination with the insecticidal trait. The insecticidal protein being expressed has specific activity to the African bollworm, tobacco budworm, American bollworm and pink bollworm[11].

Further information regarding these events has been obtained by accessing the United States Environmental Protection Agency (USEPA) documents, patent applications and documents of the Australian Competent Authority. The Syngenta petition to the USEPA (docket ID number 2003-0164)[4] reported that the Vip3A gene in the transformed plant is very similar to Vip3A like genes occurring commonly in a variety of Bt sources. Mammalian toxicity tests of the Vip3A protein were conducted[4] by monitoring impacts of administering high doses of the Vip3A protein to mice, measuring degradation of Vip3A in simulated gastric fluid and checking for sequence homology of the Vip3A protein to proteins known to be mammalian toxins or human allergens. Their conclusion was that the Vip3A protein will be non-toxic to humans. C1 also contains an antibiotic resistant marker gene (*hph*) conferring resistance to hygromycin[12]. C2 does not contain this selective marker. Hygromycin B phosphotransferase (APH4) protein catalyses the phosphorylation of hygromycin and closely related aminoglycoside antibiotics.

Syngenta US Patent 6,429,360[13] for Bt Vip genes mentions changes in DNA sequence regarding the promoter, introns, terminator and polyA signals. This allows for full functioning in the plant cells of the Bt-Vip3A protein to induce apoptosis, a form of programmed cell death common to all cells with discrete nuclei (eukaryotes). Death domains and sequences are key regulators in apoptosis where a cell will suicide to avoid tissue damage as a defence say against virus invaders. The Syngenta patent discusses Vip3a toxin binding to death sequences receptors. The apoptosis death sequences receptors display a relative homology and since they have evolved in all eukaryotes, the best hypothesis is that they are related. The possibility of toxicity to mammals can therefore not be discounted and should be expected[14].

In the discussion under "Plant Expression Cassettes" in the Syngenta Investment Corporation Patent 6,429,360[13] it is stated that "The novel toxin genes of the present invention, either as their native sequence or as optimized synthetic sequences as described above, can be operably fused to a variety of promoters for expression in plants including constitutive, inducible, temporally regulated, developmentally regulated, chemically regulated, tissue-preferred and tissue-specific promoters to prepare recombinant DNA molecules, i.e., chimeric genes. Preferred constitutive promoters include the CaMV 35S and 19S promoters". In the absence of the informatiom regarding the exact promoters used for the devlopment of the transgenic lines under consideration in the application, we can only assume that the CaMV 35S promoter might form part of the plant expression cassette.

The CaMV 35S promoter has been found to have a recombination hotspot where it tends to fragment and join with other double stranded DNA in very non-specific way[15]. These hotspots are flanked by multiple motifs involved in recombination and functions efficiently in all plants, green algae, yeast and *Escherichia coli*. The potential exists for the viral genes to recombine with other viruses to generate new infectious virues[17], carcinogens and mutagens and reactivate dormant viruses.

Detractors claimed that virus infected cabbages and cauliflower have been consumed for years with no ill effects and that similar pararetroviral sequences occur widely in plants

causing no apparent harm[16]. That the intact virus causes no obvious harm in the natural host is related to the fact that its integrity is maintained and that it is adaptive to the host biology. This is unlike the fragments of naked DNA as in transformed plants where the natural regulatory mechanisms are not present[17]. A call has been made that the use of the CaMV promoter in transgenic plants be phased out due to the structural instability arising out of its use[18]. Information relating to "event specific" molecular analysis for these events have not been provided. We believe it to be necessary that such molecular characterisation be carried out for these events and submitted or if it has been carried out be made available for independent scrutiny.

Concerns Regarding the Use of Transgenic Plants

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[19.] These weeds may then be able to successfully outcompete other non-herbicide–resistant weeds[20]. This may result in increased use of herbicides in greater volumes and varieties with possible negative impacts on soil and groundwater[21]. Increased herbicide use may also result from less restrained herbicide application arising from producer confidence that the desirable plant will be unaffected.

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[22].

Insecticide Resistance and Susceptibility Effects: Nature and Development

Insecticide/Pesticide resistance is of concern due to losses incurred by food producers, disease spread by resistant insects, the introduction of newer, stronger pesticides and the increased use of pesticides. Any insect population will have individuals that are genetically able to withstand the toxic effects of pesticides. These resistant individuals will pass on their genes to subsequent generations and over time the proportion of unaffected individuals will increase. The first evidence of resistance to a Bt toxin was published in 1985[23], since when laboratory studies have selected for Bt resistance in several more susceptible species. Whilst the mechanism of insecticide resistance is very complex, studies in resistance have found the main mechanism to be a change in the membrane receptors to which the Bt toxins bind. These changes include either a change in the number of receptors (increase or decrease) or alterations in receptor binding affinity or a combination of the two[1].

Mitigation measures to slow down the development of resistance include minimising exposure to toxins and ensuring the presence of large numbers of susceptible individuals thereby retaining the susceptible genetic characteristic. Transgenic plants based on Bt are particularly susceptible to resistance development because of the continuous exposure of insects to toxins. A second method combines different modes of action e.g. herbicide and pesticide resistance, relying on the hope that the development of resistance to more

than one more control is less likely. It is also proposed that the combination of the Cry and Vip toxins with their varying modes of action is part of the strategy to delay resistance development[5]. A third method employs trap plants to lure pests away from productive crops.

The reality however is that field conditions are unpredictable and the available information on pests and their interactions is not adequate to ensure compliance with any of the proposed management models. The fact that transgenic crops produce toxin continuously is not a benefit when it comes to insecticide resistance development. The currently developed methods for producing transgenic crops do not allow for time specific expression of toxins. The use of Bt as a foliar spray as has been used by organic farmers would be a better alternative allowing for targeted treatment and avoiding toxin overexposure[1].

A Greenpeace report reviewing the Chinese experience of genetically engineered Bt cotton found adverse environmental impacts after just five years of commercial growing, concluding that the variety would be ineffective in controlling pests after eight to ten years of continuous production. Laboratory studies found that there was a build up of resistance in the cotton bollworm and that susceptibility of bollworm to the Bt toxin fell to 30 percent after 17 generations under continuous feeding with Bt cotton leaves. Other signs of destabilization of the insect community were evidenced by a significant reduction of the parasitic natural enemies of cotton bollworm and an increase in secondary pests. The loss of the primary insect pest created a vacuum for amongst others, cotton aphids, cotton spider mites and thrips in some of the cotton fields[24]

Persistence of Bt Toxin

There is a concern that constant low level exposure of the target insects to the Bt toxins could result in these organisms themselves developing resistance to the toxin[22]. This could result in the use of higher toxicity pesticides[20]. Researchers found Bt toxin in the soil after 200 days, indicating slow degradation[25].

A preliminary study on the influence of Bt toxins on glyphosate under laboratory conditions found that Bt toxins enhance the persistence of glyphosate in the soil[26]. The mechanism is unclear because soil microbial activity was not affected. The transgenic cotton has genes that code for both herbicide resistance and for production of Bt toxin. Interactions between the products of these genes have not been previously considered and more investigation is necessary to determine the combined effects.

Bt Toxicity Effects on Non-target Organisms

Non-target organisms refer to those that are not the target of the pest control method, in this case the presence of a gene coding for Bt toxins. There are several possible categories of non-target organisms, including beneficial species, such as the natural enemies of the target pests, pollinators including insects and avian species, non-target herbivores, soil organisms, endangered species such as the monarch butterfly and species that contribute to local biodiversity[27]. For the most part toxicity studies completely disregard effects on non-target organisms. Results which show no toxicity effects on non-target pests are often taken as confirmation that these organisms are unaffected. Many studies often do not take into consideration any possible pre-mediated toxicity effects[28]. For example green lacewing larvae fed the Bt toxin directly exhibited no ill effects, but green lacewing larvae fed on prey that fed on Bt maize exhibited prolonged

development times[29]. The levels of expression of Bt toxins in pollen is much higher than in other parts of the transgenic plants and this has raised concern for the impacts on especially the monarch butterfly populations[28].

The Gene Technology Technical Advisory Committee, a statutory advisory committee of the Office of the Gene Technology Regulator in Australia, in consideration of the Risk Assessment and Risk Management Plan on COT102 submitted by Syngenta advised that Syngenta should be requested to provide further information and data on the toxicity of the GMO to non-target organisms and the biochemical pathways involving Vip3A protein and that research should be commissioned to investigate potential risks to non-target insect species[30] and soil biota[12].

Toxicity Protocols of the Syngenta Cotton Events

Genes introduced into plants, whilst based on naturally occurring gene sequences, are synthesised *de novo* in the laboratory by the introduction of regulatory sequences such as introns, polyA signals, promoters and enhancers to promote gene expression in the transgenic plant. To function fully, the Bt Vip3A gene sequence has been similarly modified. The Syngenta Petition to the EPA[4] for tolerance in or near food reports that the synthesised Vip3A gene is homologous to Vip3A in several Bt strains. The changes in the regulatory sequences, previously referred to by Syngenta in the patent application, were not referenced in the EPA report of the Syngenta petition. Toxicity testing was carried out based on the toxicity impacts of the naturally occurring toxin and not on the truncated form modified to behave optimally in the plant, and the potential impacts of the inserted sequences were not measured.

Cross Pollination

Whilst it is accepted that cotton is primarily a self-pollinator (4.8.2) the possibility of gene transfer cannot be discounted. The Australian Gene Technology Regulatory Authority in granting a licence to Syngenta for the release of the cotton lines COT102, COT200 and COT102/Liberty nevertheless imposed conditions on Syngenta for the establishment of a 400m research zone around the proposed GM cotton trials comprising plantings in excess of one hectare[12]. The imposition of this condition on the granting of the licence was intended to confirm research on gene flow and to validate containment measures. According to Cotton South Africa and contrary to the notifier claim, cotton does have a wild relative, *Gossypium herbaceum* subsp. *Africanum,* found in South Africa. The native population have been utilising cotton products from this strain since the 1500's[8]. This is in addition to the other species of cotton mentioned previously [9]. The opportunities for cotton transfer to sexually compatible wild plant species is therefore not "zero".

The possibility for gene transfer in locations within the United States where wild or feral cotton relatives exist (Hawaii and Florida) has led the Biopesticides & Pollution Prevention Division (BPPD) proposing containment provisions for these states[31]. The USEPA has reviewed the potential for gene capture and expression Cry endotoxins in cotton by wild or weedy relatives of cotton in the United States, its possessions or territories. The possibility for gene transfer in locations in Hawaii and Florida, where wild or feral cotton relatives exist has led to the EPA imposing stringent sales and distribution restrictions on Bt crops within these states. These containment measures are intended to prevent the movement of Cry1Ac from Bt cotton to wild or feral cotton relatives that exist in Hawaii and Florida[32].

Trial Release

The following is a list of concerns and questions regarding the information provided by Syngenta. The designations C1, C2 and C3 will continue to be used in the subsequent sections and will refer to the respective applications for each of these events. The stated objective of the trial to evaluate (3.1) entomological efficacy and agronomic fitness makes reference to 4.3, of which the information has been designated CBI. Part of the trial aim is to harvest seeds for use in further trial in the USA in 2005. No alternative approaches/methods to the release of the GMO, as requested in the application, are identified by the Notifier.

The mode of introduction of the inserts is unclear and the nature of the molecular characterisation has not been disclosed. The lack and designation as CBI of information crucial to a meaningful and informed response necessitate a general response on the impacts of introduced gene sequences. Unintended effects of gene sequence manipulations are not always detected in the lab and may only become apparent in the long term. There are possible unintended effects of the presence of non-native fragments in the transgenic plants. The inserted gene sequences may interrupt native gene sequences and/or their promoters[27]. What is of concern here is the possible production of novel proteins from the transcription of unintended fragments. It cannot be assumed that unintended fragments are non-functional fragments or not transcribed and any such claim needs to be subjected to greater scrutiny and more investigation. Extra gene fragments in Monsanto's Roundup Ready Soya were also claimed to be non-functional and not-transcribed[33], but were later found to be transcribed to produce RNA[34,35,36.] Further, it is not clear if the insert or fragments thereof lie on any 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[27] necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment.

Syngenta claim, in response to question 4.4 of the application to the Department of Agriculture in South Africa, that no instability of the inserted gene was observed after selfing and backcrossing. No detail is given of the period (generations) that these events were observed for gene instability. The basis on which Syngenta makes these claims cannot be properly assessed, as they cite no sources or data to substantiate their claims. Secondly, 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.

Trial Release: General

This section details our responses to the notifier application responses under the heading in the application form; "Trial Release: General".

Responses to 5.1.1 and 5.1.3 refer to an Appendix C copies of which have not been provided to us. The response to 5.1.6 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.

The response to 5.2 claims that no possible hazardous or deleterious effects were identified in field studies in the US. 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. Further mention is made of the environmental studies to measure the impact of the Cry1Ab insect control protein in laboratory studies. It is not clear if the Cry1Ab protein used in the laboratory studies is the naturally occurring form or the truncated form of the gene as is found in transgenic plants with additional promoter and other inserted gene sequences. Can we assume that the lack of mention of similar toxicity studies on the impacts of the Vip3A protein suggests that these have not been carried out?

The notifier claim that the Cry1Ab protein is practically non-toxic to avian, aquatic insect and soil invertebrate species. 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[37]. Recombinant DNA fragments and Cry1Ab protein was also found in the gastrointestinal contents of pigs fed genetically modified corn [38]. Cry1Ac protoxin has been demonstrated to bind to the mucosal surface of the mouse small intestine and to induce in situ temporal changes in the electrophysiological properties of the mouse jejenum[39].

The response to 5.3 in the C1 and C2 application states that trial of the parent were carried out in the US and in South Africa. Field trials of the herbicide tolerant line were only carried out in the US. It is also not clear from the questionnaire what the release of similar GMOs might refer to – is it a reference to (a) genetically modified higher plants, (b) all plants which have been engineered to code for Bt toxins, which would then include maize, Soya and cotton amongst others or (c) Bt cotton only. It is unclear which releases are being referenced in 5.3.1 and 5.3.2 as no details of actual releases are provided in 5.3. 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 notifier and not necessarily based on actual release data.

The claim in 5.3.3 that no adverse consequences have ever been observed in the previous trial of these events is not supported by the body of literature. A simple example relates to Cry1Ab protein degradation from Bt maize in the field. Researchers found Bt toxin in the soil after 200 days, indicating slow degradation, much slower than the EPA had reported in 2000[25]. Whilst much research needs to be done to verify the impact of these transgenic fragments in mammalian guts, there is a concern about the possible impacts of Bt transgenic crops which confer resistance to antibiotics, such as that developed by Novartis[22]. There is a very real risk that the antibiotic resistance could be transferred to harmful gut bacteria.

No reference is provided for the trials in the USA and South Africa and no details of the trials trial and where this report can be found (5.4.1 and 5.4.2) is supplied.

5.5 deals with the issue of gene transfer. The notifier discusses the possible transfer of the genetic trait by pollen from transgenic plants. Cotton South Africa claim that a wild type form of cotton is found in the environment in South Africa to this day[8]. Whilst it is true that the cotton pollen grains are round and heavy, which limits their dispersal range, similarly round and heavy pollen grains of the maize plant have been found to 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[37,38]. There is still much work that needs to be done to determine behaviour of these fragments.

Question 5.6 of the application asks about possible deleterious effects on the host or related species and other organisms, which might be exposed to the transgenic plant. We understand the question to be asking more broadly about any reported deleterious effects and not just those that might be observed from handling the transgenic plants, as the notifier has appeared to interpret the question to mean. Several studies have been conducted into the potential impact of the insect resistant trait on a wide range of organisms, but the notifier has reported none of this information. Non target effects (5.8.3) of transgenic plants have been widely reported and are discussed above. There are several possible unintended fragments in transgenes and the fact of 99% homology cannot be taken as given that no unintended effects will be detected without any empirical evidence (5.8.1).

As discussed previously, no real risks have been identified by the notifier (5.9). Not even unlikely risks are identified despite the notifier defining cross pollination as an unlikely event (4.8.2). The field trials are not designed to monitor what the notifier considers to be low probability risks, such as gene transfer by cross pollination. There are no plans to monitor impacts on non-target organisms despite the various papers that have been published on the subject, as discussed previously.

The consequences of the organism persisting in the environment are not adequately addressed (5.10). From the release protocol it appears that post trial monitoring will only be for one season and the emergence of cotton volunteers through possible water dispersal, such as by flooding, and improper handling and transport has not been addressed at all. Additionally the herbicide that might be used to control any volunteers (C3) that do appear has not been identified by the notifier.

Crop or Pasture Plants

Notifier responses to the questions in the application under **Crop or Pasture Plants** makes the same claims as previously (Trial Release: General) that no adverse effects have been observed, that there is no evidence of gene transfer, toxicity effects are minimal and that there are no impacts on non-target organisms. The claims have been responded to above.

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. As stated previously, the results obtained from the numerous laboratory and field trials cannot be assessed as no details of these trials have been provided. It is usually necessary to be able to assess the cited literature so as to make an assessment of research design and its relevance to the situation *in situ*. Experiments are often poorly designed or conducted under very controlled and artificial conditions that make meaningful extrapolation to the situation in the field difficult if not impossible.

Main Findings and Response to the Notifier Application

- To ensure a meaningful and comprehensive response to the notifier application it would have been useful if the notifier had provided detail specifically regarding the molecular characterisation information and a more explicit presentation of the data, methods, analyses and interpretations. It is unclear why some of the information that is available within the public domain such as in EPA petitions and patent applications is marked as CBI. All this designation has served is to make more difficult our task of accessing this information, which is surely not in the interests of a transparent, fair and equitable engagement by the notifier with the public.

- No assessment could be made of the stability of the transgenic line as none of the information regarding the molecular characterisation has been made available. The current European Directive (2001/18/EC) on the deliberate release of GMOs recommends an event-specific characterisation of the insert, which gives the structure of the insert as well as the host genome sequences flanking the insert, proving insert stability over successive generations. We do not know if any such characterisation was carried out.

- It is not clear which transgenic lines will be cultivated and at which of the proposed sites. The details of the site are contained within Appendices, copies of which have not been supplied to us. The document entitled "Risk Assessment for the import of herbicide tolerant cotton events from the USA" has appended to the back a list of eight trial sites. Are we to assume that these sites apply only to field trial with the herbicide tolerant strain as the corresponding risk assessment documents for the COT102-Cry1Ab and COT200-Cry-1Ab have no trial site and situation information.

- 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. 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?

- 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. Claims are made regarding toxicity and possible harmful impacts of the transgenic organism on the biosystem without reference to any literature. 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 – 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.

- Syngenta 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. Annex III details the steps to be taken to achieve this objective. These include the identification of any novel genotypic and phenotypic characteristics associated with the GMO that may have adverse effects on biodiversity in the likely receiving environment, taking also into account the risks to human health; an evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO, an evaluation of the consequences should the adverse effects be realized; an estimation of the overall risks posed by the GMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized; a recommendation as to whether or not the risks are acceptable or manageable, including where necessary, identification of strategies to manage these risks; and where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or implementing appropriate risk management strategies and/or monitoring the GMO in the receiving environment. We are not in a position to make a determination of whether Syngenta has complied with the Protocol in terms of the Risk Assessment as the bulk of the information has been designated as CBI by the notifier.

- Article 16 of the Biosafety Protocol states says that each Party (i.e. South Africa) shall endeavour to ensure that any GMO, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use. The application for trial release claims that field trials have been carried out in the USA. Despite our request for the field trial information, this has not been forthcoming and we are unable to comment on whether Syngenta has complied with the Protocol in this regard.

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.

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.

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.

On the 3 June 2004, the Centre wrote to the Director-General (DG) of the Department of Environmental Affairs and Tourism (DEAT) to seek his confirmation that these statutory obligations have been complied with.

The Centre has sought confirmation also from the Registrar as to whether the said provisions had been complied with by the Applicant. However, to date, neither the DG of DEAT nor the Registrar, has responded to these enquiries. To date, no proof has been furnished that the applicant has indeed complied with these provisions.

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

In any event, it is our contention that if the EC is satisfied that the applicants have been able to produce a Scoping Report, (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-

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

-

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

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.

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. 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;

-

-

-

(vii) that a risk averse and cautious approach is applied, which takes into account the limits of current knowledge about the consequences of decisions and actions;

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

Section 2(4)(i) provides:

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

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

"24 Implementation

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

(a) the environment;

(b) socio-economic conditions; and

(c) cultural heritage;

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

-

-

-

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

(a) investigation of the environment likely to be significantly affected by the proposed activity and alternatives thereto;

(b) investigation of the potential impact, including cumulative effects of the activity and its alternatives on the environment, socio-economic conditions and cultural heritage, and assessment of the significance of the potential impact. **(emphasis added).**

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;**

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

7. **The obligation to evaluate the social, economic and environmental impacts of proposed activities (section 2(4)(I) of NEMA; and**

8. **The obligation to have regard to the cumulative potential impacts and effects of proposed activities on the environment, socio-economic conditions and cultural heritage (section 24(7)(b) of NEMA.**

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

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.

REFERENCES

[1] Neppl, C. C. (2000) Management of resistance to Bacillus thuringiensis toxins. *The Environmental Studies Program, University of Chicago*. May 26, 2000. http://camillapede.tripod.com/bapaper.html

[2] Tappeser, B. The differences between conventional Bacillus thuringiensis strains and transgenic insect resistant plants. Possible reasons for rapid resistance development and susceptibility of

non-targeted organisms. Third World Network. Briefing Paper No. 1. http://www.twnside.org.sg/title/diffe-cn.htm

[3] Yu, C-G., Mullins, M. A., Warren, G. W., Koziel, M. G. and Estruch, J. J. (1997) The *Bacillus thuringiensis* vegetative insecticidal protein Vip3A lyses midgut epithelium cells of susceptible insects. *Applied and Environmental Microbiology*. **63 (2)**, 532-536

[4] USEPA (2003) Bacillus thuringiensis VIP3A insect control protein; notice of filing a pesticide petition to establish a tolerance for a certain pesticide chemical in or on food. June 6, 2003. Docket ID:2003-0164. http://www.epa.gov/fedrgstr/EPA-PEST/2003/June/Day-06/p14199.htm

[5] Lee, M. K., Walters, F. S., Hart, H. Palekar, N. and Chen, J-S. (2003) The mode of action of Bacillus thuringiensis vegetative insecticidal protein Vip3A differs from that of Cry1Ab δ-endotoxin. *Applied and Environmental Microbiology*. **69 (8)**, 4648-4657. Mikyong.Lee@Syngenta.com

[6] Nielsen, K. M (2003) An assessment of factors affecting the likelihood of horizontal gene transfer of recombinant plant DNA to bacterial recipients in the soil or phytosphere. *Collection of Biosafety Reviews Vol1*. International Centre for Genetic Engineering and Biotechnology. Pp96-149

[7] Gossypium (Cotton). Museum of Cape Town. http://www.museums.org.za/bio/plants/malvaceae/gossypium.htm

[8] Cotton South Africa. History of Cotton in SA. http://www.cottonsa.org.za/history_cotton_sa.html

[9] Leistner, O.A. and Bredenkamp, C.L. (2000). Malvaceae. In O.A. Leistner (ed.), Seed plants of southern Africa: families and genera. Strelitzia 10: 347-352. National Botanical Institute, Pretoria.

[10] Bredenkamp, C.L. and Leistner, O.A. (2003). *Gossypium*. In G. Germishuizen & N.L. Meyer (eds), Plants of southern Africa: an annotated checklist. Strelitzia 14: 622. National Botanical Institute, Pretoria.

[11] Application for intentional (Conduct a trial) of a genetically modified organism into the environment in South Africa. *Department of Agriculture, South Africa*. Applicant: Syngenta South Africa (Pty) Ltd.

[12] Executive Summary of the Risk Assessment and Risk Management Plan for Application No. Dir 036/2003. (2003) *Office of the Gene Technology Regulator, Australia.*

[13] United States Patent 6,429,360. Syngenta Investment Corporation.

[14] Cummins, J. Death domains and sequences are late entries into crop genetic modification. jcummins@uwo.ca

[15] Kohli, A., Griffiths, S., Plcios, N., Twyman, R. M., Vain, P., Laurie, D. A. and Christou, P. (1999) Molecular characterization of transforming plasmid rearrangements in transgenic rice reveals a recombination hotspot in the CaMV 35S promoter and confirms the predominance of microhomology mediated recombination. *The Plant Journal*. **17**, 591.

[16] Hull, R., Covey, SN. and Dale, P. (2000) Genetically modified plants and the 35 S promoter: assessing the risks and enhancing the debate. *Microbial Ecology in Health and Disease*. **12**, 1.

[17] Ho, M-W. A brief history of the CaMV 35S promoter controversy. www.i-sis.org.uk. *Personal communication.*

[18] Christou, P., Kohli, A., Stoger, E., Twyman, R. M., Agrawal, P., Gu, X., Xiong, J., Wegel, E., Keen, D., Tuck, H., Wright, M., Abranches, R. and Shaw, P. (2000) Transgenic plants: a tool for fundamental genomics research. *John Innes Centre & Sainsbury Laboratory Annual Report 1999/2000*. p. 29.

[19] Greenpeace (2002) Environmental dangers of insect resistance *Bt* crops. *Greenpeace Briefing. Genetic Engineering Briefing Pack*. December 2002.

[20] Ervin, D. E., Welsh, R., Batie, S. S. and Carpenter, C. L. (2003) Towards an ecological systems approach in public research for environmental regulation of transgenic crops. *Agriculture Ecosystems and Environment*. **99**, 1.

[21] Greenpeace (1997) Glufosinate and genetic engineering. economic and environmental implications of herbicide resistance. *Greenpeace, International Genetic Engineering Campaign, Background Information*. 04/97.

[22] Greenpeace (2000) Genetically engineered crops: Soya, maize, oilseed rape and potatoes. *Greenpeace Briefing. Genetic Engineering Briefing Pack*. January 2000.

[23] McGaughey, W. H. (1985) Insect resistance to the biological insecticide *Bacillus thuringiensis*. *Science*. **229**, 193-195

[24] Greenpeace (2002) Adverse environmental Impacts of GE Bt Cotton. Chinese Experience Illustrates the need for International Liability Rules. June 4, 2002. http://archive.greenpeace.org/geneng/highlights/gmo/jun3_china.htm

[25] Zwahlen, C., Hilbeck, A., Gugerli, P. and Nentwig, W. (2003) Degradation of the Cry1Ab protein within transgenic *Bacillus thuringiensis* corn issue in the field. *Molecular Ecology*. **12**, 765

[26] Accinelli, C., Screpanti, C., Vicari, A. and Catizone, P. (2004) Influence of insecticidal toxins from *Bacillus thuringiensis* subsp. *kurstaki* on the degradation of glyphosate and glufosinate-ammonium in soil samples. *Agriculture Ecosystems & Environment. In Press.*

[27] Snow, G. A., Andow, D. A., Gepts, P., Hallerman, E. M., Power, A., Tiedje, J. M., and Wolfenberger, L. L. (2004) Genetically engineered organisms and the environment: Current status and recommendations. *Ecological Society of America Position Paper*. ESA Public Affairs Office. February 26, 2004.

[28] Summary Notification Information Format for products containing genetically modified higher plants (GMHPs) in accordance with directive 2001/18/EC. C/ES/01/01. http://gmoinfo.jrc.it/csnifs/C-ES-01-01.pdf

[29] Hillbeck, A., Moar, W, J., Pusztai-Carey, M., Filippini, A. and Bigler, F. (1998) Toxicity of *Bacillus thuringiensis* Cry1Ab toxin to the predator *Chrysoperla carnea* (Neuroptera: Chrysopidae). *Environmental Entymology*. **27**, 973

[30] Gene Technology Advisory Committee. Communiqué No. 10. http://www.ogtr.gov.au/pdf/cmmittee/10thcommgttac.pdf

[31] EPA Pesticide fact sheet for Bollgard Cotton. Monsanto Biotech Basics. http://www.biotechknowledge.com/biotech/bbasics.nsf/product_information_bollgard_cotton_pest.html?OpenPage

[32] Cotton Relatives. http://www2b.abc.net.au/rural/grow/newposts/0/post38.shtm

[33] Monsanto (2000) *Dossier containing molecular analysis of Roundup Ready Soya.* http://www.foodstandards.gov.uk/pdf_files/acnfp/dossier.pdf available at http://www.foodstandards.gov.uk/committees/acnfp/acnfpassessments.htm

[34] Greenpeace comments on: SNIF for the deliberate release and placing on the EU market of the 1507 maize, C/ES/01/01. http://www.greenpeace.se/files/200-2399/file_2308.pdf

[35] Monsanto (2002a) Transcript analysis of the sequence flanking the 3' end of the functional insert in Roundup Ready Soybean event 40-3-2. http://www.food.gov.uk/science/ouradvisors/novelfood/assess/assess-uk/60500

[36] Monsanto (2002b) Additional characterisation and safety assessment of the DNA sequence flanking the 3' end of the functional insert of Roundup Ready Soybean event 40-3-2. http://www.food.gov.uk/science/ouradvisors/novelfood/assess/assess-uk/60500

[37] Heritage, J. (2004) The fate of transgenes in the human gut. *Nature Biotechnology*. **22(2)**, 170. http://www.nature.com/cgi-taf/DynaPage.taf?

[38] Chowdhury, E. H., Kuribara, H., Hino, A., Sultana, P. and Mikami, O. (2003) Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn. *Journal of Animal Science.* **81**, 2546.

[39] Vazquez-Padron, R. I., Gonzales-Cabrera, J., Garcia-Tovar, C. Neri-Bzan, L., Lopez-Revilla, R., Hernandez, M., Moreno-Fierro, L. and de la Riva, G. A. (2000) Cry1Ac protoxin from Bacillus thuringiensis sp. Kurstaki HD73 binds to surface proteins in the mouse small intestine. *Biochemical and Biophysical Research Communications*. **271**, 54.

[40] Burris, J. (2002) Adventitious pollen intrusion into hybrid maize seed production fields. *American Seed Trade Association*. http://www.amseed.com/govt_statementsDetail.aspid-69