Objections to the Application made by Dow AgroSciences in Respect of Event TC1507 to the National Department of Agriculture, South Africa

Prepared by

Mariam Mayet and Shenaz Moola

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AFRICAN CENTRE FOR BIOSAFETY
13 The Braids Road Emmarentia, 2195
Johannesburg, South Africa.
Tel: 27 11 646-0699
E-mail: mariammayet@mweb.co.za

The Registrar: Genetically Modified Organisms
National Department of Agriculture

The Chairperson: Executive Council
Genetically Modified Organisms Act

By Fax and Email

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The African Centre for Biosafety (hereinafter referred to as "the Centre") is a non-profit organisation, working on biosafety issues, in the public interest. The Centre hereby submits its **comprehensive objections** to the application made by DowAgrosciences ("the Applicant") to the National Department of Agriculture ("NDA"), the Registrar: Genetically Modified Organisms Act No. 15 of 1997 ("GMO Act"); the Executive Council ("EC") established in terms of section 3 of the GMO Act for authorisation to allow it to conduct field trials of genetically modified (GM) maize, transformation event TC1507.

We have a reasonable expectation that in considering our objections to the Applicant's application, the EC will act in accordance with the principle of procedural and substantive fairness as enshrined in section 33 of the Constitution and the Promotion of Administrative Justice Act 3 of 2000.

Structure of Objections

This document is structured as follows:

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

Summary of grounds for rejection of Dow Agrosciences application

1. Provision of misleading and false information.

Dow, Pioneer and Mycogene provided incorrect, misleading and/or false information to the competent authorities of Argentina, Spain and the Netherlands in order to obtain approvals in those countries.

The provision of false and misleading information calls into question the veracity of all information furnished by Dow Agrosciences, and for that matter, Pioneer Hi-Bred to the South African and indeed, other competent authorities elsewhere in the world, tasked with regulating GMOs. As such, the information provided by Dow in its application cannot be relied upon as being truthful.

The Centre is thus of the view that the EC should refuse the Applicant's application on the grounds that the information furnished by the Applicant cannot be trusted.

2. Rights of access to information denied

The Centre has applied to the NDA in terms of the Promotion of Access to Information Act ("PAIA") for access to certain information in order for it to exercise its rights as contemplated by the provisions of the said PAIA read together with section 23 of the Constitution. However, such information has not been furnished to the Centre.

Instead the Centre has been furnished with a 23-page document, which is nothing more than a list of unsubstantiated answers by the Applicant, to what looks like a questionnaire prepared by the NDA. The inadequacy of the information submitted by the Applicant in these 23 pages, have been fully canvassed in these submissions.

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 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 application brought by Biowatch has already been argued before Dunn AJ, 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 to access to the information which it is entitled to in this regard.

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

2. Despite the expression of the introduced gene sequences having been confirmed by molecular characterisation and protein expression analysis, unintended effects that are not detected in the lab and that may only become apparent in the long term, cannot be ruled out.

3. 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.

4. 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 are at risk of exposure to Bt toxins.

5. 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.

6. 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.

7. 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.

8. 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. Several EU competent authorities (Netherlands and Spain) have taken several years to grant permission and the UK competent authority (ACRE) declined permission for cultivation in April of this year

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

It is the Centre's 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, it is our respectful submission that the application must be refused because the statutory framework obliges the EC to *inter alia* adopt a risk averse approach in assessing environment hazards and to evaluate the social and environmental impacts of the proposed activities and to have regard to the cumulative potential impacts of such activities on the environment.
Regard must be had in particular, to the explicit purpose of the field trial, namely to "gather information to substantiate EU registrations". Hence, it is the Centre's respectful submission, that the commercial interests of the Applicant to further its aims to gain EU registrations for event TC1507, and in so doing, utilise the land of South Africa as its experimental "guinea pig", is not a justifiable and reasonable limitation on the rights as contemplated in section 36 of the Constitution.

5. Failure to Comply with ECA and ECA Regulations

The genetic modification of organisms 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

Preliminary Issues

Discrepancies in information provided

1. On the 2nd June 2004, the African Centre for Biosafety ("Centre") applied to the National Department of Agriculture (NDA), in terms of the Promotion of Access to Information Act for access to certain information pertaining to Dow Agrosciences' application for the field trials of Genetically Modified maize, transformation event TC 1507. The Centre specifically requested access to a summary of the results of previous field trials.

2. On the 11th June 2004, the NDA responded to the Centre's request by fax. In respect to the request for access to the summary of the previous field trials, the NDA advised as follows " This is the first application submitted by Dow Agrosciences for trial release of this event. However, Pioneer obtained a permit in 2001 for trial release with this event, but this trial never took place due to internal decision taken by Pioneer."

3. On the 18th June 2004, Ms Mayet, from the Centre, telephoned Mr Koos Snyman from Dow Agrosciences (Dow), whereupon Mr Snyman confirmed that the application for field trials was in fact Dow's first in South Africa and that as far as he was concerned, he had no knowledge whether Pioneer Hi-Bred (Pioneer) had conducted any field trials in South Africa, as such information would not be forthcoming from Pioneer, since Dow and Pioneer were in fact competitors. Mr Snyman explained that Dow had acquired certain rights in respect of GM maize event TC1507, as a result of Dow having bought Mycogene Seeds.

4. On the 18th June 2004, Ms Mayet telephoned Mr Ruben Venter from Pioneer and requested information from the said Mr Venter regarding the conducting of field trials in South Africa by Pioneer of GM maize event TC1507. Mr Venter requested that Ms Mayet reduce her queries in this regard in writing, which she duly did. However, to date, no reply to this enquiry has been forthcoming from Pioneer.

5. On the same day, Ms Mayet wrote to Ms Michelle Vosges from the Directorate: Genetic Resources of the NDA requesting confirmation whether Pioneer had conducted any field trials in South Africa. A further email was sent on the 21st June 2004, to the Senior Manager: Genetic Resources Management of the NDA who is also the Registrar appointed in terms of section 8 of the Genetically Modified Organisms Act No. 15 of 1997 (GMO Act) seeking similar confirmation.

6. On the 21st of June 2004, and in response to the said queries made to the NDA, Ms Vosges telephoned Ms Mayet whereupon the former advised the latter of the NDA's written communication already furnished to the Centre contained the information regarding the status of any field trials regarding event TC1507 and that she had nothing further to add or subtract from that communication. Ms Mayet then confirmed this telephonic communication by way of an email to Ms Vosges immediately after the telephone conversation. To date, Ms Vosges has not contradicted this email.

7. The situation thus, is that according to Dow and the NDA, no field trials had taken place in South Africa with GM maize transformation event TC1507 by either Dow or Pioneer (or anyone else for that matter.)

8. In direct contradiction to this information, the Centre has discovered that in fact, Pioneer and Dow has represented to the competent authorities in Argentina, the Netherlands and Spain, that it had conducted field trials in South Africa.

Argentina

Application was made to CONBIA, Argentina, Dow Agrosciences S.A and Pioneer Hi-Bread SA, SAGPyA N° 209 (1-9-03) for the environmental release of GM maize TC 1507 " Maíz Resistencia a Lepidópteros y tolerancia a Glufosinato de Amonio" http://www.sagpya.mecon.gov.ar/0-0/index/programas/conabia/bioseguridad_agropecuaria2.htm

The Application was granted and in this regard, CONABIA's decision makes the following remarks in English translation [***TC1507 has been field tested in South Africa in the years 1998 and 2000"***] "El maíz genéticamente modificado conteniendo el evento de transformación ***TC1507*** ha sido ensayado a campo en Estados Unidos de América desde el año 1997, en Chile desde el año 1998, en Brasil en el año 2000, en Canadá en el año 2000, en Francia en los años 1999 y 2000, en Italia en los años 1998 a 2000, en Sudáfrica en los años 1998 y 2000 y en la República Argentina desde el año 1997 hasta la fecha." http://www.sagpya.mecon.gov.ar/12/DocDecisionTC1507.PDF

Spain

On the 11 July 2001, Dow Agrosciences, Pioneer Hi-Bred and Mycogene Seeds made application to the Spanish competent authority under notification C/ES/01/01 for cultivation and import of grain and grain products for storage and processing into food, animal feed and industrial uses" http://gmoinfo.jrc.it/csnifs/C-ES-01-01.pdf

In such notification, the applicants, Dow, Pioneer and Mycogene claim on page 21, they had conducted field trials in South Africa. In this regard, the say the following:

a) Release country

South Africa.

(b) Authority overseeing the release

Ministry of Agriculture.

(c) Release site

One site.

(d) Aim of the release

Research.

(e) Duration of the release

One season.

(f) Aim of post-release monitoring

Control of potential volunteers.

(g) Duration of post-release monitoring One season.

(h) Conclusions of post-release monitoring The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.

(i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health and the environment observed

The Netherlands

On the 11 November 2002, Pioneer Hi-Bred and Mycogene Seeds made application to the Dutch competent authority under notification C/NL/00/10 for "import of grain and grain products into the EU for storage and processing into food, animal feed and industrial uses." http://gmoinfo.jrc.it/csnifs/C-NL-00-10.pdf for dutch SNIF

Similarly, on page 21 of the said notification document, Dow, Pioneer and Mycogene allege the following about the conducting of field trials in South Africa:

a) Release country

South Africa.

(b) Authority overseeing the release

Ministry of Agriculture.

(c) Release site

One site.

(d) Aim of the release

Research.

(e) Duration of the release

One season.

(f) Aim of post-release monitoring

Control of potential volunteers.

(g) Duration of post-release monitoring One season.

(h) Conclusions of post-release monitoring The 1507 maize plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 1507 maize.

(i) Results of the release in respect to any risk to human health and the environment No adverse effects on human health and the environment observed

Credibility of the Applicant, Dow Agrosciences

It is evident from the above, that Dow, Pioneer and Mycogene provided incorrect and misleading information to the competent authorities of Argentina, Spain and the Netherlands in order to obtain approvals in those countries.

The provision of false and misleading information calls into question the veracity of all information furnished by Dow and Pioneer to the South African and other competent authorities tasked with regulating GMOs. As such, the information cannot be relied upon as being truthful.

The Centre thus respectfully requests that the Executive Council, established in terms of section 3 of the GMO Act refuse Dow's application and conducts an investigation and independent verification of all information submitted by Dow in regard to the current application.

The Centre will separately, make representation to the Executive Council to conduct a public enquiry in terms of section 4 of the Promotion of Administrative Justice Act No 3 of 2000, in respect to the approval granted by the Executive Council to Pioneer on the 11 November 2001 under permit number 17/3(6/02/255) for commodity use as

food/feed in South Africa. The Centre will also oppose any application or attempts made by Pioneer for the import of GM maize TC1507, directly or indirectly, pursuant to such approval or otherwise. Similarly, the Centre will respectfully request that the Executive Council endeavours to seek independent verification of all information submitted by Pioneer in support of its application for commodity use as food/feed in South Africa and any application, whether direct or indirect, for the importation of such maize.

Access to Information Denied

On the 2nd June 2004, the Centre made application in terms of PAIA for access to the following information:

A copy of **the application and risk assessment** in respect of Dow Agrosciences' application for field trials for its GM maize TC1507, in the Potchefstroom area, in particular information on:

- The molecular characterisation;
- Toxicity studies
- Studies on impact on non-target organisms;
- Expression levels of bt toxin
- Degradation levels of Cry1 F
- Risk management and emergency measures proposed.
- Exact location of field trial sites
- Summary of previous field trial releases

In response to this request, the Centre was furnished with a 23 page document, including correspondence. This document does not include the risk assessment; nor information pertaining to the molecular characterisation; nor the toxicity studies (which are in fact available, since a food and feed safety assessment has ostensibly been conducted by the Executive Council, because a commodity clearance permit had been issued for this GM maize event, as long ago as 11 November 2002 to Pioneer Hi-Bred); nor the expression levels of the Cry 1 F gene, nor the studies on the impact on non-target organisms.

The said 23 page document furnished to Centre is nothing more than a list of answers by the Applicant, to what looks like a questionnaire prepared by the NDA. The inadequacy of the information submitted by the Applicant in these 23 pages, have been fully canvassed elsewhere including repeated reference to a mysterious Annex I in the said questionnaire by the applicant, notwithstanding that the said Annex I, appears to contain pertinent information relating to the molecular characterisation.

On the 17th June 2004, the Centre wrote to the Registrar, placing on record the failure to provide it with the information requested and again, requested that the said information be furnished to it.

Specific mention was made in the said letter to have access to the environmental impact assessment, the Applicant is in terms of sections 21 and 22 of the Environment Conservation Act read together with section 6 of Regulations GNR 1182 of 5th September 1997, that the Applicant is obliged to conduct. The Centre pointed out that

access to the said EIA should form part of the papers before the EC, before it can make a decision and it is the Centre's view that the said EIA, is an integral to the risk assessment. In any event, conducting the said EIA is a statutory duty placed on the Applicant, and therefore, the said EIA, is a matter of public record.

To date, the Registrar has failed to respond to the said letter.

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 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 Notice of Motion, 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.

Scientific Assessment

Application for Trial Release of TC1507: Available Information
A copy of the application submitted by Dow AgroSciences (the Notifier) for field trial of TC1507, 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. The list of cited references in response to the application questions has not been provided, nor has Annex I. Annex I appears to include information pertinent to the molecular characterisation of TC1507.

The Host Plant and TC1507: Description and Characteristics
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[1]. 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[1,3].

TC1507 is a transgenic maize line that has been engineered to produce an insect control protein Cry1F as well as withstand the use of glufosinate-ammonium herbicides. This has been achieved by the introduction of two genes, *cry*1F and *pat* into the maize hybrid line Hi-II by biolistic (particle acceleration) transformation[1]. Cry1F protein confers resistance against lepidopteran insect pests, in particular the European corn borer (*Ostrinia nubilalis),* the pink borer *Sesamia* spp.), fall armyworm

(*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and southwestern corn borer (*Diatraea grandiosella*)[1,3]

Glufosinate-ammonium salt (or phosphinothricin), often referred to as just glufosinate, is a broad-spectrum contact herbicide that behaves sufficiently like the amino acid glutamate to enable it to disrupt the conversion of glutamate to glutamine. It disrupts the enzyme mediated reaction by inhibiting glutamine synthetase activity in susceptible plants, resulting in reduced glutamine production. Glutamine synthetase also regulates ammonia levels by detoxification and disruption of the enzyme activity results in elevated ammonia levels[1,2]. The *pat* gene codes for phosphinothricin-N-acetyltransferase, an enzyme which catalyses phosphinothricin acetylation effectively rendering it inactive and thereby enabling transformed plants to withstand phosphinothricin based herbicide applications.

Responses to questions 4.1 and 4.8.2 of the Dow AgroSciences application makes the claim that teosinte (*Zea mays* ssp. Mexicana) might be an ancestor of maize but goes further to state that that this evidence is in contention and the possibility of there being a bridge between cultivated and wild *Zea* species is unlikely. The Canadian Food Inspection Agency is cited as the source of this claim, but no details of the reference are provided. None of the references referred to are cited, which makes an assessment of these claims very difficult.

Molecular Characterisation and Gene Stability of TC1507

Notwithstanding the summary responses in the application, coupled with the lack of provision of the associated documentation, the Summary Notification Information Format (SNIF), notification number C/ES/01/01, submitted jointly by Pioneer Hi-Bred and Mycogen Seeds (c/o Dow AgroSciences LLC) developers of TC1507 maize, to the Competent Authority of Spain, has been used as a source for information relating to the genetic modifications[3].

Particle acceleration was used to introduce a linear fragment of DNA containing the *cry*1F and *pat* genes and their regulatory coding sequences into maize cells[3]. The cry1F gene isolated from *Bacillus thuringiensis* subsp.*aizawai* is under the control of a ubiquitin promoter, *ubi*ZM1 from *Zea mays* and an ORF25PolyA terminator from *Agrobacterium tumefaciens*. The *pat* gene derived from the soil actinomycete *Streptomyces viridochromogenes* is under the control of the Cauliflower Mosaic Virus CaMV35S promoter and terminator[3].

Detailed characterisation by Southern blot and DNA sequence analysis has confirmed the presence of 6186bp of the 6235 insert containing the target *cry*1F and *pat* genes and associated regulatory sequences. Additionally, non-functional DNA fragments have been inserted into the host plant. These include:

- A 335bp sequence of the *cry*1F gene with no *ubi*ZM1 promoter sequence and a 15bp sequence of the *cry*1F gene, both located at the 5' end of the insert;
- Two *pat* gene fragments lacking regulatory elements located at the 5' border and a fragment of the *pat* gene located at the 3' end;

- A fragment of the polylinker region and *ubi*ZM1 promoter at the 5' end, and
- An inverted sequence of a part of the ORF25PolyA terminator sequence located at the immediate 3' end[3].

Possible Unintended Effects of the non-functional DNA Fragments in TC1507

Despite the expression of the introduced gene sequences having been confirmed by molecular characterisation and protein expression analysis[3], 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[4,5].

That this has occurred in the development of TC1507 is not in question. The inserted gene sequences may interrupt native gene sequences and/or their promoters[5]. What is of concern here is the possible production of novel proteins from the transcription of the unintended TC1507 fragments which have two open reading frames (ORF). The claim that these "non-functional" fragments are not transcribed[3] 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[6], but were later found to be transcribed to produce RNA[4,7,8].

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[5] necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment.

The assertion by Dow AgroSciences (question 4.4 of the application to the Department of Agriculture in South Africa) that the inserted gene is no different from naturally occurring plant genes and that any instability will only affect the transformed plant is not so clear cut. Firstly, the basis on which Dow AgroSciences 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[5].

As a final point regarding the molecular characterisation of TC1507, it is important to note that the UK competent authority, ACRE (Advisory Comment on Releases to the Environment) in response to notification ES/01/01, dated 29 April 2004, did not give its consent for cultivation and requested further clarification of the PCR-based event-specific detection protocol because of an apparent contradiction in the information provided on the characterisation of the insert[9].

Stability of the CaMV Promoter

The *pat* gene of TC1507 coding for phosphinothricin-N-acetyltransferase is under the control of the Cauliflower Mosaic Virus CaMV35S promoter and terminator[3]. 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[10]. 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[11], 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[12]. 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[11]. 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[13]. Information relating to "event specific" molecular analysis for TC1507 has not been provided. Interestingly, Monsanto conducted these analyses for Roundup Ready Soya and found the transgenic insert scrambled as was the host genome at the insertion point. This data was not submitted as part of the Monsanto application. We believe it to be necessary that such molecular characterisation be carried out for TC1507 and submitted or if it has been carried out be made available for independent scrutiny.

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[5]. 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 prey-mediated toxicity effects[3]. 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[14].

Expression Levels of Bt Toxin

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[4].

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[15].This could result in the use of higher toxicity pesticides[16]. Researchers found Bt toxin in the soil after 200 days, indicating slow degradation[17].

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[24]. 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[2]. Glufosinate in particular is defined as being persistent, mobile in soil and highly soluble in water. The large scale cultivation of glufosinate resistant crops will result in an increase in the use of glufosinate with concomitant negative environmental impacts. The full impact of glufosinate on groundwater can only really be determined by long-term monitoring programmes.

The acetylation of phosphinothricin in glufosinate resistant oilseed rape was found to result in the production of N-acetyl-L-phosphinothricin which exhibits little or no degradation and which has been shown to be converted into the active herbicidal form in the digestive tract of warm-blooded animals[18]. This has serious implications for consumers of oilseed rape products. A study has found that Bt toxins can persist in the environment for up to 200 days[20]. A preliminary study on the influence of Bt toxins on glufosinate under laboratory conditions found that Bt toxins in soil enhance the persistence of glufosinate in the soil[19]. The mechanism is unclear because soil microbial activity was not affected. TC1507 has genes that code for both herbicide resistance and for production of Bt toxin. Interactions between the products of these genes has not been previously considered and more investigation is necessary to determine the combined effects.

Trial Release

The following is a list of concerns and questions regarding the information provided by Dow AgroSciences in the section entitled **Trial Release: General** of the application form. In general, the responses to the questions in this section are often vague or incomplete with apparently contradictory responses.

In 5.1.4b it is stated that there will be post-harvest destruction of all maize plants at the trial site and immediately thereafter that there might be some plants returned to the US. It is unclear what plants are being referred to and whether plants are going to be transported post-harvest or not and if they are, what containment measures will be employed. The means of destruction of the plants post-harvest is not detailed. The response to 5.1.6 makes mention of the use of Paraquat, followed by dicing to bury the material on site as part of contingency measures in the event of storms, floods and bush fires. Are we to assume that Paraquat will be used to destroy plants and seeds post-harvest? The use of herbicides “such as Paraquat” suggests that other herbicides might be considered. What are the alternatives that might be considered?

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 - the use of herbicides under such circumstances does not appear to be a safe and environmentally sound option.

The response to 5.2 explains why maize is not considered to be a weedy species and why gene transfer is unlikely to occur; possible hazardous or deleterious effects are not identified. 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 5.3 provides details of notifications and whether these have been granted consent or not. No information is provided on actual releases. In South Africa, Pioneer was granted a permit for a trial release in 2001 which was not carried out due to internal decisions by Pioneer; the basis of these decisions is not known. On 29th April 2004 ACRE took a decision not to grant consent for cultivation of 1507 maize[9]. 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 maize 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 detailed experimentation revealed no factors of greater or lesser risk is not supported by the body of literature. A 1988 Environmental Protection Agency (EPA) *Bacillus thuringiensis* registration standard is cited as support for the notifiers claim. A substantial quantity of research has been carried out in the 16 years since that registration standard. 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[20]. The notifier also cites the 1988 EPA registration standard to support the claim that the "naturally occurring" protein is practically non-toxic to avian species and mammals. 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[21]. Recombinant DNA fragments and Cry1Ab protein was also found in the gastrointestinal contents of pigs fed genetically modified corn[22]. 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[23]. Given the lack of a detailed reference and the comments by the notifier, it is not clear which transgenic form of *Bacillus thuringiensis* the 1988 EPA registration standard refers to. 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 [15]. There is a very real risk that the antibiotic resistance could be transferred to harmful gut bacteria.

The protein produced by the transgenic plant is also not the same as the "natural" protein. Bt toxins in foliar spray preparations, used by organic farmers to control insect pests remain in an inactive state until they are processed in the gut of susceptible insect larvae[24]. The mechanism of operation of Bt plants on the other hand is quite different. The *Bt* gene in transgenic plants contains an artificial truncated form of the gene, modified to behave optimally in the plant and yielding the toxin after

considerably less plant processing by the introduction of regulatory sequences such as introns, polyA signals, promoters and enhancers[25]. In North America regulator evaluation of Bt toxin activity has been based on the natural form of the toxin and not the toxin produced in the genetically modified crop.

No reference is provided for the trial in the USA and no details of trial and where this report can be found (5.4.1 and 5.4.2). In addition, the application for a trial release for TC1507 was made in South Africa by Pioneer. In Spain (Notification number C/ES/01/01) and the Netherlands (Notification number C/NL/0010) notification was led by Pioneer Hi-Bred in conjunction with Mycogen Seeds (c/o Dow AgroSciences).

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. A paper published in 1972 by Raynor et al. is cited for the study of pollen dispersal and states that at 60m from the edge of the field, the number of pollen grains is 7.1 x 103 grains.m-2. 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 viable26. 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 mammals21,22. 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. In particular effects on the Monarch butterfly, which inadvertently ingest maize pollen whilst feeding, have been widely reported[27,28], but none of this information has been reported by the notifier.

The text of the Pioneer paper was not provided to us (5.8.1). We could therefore not make an assessment of the validity of the claims that no compounds toxic to humans were produced as a result of the genetic modifications. Non-target effects (5.8.3) of transgenic plants have been widely reported and are discussed above.

As discussed previously, no real risks have been identified by the notifier (5.9). The field trials are not designed to monitor what the notifier considers to be low probability risks, such as gene transfer (5.2). 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 maize volunteers through possible water

dispersal, such as by flooding, and improper handling and transport has not been addressed at all.

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. These 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 "regular" 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 greenhouse 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.

Risk Assessment
The risk assessment could not be assessed at all as it appears that the bulk of the pertinent information is contained in Annexures copies of which we have not been provided.

Conclusions 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 toxicity and possible harmful impacts of the TC1507 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 and the very recent decision by ACRE not to grant a cultivation permit for TC1507 bear out these concerns.

The Statutory Framework

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

- The Constitution of the Republic of South Africa (Act 108 of 1996) ("the Constitution");
- The Environment Conservation Act 73 of 1989 ("ECA);

- The regulations concerning activities identified under section 21 of the ECA and embodied in Government Notice R1182, Government Gazette 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) on the 3 June 2004, 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;

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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) 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, to ensure that all activities involving the use of GMOs are carried out in a way that limits possible harmful consequences to the environment and, further to ensure that GMOs do not present a hazard to the environment. For a number of reasons discussed in these objections, it is our contention that the proposed field trial of GM maize TC1507 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 has a direct bearing on the regulation of GMOs, more particularly, environmental releases of GMOs. These include-

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

"(ii) that pollution and degradation of the environment are avoided, where they cannot be altogether avoided, are minimised and remedied;

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(vii) <u>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;</u>

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

Section 2(4)(i) provides:

"<u>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.</u> (emphasis added).

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

"24 Implementation

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

(a) <u>the environment;</u>
(b) socio-economic conditions; and
(c) cultural heritage;

<u>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</u> and reported to the organ of State charged by law with authorising, permitting or otherwise allowing the implementation of an activity.

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

(a) investigation of the environment likely to be significantly affected by the proposed activity and alternatives thereto;
(b) <u>investigation of the potential impact, including cumulative effects of the activity and its alternatives on the environment, socio-economic conditions</u> 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;
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 statutory framework obliges the EC to *inter alia* adopt a risk averse approach in assessing environment hazards and to evaluate the social and environmental impacts of the proposed activities and to have regard to the cumulative potential impacts of such activities on the environment

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