SUBMISSION REGARDING MONSANTO'S APPLICATION FOR A TIME EXTENSION OF AN EXISTING PERMIT FOR ACTIVITIES WITH GMO'S IN SOUTH AFRICA – TRIAL RELEASE

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INTRODUCTION

In 2007 Monsanto South Africa applied for and was granted a trial release permit to conduct field trials with maize event MON87460 (permit no 17/3(4/09/242)) for which Monsanto is now seeking a time extension. Earlier this year, the African Centre for Biosafety submitted its objections to applications by Monsanto to the South African Department of Agriculture, Forestry and Fisheries (DAFF) to import 35 hybrids of MON87460 and to continue the field trials.[1] The full text of the original objection is appended hereto as Annexure A.

ACB CONCERNS

Monsanto South Africa has submitted a response to some of ACB's concerns to DAFF, a copy of which has been made available to ACB. The ACB would like to reiterate its main concerns regarding the field trials of event Mon87460 and respond to some of the Monsanto comments.

1. The possibility of any real yield benefit to be derived from the transformed plants is not rated very high by Monsanto. The risks of exposing the environment the public and environment to such a product cannot be justified within this context.

2. Incomplete molecular characterisation information and detail on subsequent genetic evidence to confirm the original transformations makes complete assessment of the transformation event impossible.

3. The development of the MON87460 event has not been optimised to minimise gene flow of ARMG and it is not clear why this was not done.

4. No health and safety and human health impacts from possible consumption of MON 87460, in the event of gene flow and/or handling spills, are included in the application. This hampers the public's ability to contribute or engage meaningfully in any discussions regarding GE foods or be able to make informed choices about matters that so closely impact on them.

5. More sustainable agro-ecological approaches to farming should be supported and promoted by DAFF. Such approaches help maintain soil diversity through crop rotations that balance soil nutrients and promote the use of natural readily available inputs like compost and manure which replenish the soil.

6. The consultation process is not sufficiently long to enough to enable full and meaningful public participation and the information made available to the public is kept to a minimum.

7. The original decision by the South African regulatory authority to permit field trials of MON87460 has not been made publicly available through the Biosafety as

Clearing House (BCH) in terms of Article 20 of the Cartagena Protocol and constitutes non-compliance with the Cartagena Protocol, to which South Africa became a party in August 2003. 19 decisions regarding LMOs have been posted while the South African government has granted over 2000 permits since 1999. The ACB cannot therefore meaningfully respond to the original regulatory authority assessment. This also calls to question whether the resources and capacity within the South African DAFF are optimally geared to ensure thorough and complete assessment of applications for the introduction of GMOs into the environment.

According to Monsanto:

> MON 87460 is expected to provide significant value to maize producers and consumers due to reduced yield loss under water-limited conditions. Improved yields under water-limited conditions will help to ensure a stable grain supply, even in years with low rainfall. Higher maize yield per hectare may help conserve the total number of hectares needed to meet the needs for food, feed and biofuel uses or produce more maize grain on the same number of hectares already used for maize production. Positive impacts on yield and improved yield stability will provide value to producers, consumers and the environment.
>
> While much progress has been made to improve maize yield in water-limited environments through breeding, selection, and agronomic management practices, there remains potential for additional improvement. Biotechnology provides additional tools that can be used in combination with breeding and agronomic practices to enhance productivity. A study with conventional maize hybrids that were commercially available between 1953 and 2001 estimated that conventional breeding under water-limited conditions provided levels of tolerance that led to yield increases of approximately 1% per year when those conventional hybrids were cultivated in water-limited environments (Campos et al., 2006). Biotechnology is expected to provide yield increases of 6% or more. This level of yield increase represents significant value to farmers.

The ACB and broader civil society are not in any position to assess the Monsanto statement regarding yield due to the unavailability of the field trial data as it is designated Confidential Business Information.[2] Can DAFF provide evidence of an independent assessment of the field trial data?

According to Monsanto:

> **"Drought tolerance is complex, mediated by multiple genes and regulatory pathways. Not easy to engineer into plants"**
>
> Developing MON 87460 has indeed required significant effort by Monsanto. The CSPB gene does, in fact, successfully allow MON 87460 to produce better yields than would otherwise be possible under water-limited conditions. Two recent publications (Nelson et al., 2007; Castiglioni et al., 2008) successfully demonstrated the utility of single gene approaches for imparting drought tolerance in maize.

ACB is aware of other studies the results of which have been published in a Monsanto Review by Castiglioni et al (2008)[3] which summarises the results of experiments relating to the development of drought-tolerant maize over a four year period. Whilst this review discusses growth and yield benefits resulting from the expression of CSBP from *B. subtilis* in

maize grown under drought conditions, it does not specifically mention MON87460 maize. Any claims made regarding Mon87460 and yield benefits must be event-specific.

According to Monsanto:

> irrelevant to systemic use of kanamycin. In 2009, the European Food Safety Authority (EFSA) published its scientific opinion on the safety of antibiotic resistance markers. EFSA concluded that oral uses of aminoglycoside antibiotics would not be compromised by the presence of NPTII in food (EFSA, 2009).

and

> *EFSA Statement (2009)*
>
> The ACB cites the EFSA Statement (2009): "Kanamycin and neomycin are both categorized by the WHO Expert Group on Critically Important Antimicrobials for Human Health as 'Highly Important Antimicrobial'… The increasing occurrence worldwide of "extensively drug-resistant" (XTB) isolates of MTB with resistance to second-line antibiotics such as kanamycin is a cause for global concern."
> The EFSA statement concludes this paragraph with the following sentence: "**The *npt*II gene has not been implicated in such resistance.**"

The EFSA statement immediately goes on to say that:

> *"There are limitations related among others to sampling, detection, challenges in estimating exposure levels and the inability to assign transferable resistance genes to a defined source. The importance of taking these and other uncertainties described in this Opinion into account requires to be stressed."*[4]

The ACB has stressed time and again to DAFF and the former Department of Agriculture our concern that due consideration is not taken of the uncertainties prevalent in the development of genetically modified food crops. What approaches has Monsanto adopted to ensure that the role of variability of natural systems and its contribution to uncertainty has been adequately assessed in the risk assessment? What independent verification, if any has been carried out by DAFF?

It must be noted that the ACB cited EFSA because it acknowledges the contribution of different regulatory and monitoring bodies around the world and takes account of different opinions in the ongoing debate around genetically modified organisms. That is not to say however that the opinions of these bodies are definitive positions and must be blindly applied within a South African context. The EFSA statement was quoted to highlight that within EFSA's own structures there are dissenting views.

In fact in 2009 despite a decision from EFSA that Mon810 was safe, France and five other EU members (Austria, Germany, Greece, Hungary and Luxembourg), suspended sowing of Monsanto's MON810 maize, invoking safeguard clauses on the grounds of potential environmental hazard.[5]

Monsanto goes on to say further:

> *Horizontal gene transfer*
>
> The factors affecting the potential for HGT between genetically modified plants expressing antibiotic resistance marker genes and microorganisms in the environment have been extensively studied (Nielsen *et al*., 1998; Smalla *et al*., 2000; Kay *et al*., 2002; Tepfer *et al*., 2003; Demanèche *et al*., 2008). HGT of *nptII* from transgenic plants to bacteria has been demonstrated in laboratory studies, but only under optimized conditions using a strong selection pressure and recipient bacterial strains harboring the *nptII* gene carrying deletions to produce high sequence homology (Gebhard and Smalla, 1998; Tepfer *et al*., 2003). HGT is known to be a rare event and has not been detected under field conditions (Nielsen *et al*., 1998; Demanèche *et al*., 2008). Transformation frequencies (the frequency of foreign DNA incorporation into the microbial genome) likely to be encountered in the field are low, representing environmental significance only on an evolutionary time scale.

There are a few published studies into whether ARMGs present in genetically modified plants can spread horizontally to exposed microbial communities in agricultural soils and in the intestines of human volunteers.[6,7,8,9] These studies examined bacterial population for putative transformants carrying the genes of interest by phenotypic screening. Also, the non-culturable fraction of bacteria present in soil or the intestine was sampled, without identifying the HGT events.[10] Nielsen and Townsend reported that horizontal gene acquisitions occurring into non-culturable bacteria (generally non-culturable, or not responsive to the media and conditions selected in the studies) remain exceedingly difficult to detect.[11] The overall findings of these studies were that no transgene acquisitions were detected in the genomes of the exposed bacterial populations which would appear to support the Monsanto contention. However, several aspects of the design of these studies have been questioned.[11]

For example, the approach used in these studies provides only a limited ability to detect rare bacterial transformants carrying the transgene. This is due in part to exceedingly low probability that the analysis will reveal transformants due to the high number of bacteria naturally present in the environments sampled, and also the high intrinsic background resistance to the antibiotics used to select bacteria carrying ARM genes.[10] The estimates are that all the field studies to date have examined HGT processes occurring in bacteria present in less than 2 g of combined sample material[11] and at sampling times that might not necessarily reflect a true situation. It may take a prolonged period (weeks, years, or decades), for the transformants carrying ARM genes to reproduce to sufficient numbers to be detected by monitoring.[11] The limitations in experimental technique and protocols applied and the sampling limitations might not necessarily detect HGT of ARMGs. This underlies the requirement for more concentred research effort into sampling strategies and greater understanding of bacterial population genetics in order to enable informative monitoring of HGT processes occurring in natural bacterial populations exposed to ARM genes from GMOs.10

In respect of pollination, according to Monsanto:

Effect of wind speed and direction on cross-pollination (GM field upwind or down-wind) Example of canola pollen 3km away.

Gene flow (often used synonymously with the term "outcrossing" or "cross pollination") is a natural biological process that occurs in most crop species, including maize. In order for successful cross pollination to occur plants must be sexually compatible, in close proximity for cross pollination to take place, and flower at the same time. Once in the atmosphere, pollen grains must remain viable long enough to be able to reach a viable silk to complete the pollination process. Average maize pollen completely loses viability after two hours of atmospheric exposure (Luna et al., 2001; Aylor, 2003).

Pollen dispersal from insect-pollinated crops is influenced by the number, type, behaviour and range of pollinators.[12] The chances of pollen from a GM crop pollinating with a non GM crop is a function of the availability and viability of pollen emitted from the GM crop and its delivery to the stigma of a non GM plant.[13] Pollen distribution is typically leptokurtic with most pollen spreading close to the plant, and only a small amount moving over longer distances. Maize is an example of this with most maize pollen falling within about 30m of the pollen source.[14] This leptokurtic pattern of dispersal is observed in maize and makes it effectively "impossible to attain the distance up to which 100% of deposited pollen is contained within, especially when insect-mediated transfer is considered".[15] The rate of long-distance hybridization may be significant when the large numbers of transgenic crops potentially being cultivated is considered with each additional field increasing the chances of long-distance pollen flow occurring.[16]

Some references, as cited in Treu and Emberlin (2000)[17] suggest a viability period between 3 hours to 9 days depending on environmental variables; as compared to a viability period of about one hour for wheat. And at wind speeds of 2m/s, with convection currents keeping pollen aloft, maize pollen could travel 7.2km within the 24 hour maize pollen viability period.[18]

In respect of protein digestibility, Monsanto state:

With the exception of the single amino acid substitution at the N-terminus, the sequence of MON87460-derived CSPB is identical to the source organism (*B. subtilis*) and therefore its binding to single stranded nucleic acids would be no more stable (or unstable) to digestion, cooking or processing. Therefore, there is no reason to believe that CSPB:nucleic acid complexes derived from MON 87460 would behave differently to bacterially-derived CSPB:nucleic acid complexes that humans are already exposed to.

Has Monsanto provided any evidence to show the dissociation of CSPB:nucleic acid complexes under conditions relevant to the human digestive tract, particularly the normal post-meal pH, and especially at the much higher pH characteristics of infants' stomachs?[19,20,21]

Can Monsanto supply information on the protocols applied and whether these conform to FAO/WHO standard protocol for their in vitro digestibility studies (FAO/WHO 2001) in

addition to any other protocol?[22] The FAO/WHO standard calls for comparative data on relative stability of recombinant CSPB to a suite of known allergenic- and non-allergenic proteins (FAO/WHO 2001). What tests have been conducted to measure the rate at which recombinant CSPB and its breakdown products are digested relative to known standard proteins? The FAO/WHO standard calls for recombinant CSPB to be assessed in its principal edible form - have these tests been conducted?[22]

There is a long history of Monsanto field trials in South Africa:

> Monsanto has been conducting maize field trials in South Africa in terms of the GMO Act for more than 13 years, with no ecologically disruptive impacts or harmful effects recorded as a result of these trials. Robust containment and isolation measures are in place to prevent pollen flow and in case of accidental release, Monsanto will take full responsibility to ensure appropriate mitigating measures are implemented.

Whilst we are aware that field trials of GMOs have been undertaken in South Africa, we are not aware of any independent monitoring of the impacts of GMOs on the environment. SANBI is tasked with conducting research into the environmental impacts of genetically modified organisms (GMOs) in South Africa including research on non-target organisms, target organisms, gene flow and ecological impacts. SNABI has the very clear mandate to "monitor and report regularly to the Minister on the environmental impacts of all categories of genetically modified organisms, post commercial release, based on research that identifies and evaluates risk".[23] SANBI consider GMO Research and Monitoring important because,"SANBI has been mandated to develop a monitoring programme suited to a South African environment and farming culture. One such way is to utilize structured risk analysis tools and stakeholder involvement to determine the most relevant biodiversity monitoring endpoints."[23] We keenly await the invitation to participate as stakeholders by the GMO Monitoring Research Unit at the South African National Biodiversity Institute (SANBI).[23]

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ANNEXURE A

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ACB's objection to Monsanto's application for trial release of drought tolerant GM Maize MON87460

Prepared for the African Centre for Biosafety by Dr. Shenaz Moola

9th April 2010

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INTRODUCTION

In 2007 Monsanto South Africa applied for and was granted a trial release permit to conduct field trials with maize event MON87460. This was a multi-season permit allowing for the field trials to continue for three seasons commencing 2007/2008. The field trials are currently in their final growing season and Monsanto have submitted an application to the South African Department of Agriculture, Forestry and Fisheries (DAFF) to import 35 hybrids of MON87460 and to continue the field trials.[1]

In total there are 4 applications that we are responding to including:

1. "Application for authorisation to import LMO's intended for intentional introduction into the environment (trial release) of South Africa" – extension of permit 17/3(4/07/015) to import 139kg of seed (designated "A" for referencing purposes in this discussion)

2. "Application for authorisation to import LMO's intended for intentional introduction into the environment (trial release) of South Africa" – extension of permit 17/3(4/09/242) to import 144kg of seed (designated "B" for referencing purposes in this discussion

3. "Application for a time extension of an existing permit for activities with GMO's in South Africa – Trial Release" – (designated "C" for referencing purposes in this discussion)

4. "Application for a time extension of an existing permit for activities with GMO's in South Africa – Trial release of MON 87460, Permit 17/3(4/07/015)" (designated "D" for referencing purposes in this discussion)

The field trials of MON87460 by Monsanto are presented as forming part of the larger Water Efficient Maize for Africa (WEMA) Initiative. WEMA is a public-private initiative led by the African Agricultural Technology Foundation (AATF) and involves a partnership between the national agricultural agencies from Kenya, Uganda, Tanzania, Mozambique and South Africa, the Maize and Wheat Improvement Center (CIMMYT) and Monsanto. This forms part of the AATF's Drought Tolerant Maize for Africa (DTMA) Project.[2]

The South African regulatory framework for public input and comment, regarding the introduction of Living Modified Organisms (LMOs) into the environment, is extremely limiting and does not allow for meaningful engagement by civil society regarding these applications. As a result, the African Centre for Biosafety (ACB) was unable to submit comment on the initial 2007 Monsanto applications within the

constraints of the timeframe imposed by the regulations. However, in May 2007, the (ACB) placed on record its concerns about the granting of the field trial permits (17/3(4/07/015) and 17/3(4/09/242)).

This document reiterates our initial concerns and places on record our objection to the continued exposure of the environment to genetically modified maize and our objection to the granting of these applications.

OUR MAIN CONCERNS

We have previously raised several concerns about the event in question. These relate to uncertainty regarding the nature of the modification, how realistic the anticipated developer outcome is, possible adverse ecological impacts of introduction of the event into the environment and a request for consideration of more readily available, more easily implementable, less costly and more sustainable alternatives.

THE NATURE OF DROUGHT AND DROUGHT TOLERANCE

Water plays a crucial role in the survival of plants by fulfilling the roles of solvent, transport medium and evaporative coolant as well as providing the energy necessary to drive photosynthesis, the natural plant process which synthesizes organic food.[3] Under conditions of drought, water loss in plants may result in negatively impacting plant metabolism. Water deficiency is a severe limiting factor in several countries and impacts on both food production and the economies of these countries. Approximately four tenths'[4] of the world's agricultural land is in arid or semi-arid regions with transient droughts causing death of livestock, famine and social dislocation. Several agricultural regions are reliant on irrigation to maintain yields. Those crop plants which can make the most efficient use of water and maintain acceptable yields will be at an advantage in these regions.

Research into drought tolerance and mechanisms for improving drought resistance are underway internationally to provide solutions to the problems of water deficiency, to save water used in agriculture and to ensure the development of sustainable agriculture. This includes research into elucidating the mechanism of drought tolerance in plants – different plants have different genetic makeup and hence different abilities for drought tolerance.

Drought tolerance is an extremely complex phenomenon mediated by multiple genes and regulatory pathways and from the reported literature, has been shown not to be as easy to engineer into plants as more simply inherited traits governed by single genes. The coding for drought tolerance, is incredibly complex with up to as many as 60 genes implicated, all interacting in a subtle and complex way. The successful manipulation and transfer of many complex genes, which can respond to

a variety of conditions, and not produce unwanted toxins and allergens, is a long way off for current scientific knowledge with some geneticists admitting that even hoping for drought tolerance in the next 10 or 20 years may be too ambitious.[5]

In the Monsanto Summary that forms part of the application for placing of Mon87460 on the EU market, there is an admission by Monsanto that under very dry conditions, precisely the conditions under which WEMA is attempting to develop new crop varieties, the drought tolerant trait may not be effective in producing a viable yield: [6]

"Under well-watered conditions, grain yield for MON 87460 is equivalent to conventional maize. Under water-limited conditions, grain yield loss is reduced compared to conventional maize. However, like conventional maize, MON 87460 is still subject to yield loss under water-limited conditions, particularly during flowering and grainfill periods when maize yield potential is most sensitive to stress, by disrupting kernel development. Under severe water deficit, maize grain yield for MON 87460, as well as conventional maize, can be reduced to zero."

What then is the benefit of such extensive research and development effort? On the other hand, if, as Monsanto claims, the maize does confer some advantage under water-stressed conditions, then the potential for proliferation and persistence must be re-assessed within this context and cannot be considered to be limited to those areas with a lower limit of summer rainfall of 15cm.[7]

GENETIC MODIFICATION

NATURE OF THE MODIFICATION

In order for the ACB to submit a full and comprehensive response to DAFF, it needs to have a complete view of the molecular characterisation on MON 87460 so as to understand the genetic material introduced into the host genome. At a minimum, this include:

1. Details on the transformation method together with a detailed description of the introduced DNA sequences;

2. The characterisation of the inserted DNA including any rearrangements that might have occurred during transformation, and

3. Information of the genetic stability of the inserted DNA and any accompanying expressed traits.

From the Monsanto Application to DAFF we have been supplied with limited molecular characterisation information, detailed below.

MON87460 maize was generated by the transformation vector, plasmid PV-ZMAP595 which contains two expression cassettes. The *cspB* expression cassette contains the coding sequence of the *cspB* gene from *Bacillus subtilis* which encodes cold shock protein B (CSPB). The *nptII* expression cassette, containing the coding sequence of the *nptII* gene from *Escherichia coli*, is under the control of the 35S promoter from cauliflower mosaic virus (CaMV), with the termination signal provided by the 3' terminator sequence of the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens*.

The modified maize therefore has two new genes, one bacterial gene encoding cold shock protein B and a marker gene encoding antibiotic resistance. The antibiotic resistance marker gene encodes for the bacterial enzyme neomycin phosphotransferase and confers resistance to antibiotics including kanamycin, geneticin and neomycin.[8] The marker gene is included during the development of the event for purposes of allowing selection in the lab of transformed plants.

The details of what Monsanto has identified as the functional elements are detailed in two of the applications (C-page2, D-page 2) with "any section of the vector not listed in Table 1 but shown in the plasmid map" being "non-transcribed vector sequences that do not contain any functional genetic elements". No further detail is provided on these or on the open reading frames present as a result of the modification.

The lack of complete sequence information makes an assessment of the gene expression cassette nigh impossible. Agrobacterium-mediated transformation is characterized by multiple fragments and gene rearrangements.[9,10] Inserted gene sequences may interrupt native gene sequences and/or their promoters and additional code fragments are not necessarily non-functional and may be transcribed. Extra gene fragments in Monsanto's Roundup Ready Soya were also claimed to be non-functional and not-transcribed,[11] but were later found to be transcribed to produce RNA.[12,13.] Unintended effects that are not detected in the lab and that may only become apparent in the long term cannot be ruled out.

HORIZONTAL GENE TRANSFER (HGT) AND ANTIBIOTIC RESISTANCE MARKER GENES

An antibiotic resistance marker gene (ARMG) has been used in the development of MON87460. Specifically, the *nptII* gene from *Escherichia coli* which expresses the enzyme neomycin phosphotransferase II (NPTII) has been used. NPTII inactivates principally kanamycin, geneticin and neomycin by phosphorylation.

Horizontal gene transfer (HGT) is the transfer of genetic material between organisms, outside the context of parent to offspring reproduction[14],[15] typically by

infectious transfer[16]. HGT frequencies are now known to be much higher than originally thought. The evolution of antibiotic resistance, for example, is an indicator of the frequency of gene transfer, given that antibiotics have been used in medicine only for about 50 years[16]. The intentional modification of plants could through horizontal gene transfer result in the unintentional modification of other organisms.

Kanamycin, contrary to popular belief, is still used in medical applications, e.g. prior to endoscopy of the colon and rectum[17] and to treat ocular infections[18]. It is well known that there is cross resistance between antibiotics of a particular type[15]. Neomycin was found to cross react with kanamycin B in inhibiting RNAse P ribozyme 16s ribosomal RNA and tRNA maturation[19]. Other aminoglycoside antibiotics including streptomycin, gentamycin and tobramycin, which are used to treat human disease, have exhibited cross resistance[15]. The possibility of transfer of the marker by HGT, and subsequent adverse effects on human and animal health, cannot be ruled out in those cases where these antibiotics are still being used.

In the development of MON 87460, the residual *nptII* gene is gratuitous especially since it is bordered by loxP sites and thus could have been removed. Since the gene and trait are unnecessary and could be removed, why was this not done by the developer to minimise the potential risks through HGT?

Monsanto cites the European Food Safety Authority (EFSA) Statement [20] that antibiotic resistance markers have "no adverse effects on human health and the environment" in support of its use of an ARMG (C-page1). The EFSA opinion is not as unequivocal as is suggested by Monsanto. What EFSA does says, is"

"Kanamycin and neomycin are both categorized by the WHO Expert Group on Critically Important Antimicrobials for Human Health as 'Highly Important Antimicrobial'. Kanamycin is used as a second-line drug for the treatment of infections with multiple drug-resistant tuberculosis (MTB). The increasing occurrence worldwide of "extensively drug-resistant" (XTB) isolates of MTB with resistance to second-line antibiotics such as kanamycin is a cause for global concern."[20]

and;

"There are limitations related among others to sampling, detection, challenges in estimating exposure levels and the inability to assign transferable resistance genes to a defined source. ***The importance of taking these and other uncertainties described in this Opinion into account requires to be stressed****."*[a,20]

"Notwithstanding these uncertainties, the current state of knowledge indicates that adverse effects on human health and the environment resulting from the transfer of

[a] Own emphasis

*these two antibiotic resistance genes from GM plants to bacteria, associated with use of GM plants, are **unlikely**".*[a]

Further, two senior from EFSA's biohazard panel (Dr. Christophe Nguyen-Thé and Dr. Ivar Vågsholm), which was jointly responsible for the assessment, did not agree with the conclusions of the EFSA statement. They countered that "adverse effects [...] cannot be assessed" and that the probability of gene transfers from plants to bacteria ranges widely "from unlikely to high". Their objections are included in the EFSA statement.[20]

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,[10] especially in higher organisms necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment. Further, if transgenes behave just like naturally occurring genes, then they have the potential to be inherited in the same way and persist indefinitely in cultivated or free-living populations. Any mixing of native and transgenic plants whether by dispersal, improper handling etc., can result in the spread of transgenes. The consequences, both ecological and evolutionary of crop-to-crop gene flow are only now beginning to be investigated in any meaningful way and the possible exposure of non-target organisms, including humans to novel proteins cannot be discounted.

RESISTANCE OF DNA TO DIGESTION

There are several reported cases in the literature of both the persistence and transfer of gene sequences after ingestion of GM products. Polymerase chain reaction (PCR) has been used to demonstrate the presence of large fragments of M13 phage DNA, which had been fed to mice, in the faeces and bloodstream and in white blood cells[21]. Research published by the UK government in 2002 has shown that bacteria in human intestines had in fact taken up a novel gene from processed food containing GM Soya[22]. 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[23]. Recombinant DNA fragments and Cry1Ab protein was also found in the gastrointestinal contents of pigs fed genetically modified corn[24].

No detail is given on the Stability and digestibility of CSPB or CSPB:nucleic acid complexes, if any, to enable the ACB to comment.

POLLINATION

VOLUNTEERS

The Monsanto application to the South African government states that current agronomic processes will control any maize volunteers (A-page11, B-page11, C-page 17, D-page16). It is not expected that the GE maize will become a persistent or invasive weed, should a seed spill or inadvertent planting occur; however, maize plants have been shown to survive over a growing season, under comparatively colder conditions[25] than found in South Africa. The difficulty with genetically modified plants is that they cannot be distinguished from conventional maize by visual inspection – one maize plant looks much like the other, genetically modified or not. As a result, volunteers may go undetected. Should any volunteers arise, the resulting pollen could cross-pollinate with maize in adjacent fields, producing genetic contamination.

POLLINATION DISTANCES

"Monsanto is committed to effectively isolate the trials from any conventional maize growing in the environment surrounding the trial site" (C-page6, D-page 6)

We know that: 1) Maize is an outbreeding species that produces very large amounts of pollen and 2) Measurement of pollination distances for maize follow a leptokurtic distribution pattern, i.e., cross-pollination rapidly declines as the distance from the donor field increases.[26] A very comprehensive study on cross-pollination of maize has shown that:

1. Cross-pollination between two fields of maize at 200m occurs at levels greater than 0.1%;
2. For one of the three years in the study, cross-pollination of 2.47% was recorded at 200m from the source; and
3. a three-year mean of 1.19% cross pollination, over 11 times more than 0.1%, suggests that cross-pollination above 0.1% is a typical rather than an exceptional occurrence.[27,28]

Recently conducted research by the University of Exeter applied a new method for predicting the potential for cross-pollination, which takes account of wind speed and direction. The findings showed huge variation in the degree of cross-pollination between GM and non-GM crops of maize, oilseed rape, rice and sugar beet.[29] The levels vary depending on whether the GM field is upwind or downwind of the non-GM field. Current guidelines relating to field-to-field distances do not take into account this variation. If the GM field in a trial is downwind of the non-GM field, the trial will underestimate the potential for cross-pollination.[29]

The likelihood that even the strictest isolation distances will completely eliminate cross-pollination is very low. Studies on canola pollen flow have found seeds up to 3km away even though most falls within 100m from the source.[30] Wind currents can also hinder the effectiveness of this strategy with pollen transported to high altitudes by wind and being deposited on fields long distances away from the source without being challenged by the height of pollen barriers (such as trees).[31,32]

Seed flow is a more complicated issue because seeds can have a dormancy of years, allowing their continual movement by vectors such as animals and human activity. Contaminated harvesting equipment and transport vehicles quickly transgress spatial barriers, undermining the ability of most landscapes to harbor effective zones.[32]

In order to ensure isolation of new traits, robust measures have to be applied to prevent pollen mediated gene flow. Monsanto has not supplied any details of isolation distances or the proposed measures that it is "committed to" for effective isolation. There is no detail in the Monsanto application of the period for which fields will be monitored for volunteer growth and whose responsibility this is.

ALTERNATIVES TO GE DROUGHT TOLERANT PLANTS

Several marker-assisted selection (MAS) techniques have been developed for the improvement of polygenic traits. The advances in the development of molecular tools has allowed for improved identification, mapping and isolation of genes in a wide range of crop species.[33] Initially, markers called restriction fragment length polymorphisms (RFLPs), were used to construct linkage maps for several crop species, including maize, tomato, and rice. Later the polymerase chain reaction (PCR) revolutionized molecular marker assays because of the easy and suitable for automation.33 MAS needs to be complemented by traditional breeding programs especially in the case of drought where yield is regulated by several genes. Yet it remains a promising technique worthy of further investigation.

Traditional breeding methods and conventional selection have served farmers well in identifying drought tolerant plants. It is well documented that approaches to improving crop quality by enhancing soil quality greatly improves water retention, and generally improves crop growth, at much less cost. The US Rodale institute has carried out long-term comparisons between organic and conventional crops and found that during the drought years the organic yielded better because the soil holds more water.

The International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD),[34] an intergovernmental report modelled after the Intergovernmental Panel on Climate and commissioned by the World Bank was

carried out over 4 years and involved the collaborative effort of more than 400 scientists. Adopted by fifty-eight countries in the global North and South (excluding the United States, Canada or Australia), the IAASTD found that a agro-ecological approaches to farming, focussing on small-scale sustainable agriculture, locally adapted seed and ecological farming better address the complexities of climate change, hunger, poverty and productive demands on agriculture in the developing world.[35] The interaction with scientists is essential in assisting farmers to improve conservation technologies and developing breeding strategies in a way that does not place additional burdens under communities in already straitened circumstances.

CONCLUSIONS

From our overview of the scant details provided in the non-CBI version fo the Monsanto application to DAFF, the ACB objects we conclude that:

1. The possibility of any real yield benefit to be derived from the transformed plants is not rated very high by Monsanto. The risks of exposing the environment the public and environment to such a product cannot be justified within this context.

2. The application is silent on the measure/s to be taken to prevent pollen flow and makes an assessment of the growing conditions impossible.

3. Incomplete molecular characterisation information and detail on subsequent genetic evidence to confirm the original transformations makes complete assessment of the transformation event impossible.

4. The development of the MON87460 event has not been optimised to minimise gene flow of ARMG and it is not clear why this was not done.

5. No health and safety and human health impacts from possible consumption of MON 87460, in the event of gene flow and/or handling spills, are included in the application. This hampers the public's ability to contribute or engage meaningfully in any discussions regarding GE foods or be able to make informed choices about matters that so closely impact on them.

6. More sustainable agro-ecological approaches to farming should be supported and promoted by DAFF. Such approaches help maintain soil diversity through crop rotations that balance soil nutrients and promote the use of natural readily available inputs like compost and manure which replenish the soil.

7. The consultation process is not sufficiently long to enough to enable full and meaningful public participation and the information made available to the public is kept to a minimum.

8. The original decision by the South African regulatory authority to permit field trials of MON87460 has not been made publicly available through the Biosafety as Clearing House (BCH) in terms of Article 20 of the Cartagena Protocol and constitutes non-compliance with the Cartagena Protocol, to which South Africa became a party in August 2003. 19 decisions regarding LMOs have been posted while the South African government has granted over 2000 permits since 1999. The ACB cannot therefore meaningfully respond to the original regulatory authority assessment. This also calls to question whether the resources and capacity within the South African DAFF are optimally geared to ensure thorough and complete assessment of applications for the introduction of GMOs into the environment.

The ability of ecosystems to develop gradually, the ability to anticipate environmental health effects and very importantly, the establishment of regulatory mechanisms that can effectively, efficiently and credibly manage risks associated with the use of GMOs has not kept apace with the rapid introduction of GMOs. Traditional breeding practices have an established history of safe use dating back several years as opposed to the application of recombinant DNA technology for human use, which is as young as 22 years when genetically modified bacteria-produced insulin was first introduced and even younger for genetically modified plants at ten years.

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