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South Africa

ACB's Objection to Syngenta's application for general release of GM Maize GA21

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1 SCIENTIFIC ASSESSMENT

1.1 SYNGENTA APPLICATION AND AVAILABLE INFORMATION

This paper has been drafted in response to an application by Syngenta for the general release of all seed and derived products from the genetically modified GA21 maize including products from inbred lines and hybrids (white or yellow maize) obtained by conventional breeding of event GA21. A copy of the application submitted by Syngenta (the Notifier), excluding confidential business information, to the Department of Agriculture, Forestry and Fisheries (DAFF), has been furnished to the African Centre for Biosafety (ACB).

This document includes:

- Some sections of the application (confidential business information deleted) covering a brief description of the genetically modified plant, conditions for general release, description of a any plant-derived product, a brief summary of field trials undertaken, responses to specific questions as defined in DAFFs application regarding gene flow, human and animal health, environmental impacts and protection, socio-economic impacts, monitoring and accidents and pathogenic and ecological impacts, approaches to waste disposal and risk management and a monitoring and post market monitoring plan.
- The Risk Assessment Form;
- A List of the Appendices (excluding most of the appendices themselves);
- A copy of the Public Notice; and
- Appendix 24: Environmental Risk Assessment

For the purposes of this discussion, page numbers in parentheses e.g., (Page “x”), refer to the corresponding page in the Syngenta application.

This discussion makes several references to Monsanto Company and Monsanto Company reports especially in the discussions around the molecular characterisation and possible unintended effects arising from some of the features of GA21. To place this in context, Roundup Ready corn was developed by Monsanto Company and DEKALB Genetics Corporation. Over time, Monsanto licensed seed companies Garst and Golden Harvest, to develop corn hybrids from crossing a GA21 corn line with another line. Syngenta acquired Garst and Golden Harvest in 2004 and this included their inbred corn lines containing the GA21 event and announced its intention to start offering the GA21 technology. Monsanto filed a lawsuit against Syngenta alleging patent infringement and Syngenta initiated an antitrust action against Monsanto Company alleging that Monsanto was monopolising the market for glyphosate-tolerant corn events.[1] In 2005, Syngenta started offering GA21 hybrid

corn seeds under the name Agrisure GT[2] and in 2007 the US Federal Appeals Court ruled unanimously in favour of Syngenta Seeds Inc in this matter.

1.2 THE HOST PLANT AND GA21: BRIEF DESCRIPTION

Maize or corn (*Zea mays* L.) is grown commercially in over 100 countries primarily for the kernel, which is processed into a wide range of food and industrial goods.[3] 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.[4] *Zea mays* L. was subjected to biolistic transformation (particle acceleration) to yield GA21, a glyphosate-tolerant (Roundup Ready) maize line.

1.3 GENETIC MODIFICATIONS AND MOLECULAR CHARACTERISATION

1.3.1 SEQUENCE INFORMATION

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

A 3.49kb agarose gel-isolated *Not1* restriction fragment of the plasmid pDPG434 containing the modified maize *epsps* gene expression cassette (Page 19) was introduced by particle acceleration into embryogenic corn cells. The promoter sequence was derived from the 5' region of the rice actin gene (Page 17) and the nopaline synthase gene derived from the Ti plasmid of *Agrobacterium tumefaciens* served as terminator sequence (Page 18).

The Monsanto Summary Notification Information Format (SNIF) for GA21 field trials submitted to Spain,[5] states that 'three internal *mepsps* cassettes are estimated to be present'. In addition, a partial *mepsps* cassette, containing the full length rice actin promoter and intron, the optimised transit peptide, a truncated *mepsps* gene containing the first 289 nucleotides of the *mepsps* coding sequence and terminating in a stop codon, is present. At the 3' end of the inserted genetic elements, there is a partial *mepsps* cassette containing only the rice actin promoter and 5' mRNA leader sequence but truncating before the start of the rice actin intron.

1.3.2 POSSIBLE UNINTENDED EFFECTS OF THE NON-FUNCTIONAL DNA FRAGMENTS IN GA21

Despite the expression of the introduced gene sequences having been confirmed by molecular characterisation, unintended effects that are not detected in the lab and

that may only become apparent in the long term, cannot be ruled out. Transformation by particle acceleration is associated with multiple fragments and gene rearrangements.[6] That this has happened in the development of GA21 is not in question. The DNA sequence data shows the presence of two open reading frames[5] i.e. genes without a stop codon. What is of concern here is the possible production of novel proteins from the transcription of these unintended GA21 fragments. According to Monsanto, these are not transcribed[7] and hence do not produce protein.

The European Commission Scientific Committee on Food[8] has stated that the lack of transcription or translation signals from Northern and Western blots, does not 'preclude absolutely the possibility that the truncated gene is expressed but the possibility that this is the case will be extremely remote'.[8] Inserted gene sequences may interrupt native gene sequences and/or their promoters and additional code fragments are not necessarily non-functional and may be transcribed. Extra gene fragments in Monsanto's Roundup Ready Soya for example, were also claimed to be non-functional and not-transcribed,[9] but were later found by Monsanto to be transcribed to produce RNA.[10,11]

It is not clear if the insert or fragments thereof lie on any maize transposons and what the impact of the DNA insert is on flanking sequences. The lack of sophisticated methods for targeted insertion, especially in higher organisms[6] necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment.

1.3.3 GENE FLOW

If transgenes behave just like naturally occurring genes, then they have the potential to be inherited in the same way and persist indefinitely in cultivated or free-living populations. Any mixing of native and transgenic plants whether by dispersal, improper handling etc., can result in the spread of transgenes. The consequences, both ecological and evolutionary of crop-to-crop gene flow are only now beginning to be investigated in any meaningful way and the possible exposure of non-target organisms, including humans to novel proteins cannot be discounted.[6]

The Syngenta application acknowledges the inevitability of some seed dispersal (Page 16) and the possible germination and establishment of volunteers. But states that it is "highly unlikely" that the glyphosate tolerance trait is transferred to other plants since there are no wild relatives. Maize is a staple crop in South Africa and is widely grown, commercially, by small-scale farmers and in home gardens. Small scale South African farmers have over time nurtured and developed their own locally prized varieties of maize which are potentially under threat from the effects of gene flow. 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

Whilst it is true that the maize pollen grains are round and heavy with a high water content, which limits their dispersal range, small amounts of pollen can travel 400m or more and remain viable.[12] We know that transgenes flow - transgene fragments have been detected in mammals.[13] There is still much work that needs to be done to determine behaviour of these fragments. The original field trials were not designed to monitor low probability risks, such as gene transfer and no assessment was made of the impacts on non-target organisms despite the various papers that have been published on the subject.

In a letter penned by the Vice-president of the Health Council of the Netherlands to the Dutch Minister of Health, Welfare and Sport in 1999, regarding the assessment of safety of GA21 for the consumer, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients, it was clearly stated that "The applicant *(Monsanto)*[1] says horizontal transfer is so unlikely that this facet is considered irrelevant in the risk assessment. The Committee does not concur with this. Humans have large daily intakes of plant and animal DNA. It is conceivable that parts of this DNA, in the form of intact gene fragments, could enter the small intestine where they could be transferred to the resident microflora."

1.4 HERBICIDE TOLERANCE AND USE

1.4.1 MECHANISM OF GLYPHOSATE TOLERANCE

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

1.4.2 HERBICIDE TOLERANCE AND EFFECTS ON NON-TARGET SPECIES

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

[1] ACB Addition, for point of clarification

1.4.3 HERBICIDE USE AND GM CROPS

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

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

From a previous Syngenta application for a field trial of GA21 in South Africa, a concern was raised by the ACB that the length of field trials was too short for an adequate assessment of the impacts of herbicide use. The practice of examining herbicide use for a single season, as typically occurs with most field trials, and as was proposed for the field trial is not sound. Examination of agrochemical usage for GM crops suggest that for a full assessment of the extent of herbicide use, changes in herbicide use need to be monitored over full crop rotation cycles, not just a single harvest as is typical of a number of field scale evaluations.[19]

1.4.4 INCREASED GLYPHOSATE USE IMPACTS ON OTHER PLANT SPECIES

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

Common ragweed found in a 22 acre patch of north-central Arkansas dryland has survived heavy, and repeated, shots of Roundup.[22] Laboratory studies are still in progress, but preliminary indications are that resistance to glyphosate (Roundup) has developed in these plants. The presence of resistant ragweed is unlikely to cause major waves amongst agriculturalists as ragweed is not a threat to any major crop and there are herbicides besides Roundup to control the weed. The larger issue is the potential for agriculturally important weeds such as pigweed, tall waterhemp or

lambsquarter to develop resistance. Monsanto is well aware of the problem ragweed and is evaluating sample plants in St. Louis.[23] Developing weed resistance is a growing concern amongst farmers and Syngenta have acknowledged that 'many of these concerns with resistant weeds are realistic'.[23]

1.4.5 HEALTH AND ENVIRONMENTAL EFFECTS OF GLYPHOSATE AND GLYPHOSATE-TOLERANT GMOS

There is a paucity of experimental studies devoted to health or environmental effects of glyphosate-tolerant GMOs or glyphosate itself. Glyphosate is a broad spectrum herbicide and its usage may result in harmless plant species being destroyed. The large scale cultivation of glyphosate resistant crops will result in an increase in the use of glyphosate with concomitant negative environmental impacts. The full impact of glyphosate on groundwater can only really be determined by long-term monitoring programmes. In terms of impacts on human health, glyphosate is acutely toxic to humans and in California has been reported to be the third most commonly reported pesticide related illness amongst agricultural workers.[24] A study on mice fed GM soybean suggested that *epsps*-transgenic soybean intake was impacting on the morphology, particularly the nuclear features of liver cells, in both adult and young mice.[25] The mechanism for this effect is still to be determined.[26] Glyphosate use, an integral part of planting Roundup Ready crops, has indicated several unwanted effects on aquatic systems,[27] terrestrial organisms[28] and ecosystems.[29] Negative impacts on human,[30,31] rodent[32] and fish[33] health have also been observed.

Research carried out on the nature and extent of herbicide applications with Roundup Ready soya in the USA found that 2 to 5 times more herbicide needed to be applied compared to other popular weed management systems.[35]

1.4.6 ROUNDUP READY CROPS: THE ARGENTINEAN EXPERIENCE

Argentina was one of the first countries to authorise GM crops with the cultivation of Monsanto's Roundup Ready soya in 1997.[37,34] Large areas of Argentina's most fertile farming region in the Pampas had been suffering from serious soil erosion. Farmers experimenting with a no-tilling approach to alleviate the problem saw the introduction of a herbicide tolerant crop as a heaven-sent solution.[34] Impoverished smallholders, largely peasant farmers, leased their land out to soya farmers and by 2002 almost half of Argentina's arable land -11.6 million hectares was planted with soya, almost all of it GM, compared with just 37,700 hectares of soya in 1971.[34,35]

The demand for arable land for planting soya saw cultivation extending into more environmentally fragile areas; Argentina has lost three-quarters of its native forest to farming over the past century.[36] In 2001, Benbrook reported that Argentinean Roundup Ready soya growers were using more than twice as much herbicide as conventional soya farmers, largely because of unexpected problems with tolerant

weeds.[34,35] His warning of shifts in the composition of weed species, the emergence of resistant superweeds, and changes in soil microbiology under the existing herbicide application regime went unheeded. The outcome is the emergence of several previously uncommon species of glyphosate tolerant weed, a decline in soil bacteria, changes in soil structure and fitness with soil becoming inert thereby inhibiting the usual process of decomposition.[34] On top of all of this is a proliferation of volunteer soya. Rival's to Monsanto in the agrochemical industry began promoting their products to eradicate these volunteers with Syngenta itself, prior to obtaining GA21, advocating the use of Paraquat and atrazine[34,37] and Dow AgroSciences recommending a mixture of glyphosate with metsulfuron and clopyralid.[34,37]

Spraying of RR soya crops has resulted in devastating impacts on the health of local populations and on their environment, livestock and food crops. Studies carried out by the University of Formosa Province reported serious health problems in peasant communities arising from such fumigation on RR soya fields.[37,34] The Argentinean experience also raises issues of food security. Argentina has gone from being known as one of the world's best beef producer and the breadbasket of the world to an economy dependent on near monoculture.[35] The proliferation of soya has provoked an exodus of people from the rural areas to the cities and into extreme poverty since they cannot produce their own food.[34,35] RR soya has also won out against traditionally grown crops such as sweet potatoes, sweet maize, lentils (a staple), peas and cotton. Argentina used to produce food sufficient to feed eight times its population, now it imports milk. 'Now, in beef country, the poor are being fed with crops used for animal feed in the first world'.[35]

1.5 GENETIC MODIFICATION: DEGREE OF CERTAINTY

In general, genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed.[38] Additionally, the gaps in the knowledge regarding composition and functioning of the genomes that are often subjected to genetic manipulation compound such scientific uncertainty.38

The notifier makes the claim that the genetic modification does not introduce any new category of risk as compared to risks from conventional breeding. This is not to be taken as an apparent truth. The ability of ecosystems to develop gradually, the ability to anticipate environmental health effects and very importantly, the establishment of regulatory mechanisms that can effectively, efficiently and credibly manage risks associated with the use of GMOs has not kept apace with the rapid introduction of GMOs. Traditional breeding practices have an established history of

safe use dating back several years as opposed to the application of recombinant DNA technology for human use, which is as young as 22 years when genetically modified bacteria-produced insulin was first introduced and even younger for genetically modified plants at ten years.38

Uncertainty is a key element of the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[39] The lack of sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects allows the Precautionary Principle referenced in the Biosafety Protocol to be triggered. The precautionary principle states "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". The discussions above have identified potentially dangerous effects from the use of GA21. Further the available scientific information, as provided by Syngenta, does not allow for a full evaluation or determination of the associated risks of the use of the said transgenic line.

1.6 EFSA OPINION

Throughout the Syngenta application, the opinions and decisions of the European Food Safety Authority's (EFSA) GMO Panel are quoted and referenced (pages 13, 17, 27, 28, 30, 35, 40, 42) with a final statement on Page 43 of the application that the "conclusion of the EFSA assessment confirms that the potential risk to human and animal health or the environment arising from the placing on the market of GA21 maize can be considered negligible." The Environmental Risk Assessment (ERA) further states that the ERA has been conducted in accordance with the Guidance documents of both the South African Department of Environmental Affairs and Tourism (DEAT) and the EFSA Scientific Panel for Genetically Modified Organisms.

The EFSA, established in 2002, was tasked as serving as the central authority for the scientific evaluation of food and feed safety in the EU.[40] The mandate of EFSA is to address scientific risk evaluation for all questions related to food and feed safety and inform and communicate risks to the public. This assessment is then fed through to the European Parliament, the European Commission, and the Council of Ministers (risk management) who make a decision about a particular application based on the EFSA assessment.

All is not well at EFSA however - the EFSA is not a homogeneous body but includes representatives of its member states many of whom do not concur with EFSA findings. There has been a great deal of criticism of what is seen as EFSA's rubber stamping of anything put forward by the agro-biotech industry. This is exacerbated by the blurring of lines between EFSA and industry and the movement of personnel from EFSA to industry.

In May 2008, the former head of the GMO-panel at the EFSA, Suzy Renckens, moved directly into the genetic engineering industry without any objections or restrictions being imposed by the authority. In her own words, Ms Renckens stated that she in future would also be approaching the authority personally in regard to marketing approval for genetically engineered plants. In her previous position at the EFSA she had been in charge of precisely this group of experts dealing with such applications. In terms of EU staff regulations, former members of EU public services have to ask for approval from their institutions for new positions. Checkbiotech head Christoph Then raised the question in the EU of how independently the authority could act in making decisions on the licensing of genetically engineered organisms with such proximity to industry.[41] It was not until December 2009, after Checkbiotech queries and journalists enquiries that the executive management of the EFSA contacted Mrs Renckens and pointed out that her work was subject to approval for up to two years after her resignation to which she replied that EFSA already knew about her work though the meetings that she had already held with the authority in her new position at Syngenta.[41] This raises questions about the ability of the EU to ensure the independence of the GMO panel.

In the midst of a crucial debate last year in the EU on the reform of the EU authorization system for genetically modified organisms (GMOs), EFSA went ahead and issued positive opinions on a Syngenta pesticide-producing maize (Bt11) and a Pioneer-Dow pesticide-producing and herbicide-tolerant maize (1507).[42] The European Commission health and environment director-generals recently wrote to EFSA's executive director urging the authority to assess health and environmental impacts related to the increased use of herbicides because of GM crops. In April 2008, the EFSA GMO Panel agreed to undertake a two year process to improve its capacity to assess the long-term and indirect impacts of GMOs.[42]

In December 2008, the former Chairman of the EFSA, Prof Patrick Wall, said in a video released online[43] that people have lost confidence in EFSAs ability to assess the risks of GM food. These remarks were made in advance of a meeting of the EU Council of Environment Ministers, whose agenda includes reform of EFSA's GMO risk assessment process with credible research and consideration of new scientific evidence of the health and environmental dangers of GM animal feed and food. In fact, a week prior to the sitting of the EU Council of Environment Ministers, the European Parliament submitted a Petition to the EU Commission, accusing the EFSA of failing to comply with EU regulations to protect the right of EU citizens to safe food. The petition stated that "EFSA ignores scientific evidence that GM animal feed and food are dangerous, and continues to rely on secret dossiers with partial, selective, and biased 'advocacy science' submitted by the applicant companies — which cannot be fully examined by independent scientists for peer review. Such practices are fraudulent, and place Europeans at risk since GM crops and foods cleared as 'safe' on the basis of dossier evidence may in fact be dangerous."[44]

Professor Wall went on to state that ""Science is an evolving subject, and nobody can say there's absolutely no risk. Of course there's a risk! So therefore you have to assess the risk with all the available information... People have to have confidence in the process, and if people haven't got confidence in the process, the process has to be changed! Could EFSA's risk assessment be improved? Could there be a completely different procedure required to enter the approvals process into the EU? Of course it could! But that would be a decision taken by the Commission."[45,46]

Referring to the makeup of the EFSA Panel, Professor Wall, who himself believes GM foods approved by EFSA are safe, said that the EFSA's GMO panel is "populated by experts who are comfortable with the technology; you have a lot of molecular scientists who have been playing around with recombinant DNA technology since 1969... and many of them use it in their laboratories and their research institutions and they're quite comfortable with it; and so — for them — they wouldn't see the same risks that maybe a citizen would see". Likening the situation in EFSA to a motorbike convention, he went further to say that "if you ask the motorbike riders 'do you think riding a motorbike is dangerous?' they say 'no', whereas other people would think they're half crazy!"[45]

The UK Department for Environment Food and Rural Affaires (Defra) carried out an assessment of an application from Syngenta for authorisation for the cultivation of GA21 maize in the EU, and provided an opinion on environmental risks of this application to EFSA. The Advisory Committee on Releases to the Environment (ACRE) carried out the assessment for DEFRA and found that there were potential impacts on biodiversity associated with cultivation, management and harvesting techniques of this GM maize. Although the ACRE assessment was for EFSA and pertains to the EU there is no reason why the same findings cannot be applied to South Africa. These findings refer specifically to information about herbicide regimes and the fact that herbicides regimes are evolving and cannot be strictly applied across different regions.

Further ACRE were sceptical about whether the herbicide regimes proposed by the applicant would be the regimes used in practice.[47] No details of an Environmental post-market monitoring plan for South Africa, if such a plan exists in the Syngenta application, has been provided to ACB for assessment. The Appendices list does not include such a plan. The application makes reference to data available online and specific networks for information that Syngenta could connect farmers to but makes no reference to a regular sustained monitoring programme. This is in our view inadequate and the lack of monitoring, in the event of a failure, does not allow for Syngenta and/or the general public to assess possible causes of such a failure.

South Africa, out of most of the countries on the continent has the resources and intellectual capital to conduct and arrive at its own decisions on whether or not to accept GMOS without reference to EFSA, itself riven by dissent and disagreement over its assessments and forced by public and scientific opinion to review its approach to assessments.

2 SOCIO-ECONOMIC IMPACTS IN RESPECT OF THE GENERAL RELEASE OF GA21

The African Centre for Biosafety (ACB) wishes to draw attention to a number of glaring falsehoods that support Syngenta's application, and the serious socio-economic implications we believe the granting of a permit would entail.

2.1 UNSUBSTANTIATED CLAIMS OF THE INCREASED YIELD PERFORMANCE OF GM CROPS

Syngenta's submission draws on the rather erroneous assertion that GM crops have and will continue to result in improved yields (Page 33). As has been pointed out, the vast majority of GM crops currently on the market have been engineered to infer resistance to insects or applications of chemical herbicides, not to enhance yield. This is unlike the modern varieties that emerged from the intensive breeding programmes associated with the original Green Revolution. The 2008 IAASTD assessment could not come to a firm conclusion that genetic engineering was the obvious path to more sustainable production increases. Jack Heinemann, who sits on the UN roster of biosafety experts, has concluded that "there is no conclusive data from either developed – or developing – country agro-ecosystems to support generic claims that GM crops increase yield or revenue…any general claim that GM crops will reliably produce more than conventional crops in the same environments is not scientifically substantiated".[48] Similar conclusions were reached by the Union of Concerned Scientists in their 2009 report 'Failure to yield', who surmised from a number of studies that 'it does not appear that transgenic HT (herbicide tolerant) corn (maize) provides any consistent yield advantage over several non-transgenic herbicide systems. [49]

2.2 GMOS LEAD TO INCREASED PESTICIDE USE

Contrary to disingenuous claims made in Syngenta's submission that GM crops have led to reduced applications of chemical inputs (Page 33), and are therefore more environmentally friendly than conventional agriculture, studies have consistently found that GM crops have led to an **increase** in their use. Over the past 13 years in the United States, it is reported that "compared to pesticide use in the absence of GE crops, farmers applied 318 million more pounds of pesticides over the last 13 years as a result of planting GE seeds".[50] In addition, the control of herbicide resistant weeds is becoming increasingly problematic for farmers, causing both yield losses and increased cost and herbicide application for that purpose. Alarmingly, strategies to combat this problem tend to be the development of stacked-gene events that ultimately allow even heavier doses of herbicides.[51,50]

Many studies that have shown a downward trend in herbicide applications resulting from GMO adoption have been plagued by methodological inconsistencies. For

example, insecticide use in the US has been reported to have fallen significantly with the adoption of Bt crops. However, breaking down the statistics by crop illustrates that the majority of this reduction comes from the uptake of Bt cotton. Presenting the results in an aggregated form implies that the benefits of reduced insecticide use will apply to all Bt crops.[48]

A report released in May 2009 (this is the same report cited by Syngenta as part of their application) estimated that between 1996 and 2007, GMO crops were responsible for a world-wide reduction in herbicide use of 4.6%.[52] Subsequent examination of the report has revealed several glaring examples of 'creative' arguments employed in the attainment of these figures. Initially using an industry-sponsored dataset that showed *increases* in herbicide use in the US associated with the adoption of herbicide tolerant (HT) soybeans, the authors then dismiss the dataset, jumping to the conclusion that farmers using conventional soybeans were applying less herbicide because they were facing less weed pressure. This argument does not correspond to the pattern of adoption of HT soybean in the US since 2006, which show no clear patterns of adoption between states with high or low levels of weed pressure.[53]

2.3 THE IMPACT OF AGRICULTURE ON CLIMATE CHANGE

To posit herbicide resistant crops as a contribution to mitigating climate change is an outrageous claim; the industrial agricultural model, heavily dependent on fossil fuels, has been found to be one of the most environmentally destructive activities carried out by humankind, accounting for up 20 - 30% of greenhouse gas emissions.[54] Arguments that non-till (NT) agriculture can help alleviate carbon dioxide emissions have been questioned by the Inter-governmental Panel on Climate Change (IPCC), who stated in their fourth assessment that 'adopting reduced- or no-till may also affect N_2O, emissions but the net effects are inconsistent and not well-quantified globally'.[55]

Further doubts have been cast on these claims by a recent major literature review conducted by the US Department of Agriculture (USDA). In the majority of studies used soils were only sampled to a depth of 30cm or less. The few studies that sampled below this depth found there to be no consistent build-up of carbon in the case of NT agriculture, leading the research leader of the USDA agricultural research service, soil and water management unit to conclude that the evidence for increased carbon sequestration in NT systems is 'not conclusive'.[56] If we are to shrink the carbon footprint of global agriculture, a recent study by the Food and Agricultural organization (FAO) and World Bank advised governments to begin shifting their policies toward supporting models that are based on ecological principles and cultivation for local consumption.[57]

2.4 FOOD SECURITY

The World Food Summit of 1996 defines food security as 'when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life'. The concept is built on three pillars: Availability, access, and use. *Quantity* thus is only recognized as one component of this complex, multi-dimensional issue.[58] Food security is mentioned twice in the report (Pages 33 & 34) as a positive socio-economic impact of GM crops. However, data from the UN FAO indicates that in the two countries where the proportion of arable land planted to GM crops is above 40%, Argentina and Paraguay, food security has been decreasing since the mid 1990s, when both countries first began planting GM crops. . Focusing on Africa, a recent joint-study conducted by the United Nations Conference on Trade and Development (UNCTAD) and the United Nations Environment Programme (UNEP) came to the conclusion that 'organic agriculture can be more conducive to food security in Africa than most conventional systems, and that it is likely to be more sustainable in the future'.[59] In the US (the world's largest producer of GM crops) undernourishment rates remained static between 1995 and 2006,[48] though a report released at the end of 2009 by the USDA indicated that a staggering 49 million people (one child in every 4) struggled to eat enough food through-out the year;[60] this in spite the fact that total production of maize, rice, soybean, durum wheat and spring wheat all *increased* between 2008 and 2009.[61] US secretary of agriculture Tom Vilsack attributed the 30% increase in food-insecurity from 2008 to rising unemployment, though officials at the USDA have pointed out that most of the families in which food is scarce as having at least one member in full time employment. This implicates wages and food prices as being as important contributing factors to food security as production

2.5 JOB LOSSES

Herbicide resistant crops are in essence a labour-saving technology, and Syngenta points this out themselves in their application (Page 34). Evidence from Argentina (the world's second largest GM producer in 2008/09)[62] has pointed to a strong correlation between the increased adoption of GM soy and rising levels of rural unemployment.[63] In the 2nd quarter of 2009, 80 00 jobs were lost in the agricultural sector.[64] In her budget speech, delivered in June 2009, Minister Joemat-Petterson remarked that the "primary concern is over job losses during this period and the challenge of creating sustainable jobs".[65] This concern stems no doubt from the fact that between 2000 and 2007 the formal and informal agricultural sector in South Africa shed close to 600 000 jobs. The sectors that have historically absorbed surplus rural labour, namely mining and quarrying, manufacturing and construction added another 460 000 jobs to the economy over the same period.[66] Even the gains made by these sectors have been severely curtailed since the onset of the global economic crisis, as between September 2008 and September 2009 the three sectors haemorrhaged 182,000 jobs.[67] The adoption of crops that further undermine already

diminishing and seasonal jobs in rural areas are at odds with the remarks of Minister Joemat-Petterson. Several recent studies have emphasized the link between localised, sustainable agricultural practices and improved rural human capital and livelihoods, particularly in Africa.[68]

2.6 IMPACTS ON FARMER

Syngenta's information pamphlet on the use of Touchdown herbicide explicitly warns about the danger of drift to neighbouring farmers crops. In a small-holder situation this poses a great threat to farmers not using GA21, as plots are close together. Pamphlets on safe use of GA21 are available in English and Afrikaans on the Syngenta website. These should be available in all local languages and the high incidence of illiteracy amongst rural farmers and lack of access to electronic media must be borne in mind.[69]

Caution in the literature has been expressed in lending credence to assertions that the adoption of GMOs goes hand in hand with enhanced famer profitability. The extra upfront costs of biotechnology 'packages' often burden poor farmers with undue levels of extra risk.[48] Farmers in the US (the world's largest producer of GM crops) are already experiencing debilitating increases in the price of seeds[70] and the herbicide glyphosate.[71] For small-scale and traditional farmers the introduction of GA21 could represent a shift in agricultural practice that, without careful training, can seriously impact on livelihoods and health. A study on the experience of the Massive Food Production Programme in the Eastern Cape showed some alarming socio-economic and health impacts, including crippling debt and illness to people and livestock as a result of ignorance about the safe handling of poisons.[72] What measures are being taken to ensure the safe use of chemicals where users may be illiterate or where safety information is not made available in their local language? It is unlikely that without thorough training, the strict record keeping practices that are necessary for using technology such as GA21, as well as management of intricate resistance regimes, will not be manageable for small-scale farmers with little experience in conventional agricultural practices.

2.7 'INDEPENDENT' RESEARCH

It is significant that both of the reports referenced under section 12.1 (Page 33) are from sources with well illustrated links to the biotech industry. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) website describes the organization as 'a not-for-profit international organization that shares the benefits of crop biotechnology to various stakeholders, particularly resource-poor farmers in developing countries'.[73] Less well advertised are the organization's funding sources which include, amongst others, AgrEvo, Monsanto, Novartis, and Pioneer Hi-Bred. Monsanto are even on its board.[74] PG Economics are a similarly 'independent' agricultural consultancy who count the ISAAA, Agricultural Biotechnology in Europe

(an industry lobby group)[75], Du-Pont, Monsanto Europe, Novartis, and the American Soybean Association amongst previous customers.[76]

3 CONCLUSIONS

In terms of the molecular characterisation of the event:

- It indicates several irregularities including open reading frames and a truncated constructs which could give rise to unintended gene effects
- The transfer of the herbicide-tolerant trait to weeds could result in increased herbicide application. The potential for economically important weeds developing herbicide tolerance is a cause for concern
- Glyphosate use has resulted in several unwanted effects on aquatic systems and terrestrial organisms and ecosystems
- The US experience of Roundup Ready field trials has shown a marked increase in herbicide usage, particularly glyphosate
- In the Argentinean experience, the large scale uptake of Roundup Ready Soya has had devastating impacts on food security and the environment

Furthermore, it is our contention that:

- Reliance on the assessments of EFSA is fraught with problems given the criticisms and contradictions inherent within EFSA especially in respect of its methodologies and perceived pro-industry stance, which it is itself grappling with
- The claims of the increased yield performance of GM crops are unsubstantiated
- GMO plantings contribute to increased rather than reduced pesticide use
- It is disingenuous to suggest that planting of GM crops will contribute to mitigating the impacts of climate change
- Food security is not enhanced by planting of GM crops; ensuring food security requires and multi-pronged, agro-ecological approach to agriculture
- In a country like South Africa where job creation is a driving economic and social imperative, technologies that are likely to recue jobs to the benefit only of the developer of the technology must be adopted with caution
- Technologies requiring additional inputs place additional burdens on farmers
- The GA21 technology requires a level of agricultural and functional literacy and access to information which cannot be assured for some sections of the community to whom it will be readily available – no information campaign accompanies the proposed release
- The literature cited in support of Syngenta's claims is derived from industry sources that have a financial connection with the agri-biotech industry and are nor from independent peer-reviewed sources

It is our contention that the Syngenta application cannot be adequately assessed. The information provided is sketchy at best, key information required for a full and thorough assessment of the event in question is designated confidential business information and therefore not made available to the very public who are expected to consume the product and the time allocated to review of the information is unrealistically short. In respect of the event in question, claims are made regarding gene stability and behaviour by reference to information provided by the developer of the GMO and not to any independent objective source. The basis of these claims is therefore in question. The impression gained from the Syngenta application is that any possible impacts of the release of the transgene are negligible and that the transgenic line is equivalent to the conventional type – this is a view not supported by the published literature. At a minimum, the literature indicates that a great deal more investigation has to be carried out on the impacts of transgenes before their release into the environment. The longer review process of similar applications by the EU, which are themselves often not considered rigorous enough, bear out these concerns.

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