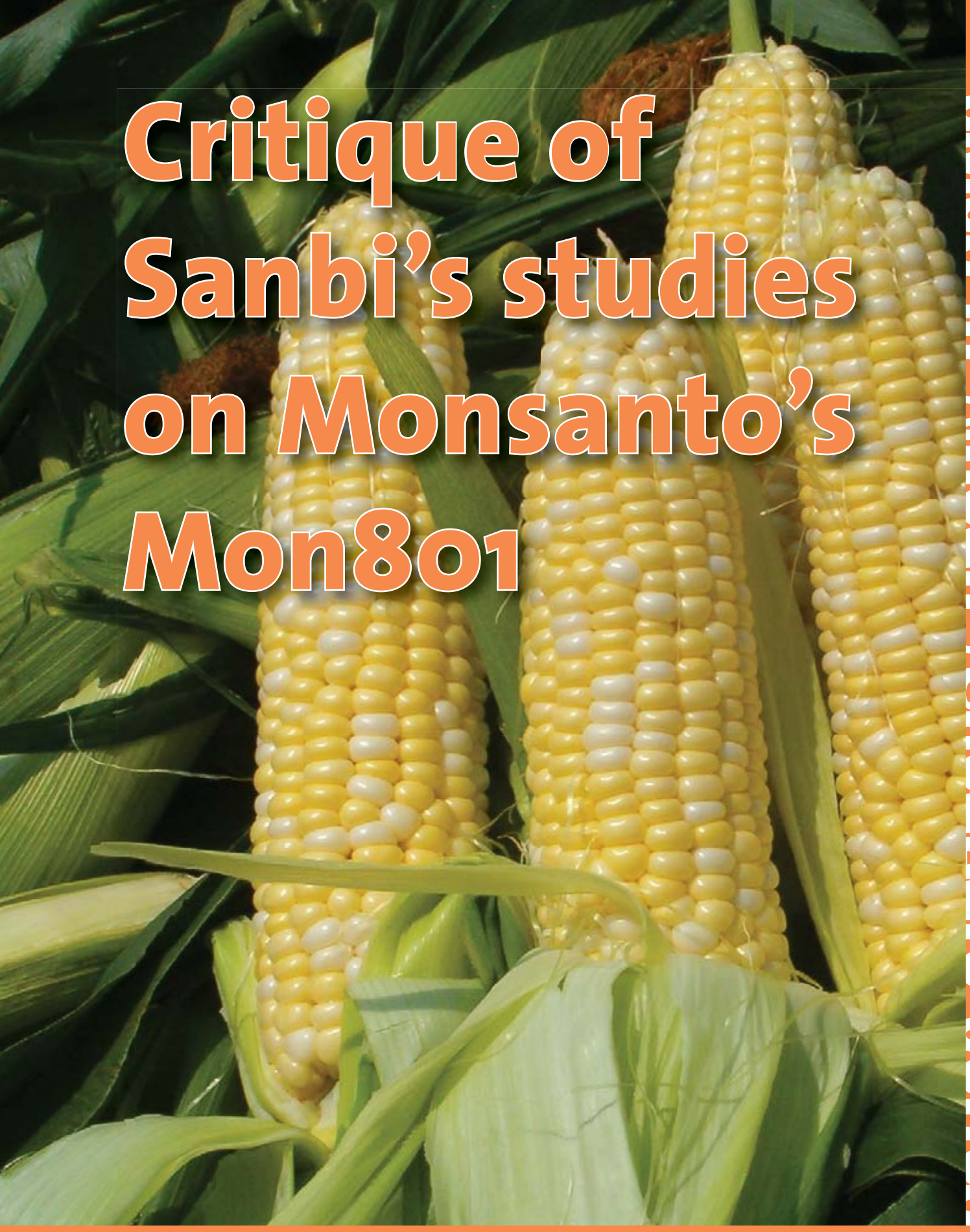

Critique of Sanbi's studies on Monsanto's Mon810

GMOs in African Agriculture series

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Contents

1. Introduction

Early in 2011, the South African National Biodiversity Institute (SANBI) published a report titled "Monitoring the Environmental Impacts of GM Maize in South Africa". The report was a culmination of a study by the Environmental Biosafety Cooperation Project (EBCP) aimed at developing a framework for monitoring of insect resistant maize, Mon810.

The project, coordinated jointly by SANBI and the Directorate of Nature Management (DNI) in Norway, included contributions by the Norway based Centre for Biosafety (GenØk) and the South African based, University of the Free Sate, University of Fort Hare and North West University.

The assessments were carried out over two planting maize seasons, 2008/2209 and 2009/2010 and were based upon a series of scientific studies that included field, glasshouse and laboratory assessments. The primary areas of interest included impacts on target and non-target organisms, impacts on soil organism biodiversity, as well as the impact of gene flow and its subsequent contribution to the development of insect resistance.[17]

The SANBI study findings are broadly that:[17]

- The varying levels of *Bacillus thuringiensis* (Bt) toxin production in different maize tissues, imply a possible contribution to resistance development
- Gene flow from Bt maize to non-Bt maize results in the production of low levels of Bt toxin, also another potential contributor to resistance development
- The presence of another *Bt*-resistant population has been detected in the North-West Province, and there is possible further spread into other provinces
- Current refugia requirements will not suffice to manage resistance in those areas where resistance has already developed
- The genetic background of the variety used and the growing environment are important considerations in terms of study design[17]

2. What is Mon810?

Mon810 (designation MON-ØØ81Ø-6), is a genetically modified (GM) maize marketed under the trade name Yieldguard, that was developed by Monsanto Company to resist attack by the European Corn Borer (*Ostrinia nubilalis*).1 The introduced genetic element from *Bacillus thuringiensis* subsp. *Kurstaki* is under the control of an enhanced CaMV[i] 35S promoter and maize heat shock protein (HSP70) intron. The terminator sequence was lost during integration and the resulting insecticidal protein produced is a truncated form of the delta endotoxin, Cry1Ab (91kD as compared to 131kD in the native form). Genetic modification was achieved by particle acceleration (biolistic transformation) of maize line Hi-II with a mixture of plasmid DNAs.1

Mon810 was the first GM crop to be approved for commercial planting in the EU in 1998. Mon810 ranks as the second most widely approved crop worldwide after an herbicide tolerant soybean.[2] In 2005 MON810 became the first GM variety to be planted in France, primarily for export to the Spanish animal feed market. In January of 2008, the French government issued a nationwide ban on the cultivation of MON810 maize, citing "serious doubts" regarding its safety. Other member states that followed suit included Austria, Hungary and Germany. These bans were placed by invoking a safeguard clause contained in both of the EU directives, 90/220/EEC and 2001/18/EC, which allow for member states to provisionally restrict or prohibit the use and/or sale of a product where it has received new scientific evidence about its potential risks to the environment or human health. In

i. Cauliflower Mosaic Virus

http://www.voltairenet.org/IMG/jpg/GMO-Ger.jpg

November 2008, the Scientific Committee of the EU, the European Food Safety Authority (EFSA), examined the basis upon which these bans were placed and concluded that no new evidence was presented that would justify overturning the original authorisation decision.

According to Monsanto, information was provided to the Advisory Committee on Novel Foods and Processes (ACNFP) of the United Kingdom in 1996, with information, Monsanto argued, demonstrated the compositional and safety equivalence of MON 810 to conventional maize.[3] There are further claims that the food and feed safety of MON 810 has been established through:

- The long history of safe use of Bt Cry proteins (including Cry1Ab);
- The rapid digestibility of Cry1Ab protein;
- The lack of toxicity or allergenicity of Cry1Ab protein, as demonstrated with bioinformatics as well as in vitro and in vivo safety studies of the protein; and
- A large margin of safety resulting from the low dietary exposure to Cry1Ab protein.3

Furthermore, it is claimed that MON 810 has been found to be as safe and nutritious as conventional maize by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals, as well as by a feed performance study using grain fed to broiler chickens.

Additionally, there are claims that environmental fate studies have demonstrated rapid protein degradation and morphological and pest susceptibility data recorded in multiple field trial confirm the phenotypical equivalence of Mon810 to conventional maize except for its protection against corn borers.3

3. What did the SANBI study find?

For the SANBI study, the main areas of assessment included:[17]

- The use of a multi-stakeholder ERA framework to determine post-market monitoring criteria for MON810
- Protein profiling of GM and non-GM maize plants
- Study to characterize the protein structure of the CryIAb transgenic (Bt) protein from MON810 maize and a comparison to the same protein produced in bacteria
- Profiling of MicroRNA
- Study of Bt expression in diverse plant tissues at different stages following planting
- A study on the impact of gene flow on the expression of Bt toxin
- Assessing the impact of target pests (Lepidoptera) in areas cultivated with MON810 maize
- The role of refugia in resistance development
- Assessing the impact of Bt maize on non-target Lepidoptera and selected non-target insects on Bt and conventional maize
- The effect of direct and indirect consumption of Bt maize on selected non-target insects
- Effects of growing Bt maize and its incorporated leaf litter on microbial diversity and mycorrhizal fungi in soil

The main approach and conclusions and recommendations of each of these studies are discussed briefly below. The individual studies do not provide extensive details in terms of methodology and results and presents the methodologies and findings in fairly broad brushstrokes.

3.1 Multi-stakeholder ERA Framework to Determine Post-market Monitoring Criteria

The SANBI study found that the inclusion of a greater diversity of participants in a second as opposed to a first workshop, where only four biological scientists were present, yielded a greater amount of ecologically relevant information for consideration in a monitoring or risk assessment programme. Furthermore, the complexity of the agro-ecosystem was found to be better represented and the number of hazards, (or interactions between MON810 maize and biodiversity), increased. No further detail is provided in the study of what stakeholder makeup constituted this greater diversity but it is suggested that biodiversity and farming practitioners were involved.[4]

3.2 Protein profiling of GM and non-GM maize plants

Developers of GM plants often claim that their novel GM food is "substantially equivalent" to a conventional food i.e. they suggest that it demonstrates the same characteristics and composition as the conventional (non-GM) counterpart. The notion of substantial equivalence has made easier the rapid commercialization of GM crops as the developers of the technology are spared extensive safety testing on the assumption that they are no more dangerous than the corresponding non-genetically engineered food.[5]

Substantial equivalence has come under increasing fire as it is argued that there are no clear and universal guidelines stipulating what to test and how similar the items in question should be. Furthermore, the current batch of accepted tests include specific chemical and biochemical analyses that provide information on a particular protein or toxin but which are incapable of detecting unsuspected or unanticipated health risks.[5]

Increased testing is part of the proposed approach to determining what, if any, differences might be present between GM plants and their non-GM counterparts. Included in these, is proteomics, i.e. the large -scale study of proteins and in particular, their structures and functions - protein profiling forms a part of this.

http://gicc.univ-tours.fr/images/projets/ogm/maize.jpg

In the SANBI study, leaves from both GM and non-GM maize plants, grown in the same field and therefore exposed to the same climatic and ecological conditions and agricultural farming practices, were subjected to quantitative protein profiling i.e. the determination of the relative abundance of each protein. This protein quantification is achieved by image analysis of the spot patterns generated by staining the proteins separated by two-dimensional (2D) gel electrophoresis, where the staining intensity of a protein spot is assumed to accurately indicate the amount of protein contained in the spot.

On average, about 400 spots per gel (GM and non-GM) were detected with far more detectable spots on the GM plant gels and with high expression difference between the GM and non-GM groups for certain proteins. This study recommended further investigation to both identify the proteins expressed at higher levels in GM plant leaves as well as determine whether these differences obtain under different environmental conditions.[6]

3.3 Study to characterize the protein structure of the CryIAb transgenic (Bt) protein from MON810 maize and a comparison to the same protein produced in bacteria

Risk assessments and testing by developers of GM events report data on a bacterial surrogates of a particular protein, rather than that produced by the plant. There is a complaint by GM crop developers that it is too inconvenient to extract sufficient quantities of transgenic protein from their plant.

The SANBI study aimed to determine whether there are any meaningful structural or functional differences between bacterially produced transgenic CryIAb (Bt) insecticidal proteins (used in safety assessments), and the plant produced versions of the protein i.e. those proteins which are consumed once the GM crop is approved but not directly tested for safety. In parallel, transgenic Bt maize (MON810) was grown under greenhouse conditions and CryIAb-expressing *Escherichia coli* were grown under standard laboratory conditions. For both, the CryIAb protein was extracted and isolated to determine its size and amino acid structure and computer simulations of secondary structural

features arising from post-translational protein modifications, each of the proteins were assessed for possible differences in biological functioning by the two versions.

There was significant difference in size found between the CryIAb proteins arising from the different hosts. Analysis of a limited portion of the protein length of each found identical amino acid compositions, which was not unexpected as the protein produces a particular desired trait in the plant. Differences in post-translational modifications suggest differences in levels of bioactivity between the bacterial and plant forms. The study proposes that the acceptability of surrogate proteins be revaluated given the observed differences in protein size and bioactivity and that further research be carried out to confirm whether the computer simulations of changes in bioactivity accompanying secondary structure differences exist in bioactivity assays.[7]

3.4 Profiling of MicroRNA

Small stretches of nucleotides, which code for pieces of RNA called microRNA or miRNA are found in plant genomes. miRNA do not code for proteins but rather serve as a cellular mechanism for the regulation of gene expression. miRNA do this by disrupting translation (the conversion into a protein) of messenger RNA (mRNA) and initiating degradation.[8] Due to their mode of action, including strong sequence specificity, it is believed that they can be more readily linked to a particular protein in the cell. The genes that are regulated by these miRNAS appear to be involved in tissue development, growth and responses to stress factors and it is thought that tracking miRNA expression can be used diagnostically as a monitoring tool under different environmental conditions.

This SANBI study proposed that the genes constituting the Mon810 trait would have an impact on miRNA expression. Preliminary results suggested differential expression for some miRNAs in developing seedlings between GM and non-GM plants of Mon810.[9] This is a relatively new diagnostic application and much work remains to be done. It is proposed that miRNAs be studied in plants that undergo major environmental stresses to better understand environmentally induced miRNA expression and its effect on GM plants.9

3.5 Study of Bt expression in diverse plant tissues at different stages following planting

The development of insect resistance to insecticides is not new and was first documented by A. L. Melander in 1914 when scale insects demonstrated resistance to an inorganic insecticide. It was hoped that the introduction of organic pesticides might change this pattern, but by 1947, housefly resistance to DDT was documented.

The utility of Bt-toxin based pest management technologies as found in Mon810 has been called into question by the reports of the development of insect resistance to Bt crops. In June 2007, Van Rensburg published a paper entitled "First report of field resistance by the stem borer, *Busseola fusca* (Fuller) to Bt-transgenic maize".[10] Two reasons were cited for the development of this resistance: 1) the lack of refugia inside irrigated plantings with farmers opting to use susceptible plantings provided under rain fed conditions in the immediate vicinity of irrigated plantings as refugia; and 2) continuous exposure of larvae of the second seasonal moth flight to sub-lethal levels of the toxin at late plant growth stages.

This SANBI study posits that the variable expression of Cry1Ab in different tissues within and between plants and at different growth stages is a major factor in the development of resistance. Not much research has been published on the levels of Bt toxin found in the silk, cob sheath and cob tissue, which are important sources of food for the African stem borer; and the study aims to determine the levels of Cry1Ab found in roots, stems, leaves, anthers, silk, cob sheaths and cobs –

http://static.guim.co.uk/sys-images/Guardian/Pix/pictures/2008/09/02/maize460.jpg

within and between plants at different growth stages from pre-flowering, flowering, green cob stage and seed maturity.[11] The findings were that there are significant differences in the level of Cry1Ab at the different growth stages as well as between different types of tissue when compared to published data. Bt toxin levels were found to increase up to flowering and then decrease up to seed maturity in roots, stems and leaves. Furthermore, a considerable range of Cry1Ab was also found in the same tissue between plants.

Another study has found that the distribution of Cry1Ab toxin varies at different points in the leaves with toxin content significantly less in leaves at the lowest leaf level, than at higher leaf levels, probably due to partial leaf necrotisation and has implications for sampling methodologies for leaves and possibly other tissues.[12] A Greenpeace report[13] on Cry1Ab concentrations in leaf samples of commercially cultivated MON810 maize plants in Germany and Spain showed a surprising pattern of plants that contained only very low Bt toxin levels and others with very high levels. Plants sampled in the sane field on the same day showed a variation factor as high as 100.

3.6 A study on the impact of gene flow on the expression of Bt toxin

This SANBI assessment was made of the levels of Bt toxin produced after cross-pollination of GM and non-GM plants over two growing seasons. The F1 plants were found to have significantly lower levels of Cry1AB compared to the parental variety. The trends in Bt production however mimicked that in the parental line with an overall increase in the level of Bt toxin from pre-flowering up to flowering followed by a decrease to seed maturity in roots, stems and leaves. Variation was also observed in the quantities of Cry1Ab toxin between the same tissues of different plants.[14]

This variable and relatively low expression effect in the F1 generation, often referred to as a gene dilution effect, might contribute to resistance development and these sub-lethal doses raises questions of the efficacy of stacked GM events.[12]

3.7 Assessing the impact of target pests (Lepidoptera) in areas cultivated with MON810 maize

The SANBI study assessed the scale of the damage caused by the target pests of the Cry1Ab toxin, i.e., Lepidoptera on Bt maize fields under irrigation in two provinces in South Africa, the North West and Limpopo provinces. For the most part, the incidence of damaged plants was low indicating high pest susceptibility to the Bt toxin except at one site in the North West province where high incidences of plant damage were observed possibly indicating the presence of a Bt resistant population.[15]

3.8 The role of refugia in resistance development

The rationale behind the planting of refugia in respect of development of insect resistance is as follows. Over time, some insects feeding on GM-plants might develop a measure of resistance to the plant- producing toxin. If these insects were allowed to cross with insects found on non-GM plants in the adjacent refugium, this would assist in "diluting" the acquired resistance and would serve as an agricultural measure for possibly preventing, but at the very least, delaying insecticide resistance development.

This SANBI study hypothesized that when farmers comply with refuge requirements; the refuge is effective in sustaining susceptible pest individuals, enabling them to mate with possible resistant survivors on the Bt maize crop and in this way, delaying resistance development.[16]

The study found that while a susceptible strain of the target insect species was maintained on non-*Bt* maize refugia, other individuals of the same population were resistant to Bt maize suggesting that the refuge had been compromised in the area where resistance occurs which was an area of non-compliance with the refuge requirements.[12]

3.9 Assessing the impact of *Bt* maize on non-target Lepidoptera and selected non-target insects on *Bt* and conventional maize

The list of indicator species to be monitored as part of a GM monitoring programme is still being determined. A study by Höss et al (2008)[17], proposes the use of *C. elegans* as a useful indicator organism in toxicity test in fields cultivated with Mon810 as it is quick and cost-effective and can be used in both aqueous media and in the field.

This SANBI study surveyed the various arthropod and plant species to build up a checklist of species inside and around maize fields (up to a radius of 400m outside the field in four provinces of South Africa. Arthropod biodiversity in maize was found to be high (281 different species) and no difference was observed in total arthropod diversity and abundance between *Bt* and non-*Bt* maize.[18] In all, plant and arthropod diversity in and around maize fields indicated between 850 and 900 different insect species and approximately 250 plants species within a 400m radius from maize fields. The data from this study is still being interrogated to prioritize Lepidoptera species for further testing and monitoring in maize fields.

3.10 The effect of direct and indirect consumption of *Bt* maize on selected non-target insects

All ecosystems are a web of complex interactions among species involving preys, predators and super-predators interactions. There is some concern that the large-scale production of transgenic crops may carry potential ecological risks to the natural enemies either directly (as herbivores) or

http://i40.tinypic.com/2ynjw9g.jpg

indirectly (as predators and parasitoids) exposed to it, as it moves through the food chain inside agro-ecosystems. This study assessed impacts on the tritrophic food chain; plant – pest – natural enemy, specifically the Lepidopteran common cutworm (Agrotis segetum), African bollworm (*Helicoverpa armigera*), black maize beetle (*Heteronychus arator*) and wire worms (toktokkie beetles) (*Somaticus angulatus*); as well as the parasitic fly, *Sturmiopsis parasitica*, which is an important larval parasitoid of stem borers in Africa and which parasitizes various lepidopteran stem borer species of importance in South Africa. The SANBI study concluded that the effects of *Bt* maize on cutworm and beetle species were negligible. For the African bollworm, however, significant numbers of larvae were found to survive after feeding on *Bt* maize ears, which is of concern since it could develop resistance and become an important secondary pest.[19]

3.11 Effects of growing *Bt* maize and its incorporated leaf litter on microbial diversity and mycorrhizal fungi in soil

During growth of Mon810 crops, the Cry1Ab toxin against lepidopteran pests is released by the roots in to the soil.[20] Additionally, during cultivation, plant residues are left in the soil, which has been found to contribute to an increase in the amount of *Bt*-protein in soil. The protein is able to persist in soils by binding to clay particles and humic acids from soils and retaining their insecticidal activity in that state for up to 40 days[21] and in some cases, up to 7 months after harvesting.[22] The leaf residue and exudates from roots of the toxin increases the potential of soil-dwelling organisms, feeding on leaf litter, to be exposed to the recombinant protein. Yet other studies have reported minimum, non-persistent, and site- specific effects with fewer nematodes, more protozoa and fewer amoebas with Mon810 residue than with the non-Bt maize.[23] Other potentially affected organisms include earthworms.

This SANBI study was carried out to determine the effects of growing *Bt* maize, or amending soil with *Bt* maize stems and leaves, on microbial diversity[24] and found no consistent effects on microbial functional diversity, mycorrhizal spore counts and earthworm numbers under both field and glasshouse conditions in the short-term. A recommendation of the study was the need for longer-term assessments of up to 15 years especially in commercial maize planting regions of South Africa.

4. The requirement for monitoring

In terms of the National Environmental Management Biodiversity Act (Act no. 10 of 2004; NEMBA), SANBI has the responsibility to monitor and report on the environmental impacts of GMOs released into the environment in South Africa.[17] The Act specifically states that SANBI:

> *"11(1)(b) must monitor and report regularly to the Minister on the environmental impacts of all categories of genetically modified organism, post commercial release, based on research that identifies and evaluates risk."*

The GMO Research and Monitoring Unit within the Applied Biodiversity Research Division of SANBI is tasked with this monitoring and reporting function. NEMBA also contains a mechanism whereby the Minister may trigger the requirement for an Environmental Impact Assessment (EIA) of a genetically modified organism (GMO) under the National Environmental Management Act (NEMA). To date, the Minister has not felt the need to trigger such an EIA and no EIAs for the release of GMOs into the South African environment have been carried out.[25]

The African Centre for Biosafety has consistently maintained the need for post commercialisation testing and monitoring for the following reasons:

- To determine if pre-commercialisation testing protocols adequately assess the risks;
- Long term monitoring is needed to record trends in predicted effects and to detect effects which were not predicted;
- Post-commercialisation testing or validation is part of quality control;
- Evidence collected over a period of time can confirm the accuracy of pre-release protocols;
- Low probability and low magnitude effects would likely escape detection in test experiments;
- To observe smaller and less frequent health risks, an appropriately long time scale is needed;
- Rigorous monitoring reassures the public; and the NDA and DOH cannot continue to ignore public health concerns, to do so is irresponsible;
- Pre-commercialisation risk analysis has several weaknesses: small scale experiments are only capable of detecting large effects (order of magnitude differences); and
- Different kinds of monitoring regimes are required for different needs;

4.1 The Proposed Monitoring Framework

Several of the studies especially in respect of biodiversity identified the need for longer-term monitoring[20,13,15]. In the Lichtenburg maize growing area of South Africa, a resistant target pest population was identified and it was found that current refugia are inadequate to prevent gene flow. This points to a need for an extensive grower education programme.

In respect of molecular characterisation and proteomics, the SANB preliminary proteomic studies identified additional detectable proteins in the Bt plants and varying gene expression levels of the same protein between GM and non-GM plants, all of which require further investigation. Not only to definitively identify the additional proteins, but also to assess the impacts of the varying expression levels both on target pests as well as environmentally. Several questions regarding the molecular characterisation of Mon810 have arisen elsewhere in recent years from observations from published studies. These include the detection of the presence of the synthetic transgene fragments in the blood[26] as well as of several unintended and novel RNA fragments such as of the ubiquitin ligase gene, which codes for an enzyme implicated in the regulation of several cellular functions.[27] The implications of these findings, in respect of biosafety, still need to be tested. This also highlights the limitation of currently utilised methodologies in the characterisation and reporting of GMO molecular information.

http://www.combipharm.co.za/images/maize-field.gif

The variability observed in Cry1Ab in the SANBI and other studies raise questions of the value of current risk assessments – it is untenable that commercial approval can be granted for GM events where the toxicity levels are in question. This also has implications for insect resistance management, as resistance development could be accelerated by sub-lethal toxin doses.[13] This question needs to be addressed in advance of any approvals and requires the advanced intervention of the regulatory authority, the Department of Agriculture, Forestry and Fisheries (DAFF) at the application stage. Key findings in a peer reviewed study by Then[28] on synergism, efficacy and selectivity of toxins, found that the mode of action of Cry1Ab is not fully understood and that contradicting theories[29,30] have even been published in the last few years. Furthermore, *Bt* toxin interaction with susceptible organisms is very complex and cannot be explained only by a linear dose-response – other models fit as well. Several external factors can impact the toxicity of Bt toxins and synergism can very often result in higher toxicity.[31,32] The synergism as mentioned can also influence the selectivity of the Bt toxin as produced in plants. Monsanto Risk Assessments[33] are often based on selectivity of the toxins used and the assumption of a linear dose–response relationship without considering synergistic effects. Recent publications expand the possibilities of possible tests that might be applied at the level of the risk assessment well in advance of any market authorisation.

In respect of stakeholder input, there has to be clear agreement between all stakeholders on the protection goals. The parameters and indictors need to be commonly understood and agreed upon. An ACB-appointed attendee to the second stakeholder workshop raised concerns that the process was compromised by the lack of access to the original Monsanto data. Participants were asked to identify all the major interaction and score their risks, a task made difficult based on the limited available information. Within this context, some value judgements were made on the basis of the limited available evidence. Any proposed monitoring program requires close cooperation between all stakeholders with clear selection criteria on the suitability of the monitoring program and evaluation plans and the identification of issues of relevance to all.

The proposed SANBI framework does not clarify the nature of the liaison between applicants, supporting organizations of monitoring programs and interested and affected parties (IAPs) in respect of the monitoring programme. It is understood that the DAFF involvement during the stakeholder discussions in the development of the SANBI Mon810 Monitoring Framework, was that of observer. There is no clarity on the inter-departmental agreements in terms of information exchange and whether the Department of Environmental Affairs (DEA) has ready access to the original applicant dossier say in the event that the DEA wishes to trigger an EIA.

The ownership and access to the raw data arising from the SANBI studies is also not clearly spelled out except to say that the proposed Centre of Excellence (CoE) will provide independent scientific data to support the national regulatory framework. Protocols for data collection and data exchange need to be clearly defined. Furthermore, there has to be good temporal and spatial correlation between any proposed monitoring programme and areas of Mon810 cultivation.

No SANBI studies were reported on the possible health impacts arising from consumption of the Mon810 of say plant residues left behind in the field. In 2009, Steinke et al[34] published a paper on a study described as "the most detailed and most precise study ever conducted worldwide"[35] that claimed "that feeding with transgenic maize does not have any impact on the food chain" and that "transgenic maize has no impact on lactating cows." This paper was an English translation of an earlier published paper by the Technische Universität München on feeding trials of Mon810.[36] An examination of the original German-language study[37] found that the original protocol had been amended in a number of ways that would have impacted on the results. For example, only 18 of the 54 cows used in the trial were fed for the full 25 months; the rest were changed at unspecified times and for unspecified reasons, without this being revealed in the English-language paper. In total, only nine of the cows were kept on the GM diet for the full research period and the data relating to the cows that survived the whole trial were aggregated with data for replacement animals. No clear reasons for animal replacement were cited. Furthermore, animals fed with GM maize required consistently higher numbers of medical treatments than did those in the control group animals. The physical condition of animals fed on conventional maize in the second lactation was significantly better than in the animals on the GM diet. No detail on organ studies or the examination of the calves is provided in the study.[38] Just to monitor environmental impacts is not adequate and the framework should extend to cover health impacts.

The SANBI studies for the most part only describe observed effects with no real or in-depth discussion of the causes for such effects, several of which are only now beginning to be understood within the broader scientific community. What the SANBI studies do indicate is how event specific the monitoring is and how a monitoring programme devised for Mon810 cannot be applied unaltered to another GM event. The proteomic data will differ between events, as will the specific modification and its target effects. The framework developed by SANBI must be seen as a preliminary framework because on the current scale of the studies, only limited conclusions were possible. It is encouraging, however, to see that SANBI has taken this initiative towards the development of such a framework.

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