Objection to Monsanto's application for an extension permit for field trials of Mon 87460

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Introduction

Field trials with MON 87460 are currently underway in South Africa at Hopetown, Orania, Pretoria, Lutzville and Delareyville. These field trials form part of a larger initiative under the Water Efficient Maize for Africa (WEMA) Project, a public-private partnership between African Agriculture Technology Foundation (AATF), Monsanto, the International Maize and Wheat Improvement Centre (CIMMYT) and the South African Agricultural Research Council (ARC). A combination of conventional breeding, marker-assisted breeding and transgenics are being used to develop maize with improved drought stress tolerance. WEMA also has partnerships with the national agricultural agencies of Kenya, Uganda, Tanzania and Mozambique. According to the permit applications, "The goal of WEMA is to provide smallholder farmers in South Africa and Sub-Saharan Africa with access to water efficient transgenic maize hybrids, royalty free, enabling them to produce more reliable harvests"[i].

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 GMO Act (1997). 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)). Further, the ACB submitted an objection to the 2010 extension application reiterating our initial concerns. Comments were also submitted in respect of an application by Monsanto for a further extension submitted to DAFF in May 2011.

The comments in this paper respond to a further application by Monsanto for the renewal of field trials for water efficient maize, MON 87460 at Hopetown, Orania, Pretoria, Lutzville and Delareyville. As before, the aim of these trials is to assess the ability of MON 87460 to use water efficiently under normal, severe and catastrophic drought conditions. Several years of ongoing field trials are requested to test drought stress tolerance.

Rational for this application

Approval for field trials with MON 87460 at Hopetown and Orania was first granted in 2007 under a multi season permit, 17/3(4/07/015). Extensions for trial activities at these sites were granted under permit 39.4(4/10/227) in 2010 and permit 39.4(4/11/312) in 2011.

Approval for field trials with maize event MON 87460 at Delareyville, Lutzville and Pretoria was first granted under permit 17/3(4/09/242) in 2009. Approval for extension of trial activities at the approved sites was granted in 2010 and 2011 under permits 39.4(4/10/229) and 39.4(4/11/313) respectively.

Monsanto has requested further field trials "to assess the ability of MON 87460 to use water efficiently under normal, severe and catastrophic drought conditions". In several of

the locations Monsanto was unable to collect sufficient data due to high rainfall. In Orania, Delarayville, Lutzville and Pretoria conditions were sufficiently dry to collect the relevant data and Monsanto would like to continue testing in order to get results over several years.

Monsanto has submitted annual reports on these trials to the registrar and a preliminary report for the current season's trials was provided in Attachment A of this application. Attachment A was not included in the information provided to the ACB, therefore we have not had access to data that has been generated from these trials to date. This lack of information seriously undermines our ability to engage in a meaningful and informed manner.

Status of approval of Monsanto's drought-tolerant maize in the USA

On 30 October 2011 the United States Department of Agriculture (USDA) approved Monsanto's petition for "non regulated status" of MON 8740, thus opening the door for the commercialisation of the event[ii]. MON 87460 gained regulatory approval in December 2011 and is expected to be sold in the United States under the brand name Genuity® DroughtGard™ from 2013[iii]. Monsanto ran field trials with 250 farmers in 2012[iv] and there is anecdotal information that commercial planting has already begun in some areas in the US. Farmers who buy the product will have to sign a licence agreement "committing to use the grain as on-farm feed or to sell the grain for domestic use due to pending import approvals in key export markets"[v].

This decision to release genetically engineered drought resistant maize marks a new era in GM technology, which up until now has been either herbicide tolerant or pest resistant. Monsanto was able to bring this new product to market through a US$1.5 billion joint business venture with BASF, aiming to bring lucrative GM "climate ready" crops onto the market[vi]. WEMA has vouched to give 4 varieties from this pipe line, royalty free, to small scale African farmers[vii] in the countries where the project is being implemented.

Our main concerns

A chief concern is the WEMA project itself. Its goal is to bring transgenic technologies to smallholder farmers "to produce more reliable harvests". We do not believe that this technology is suitable for resource poor farmers; in fact, such technology could undermine food security by replacing open pollinated maize varieties with hybrid seed that must be bought annually. Transitioning to patented seed could also put an end to seed saving and sharing practices, which act as a social safety net and contribute to agrobiodiversity. Monsanto is offering to waiver its technology fee and provide the seed at the same cost as conventional varieties; it will retain and no doubt enforce its intellectual property rights on the seed. It will be particularly objectionable if such seed is handed out to farmers for free or made available through highly subsidised credit to entice farmers away from their current agricultural practices. Experience has shown that once the subsidies and credit dry up, farmers are often deep in debt or simply unable to purchase seed and inputs. In the meantime they may have lost their open pollinated varieties[viii]. We see WEMA not as a boon to smallholder farmers, but rather as a means to

shape biosafety regulation in Sub-Saharan Africa to allow GMOs entrance on a continent that has largely rejected the technology for a number of reasons, but not least because it is at odds with African agricultural practice and conditions.

We have in our previous submissions raised several concerns about the GM maize variety in question. These relate to uncertainty regarding the nature of the modification, the low likelihood that the technology will deliver the promised benefits and possible adverse ecological impacts of introduction of the GM maize into the environment. There are more readily available, more easily implementable, less costly and more sustainable alternatives that should be considered over MON 87460. A report released this year by the Union of Concerned Scientists on drought tolerant maize, titled ***High and Dry. Why genetic engineering is not solving agriculture's drought problem in a thirsty world***[ix], has reached many of the same conclusions.

In addition, we are concerned about the lack of capacity in South Africa to manage the spate of GMOs already in SA's fields and therefore capacity to deal with a new GMO variety that may present as yet even more unknown risks. The difficultly of engaging in the decision making process and accessing the necessary information to do so meaningfully, is also of great concern to us.

The nature of drought resistance

We have in all of our comments submitted to date, highlighted the fact that drought is a complex phenomenon that is not likely to be addressed with a single gene or with a technological one-size-fits-all approach. A recent report by the Union of Concerned Scientists on the role of genetic engineering in the development of drought resistant crops, mentioned above, points out that:

> "Drought presents a particular challenge for genetic engineering because it can take many forms. Droughts vary in their severity and their timing in relation to crop growth. Related factors such as soil quality affect the ability of crops to withstand drought. These complications make it unlikely that any single approach or gene used to make a genetically engineered (GE) crop will be useful in all—or even most—types of drought. What's more, many genes control drought tolerance in plants—a particular challenge for genetic engineering, which so far can manipulate only a few genes at a time".[x]

We are unable to comment on the results of the drought tolerant field trials that have taken place in South Africa since 2007, as these results have not been released to us. However, available data on the performance of MON 87460, gained from the EU Compass website, seem to bear the above statement out. According to Monsanto's data, "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 grain fill 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."[xi]

Two years of field trials in the United States showed that MON 87460 could provide only about 6% more drought protection than conventional varieties. By comparison, it is estimated that conventional breeding has improved drought tolerance in maize in the United States by 1% per year over the last couple of decades. Given that a new GM maize variety can take up to 15 years to develop, conventional breeding turns out to be up to 3 times more effective[xii]. Less risky, less expensive and more effective technologies and practices are available. These are the solutions that need money and focus if we are to address the very real threat of water scarcity, particularly in an arid country such as South Africa.

Other approaches to drought

Traditional breeding methods, biotechnologies such as marker assisted breeding and improved farm management practices all provide avenues for dealing with drought. There are also a number of crops that are inherently more drought resistant, such as sorghum, pearl millet and cassava. However these so-called "orphan crops" have been neglected in favour of more commercially lucrative crops such as maize[xiii].

There are many excellent examples of alternative approaches to drought tolerance. For example, in 2001 CIMMYT collaborated with the ARC and smallholder farmers in Limpopo. The result was 2 open pollinated maize varieties called Grace and ZM521, which were chosen for their early maturation and higher yield under drought and low soil fertility conditions. ZM521 was shown to yield up to 34% more than other varieties[xiv]. Other properties that smallholder farmers were pleased with in these two varieties included good milling properties and in the case of Grace, its suitability for making green mielies (boiled green maize)[xv].Farmers were trained in producing the seed to contribute to local seed security and income generation and SANSOR assisted in the certification process[xvi].

In Malawi in 2009 CIMMYT released 2 drought tolerant open pollinated maize varieties of maize that showed much higher productivity than varieties without improved drought tolerance, while earlier work with tropical maize reportedly produced similar results[xvii].

The International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), 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[xviii].

In contrast, the IAASTD found that genetically engineered crops have little role to play in development and food security, saying that, "The possibility of patenting genetic modifications can attract investment in agricultural research. But it also tends to concentrate ownership of resources, drive up costs, inhibit independent research, and undermine local farming practices such as seed saving that are especially important in developing countries. It could also mean new liabilities, for example if a genetically modified plant spreads to nearby farms".[xix]

Agroecological approaches to drought tolerance would include using cover crops to improve soil structure and water content, no till practises to assist water infiltration, the use of canopy plants for shade, planting crops that are appropriate to the local environment and increasing organic matter in the soil[xx]. Interaction with scientists and farmers to improve conservation technologies and developing breeding strategies to deal with our future water scarcity is essential. Political will to ensure that this happens is also essential.

The mon87460 transgenic cassette

The characterisation of the cassette was not presented in this application, since these details are in the original application for field trials of MON 87460. These were not available at the time of this assessment. Details of the MON 87460 come from the EU GMO compass (http://www.gmo-compass.org). The genetic elements of PV-ZMAP595 intended for insertion into the maize genome between the T-DNA borders are: from the right border region, promoter and leader from the rice actin gene (P-Ract1), a non-translated intron from the rice actin gene (I-Ract1), the cspB coding sequence (CS-cspB) and a polyadenylation sequence from the transcript 7 gene (T-tr7). These elements together constitute the cspB expression cassette which is followed by the nptII expression cassette. The latter is flanked by two loxP sites and constitutes of a transcriptional promoter (P-35S), the nptII coding sequence (CS-nptII), and a polyadenylation sequence from the nopaline synthase gene (T-nos). MON 87460 contains one copy of the insert at a single insertion site hosting both cspB and nptII intact expression cassettes. No additional elements from the transformation vector PV-ZMAP595, linked or unlinked to the cspB and nptII expression cassettes, were detected in the genome of MON 87460. Additionally, backbone sequence from the plasmid PV-ZMAP595 was not detected.

CspB is an extensively studied protein known to facilitate adaptation to environmental stresses in bacteria. CspB is known to bind and unfold secondary RNA structures that compromise the ability of the cell to translate those RNA molecules, thus helping to preserve normal cellular functions. The effect of CspB expression in plants are unknown, but would be expected to exert a similar effect on RNA molecules, thereby affecting the expression levels of genes(s). As such one would expect the characterisation of MON 87460 to include studies of gene expression using techniques of RNA profiling and proteomics so that unintended genetic effects could be studied. However, these experiments have not been carried out.

Also of biosafety concern is the presence of the kanamycin antibiotic resistance marker (ARM), *nptII.* Current evidence shows that horizontal gene transfer (HGT) to bacteria does occur and occurs at a high frequency when sequence homology is present. For example, the *nptII* gene in transgenic potato plants coding for kanamycin resistance, transforms naturally competent cells of the soil bacteria *Pseudomonas stutzeri* and *Acinetobacter* BD413 with the same high efficiency as nptII genes on plasmid DNA ($3x10^{-5}$ -$1x10^{-4}$) despite the presence of a more than 10^{6} fold excess of plant DNA. However, in the absence of homologous sequences in the recipient cells the transformation dropped by at least about 10^{8} fold - 10^{9} fold. This indicates that recombination in bacteria is most efficient where sequence homology is present (de Vries and Wackernagel 1998). The *nptII* gene has many gene homologs in soil bacteria indicating an increased frequency for recombination and horizontal gene transfer. Additionally *nptII* is flanked on both sites by loxP recombination sites resulting in an enhanced recombination potential in many bacteria. Thus, it is reasonable to assume that the nptII gene has an increased likelihood of successful recombination and expression in exposed bacterial recipients. The risk of transgene escape is likely to be increased due to the presence of *LoxP* sites in the transgenic cassette. These LoxP sites are recognize by Cre recombinases of viruses that infect bacteria (bacteriopaheges) thereby facilitating recombination and increasing horizontal gene transsfer and the dissemination of the transgenic cassette and nptII ARM.

The selective pressures that would confer advantage to bacteria that have acquired a new (trans)genic element are poorly studied but may confer an advantage *per se,* since many antibiotics are produced by Actinomycete bacteria to kill competing bacteria in the soil; acquiring antibiotic resistance may acquire a selective advantage resulting in a change in soil biodiversity and functioning. Selective pressures may also include several stresses such as soil tilling or application of agrochemicals since current evidence suggests that a stress response facilitates the HGT and spread of antibiotic resistance genes. For example, the SOS response—induction of specific genes in response to DNA damage—alleviates the repression of genes necessary for horizontal transfer of the mobile integrating conjugative element SXT. This is a ~100 kb plasmid derived from Vibrio cholerae that confers resistance to the antibiotics chloramphenicol, trimethoprim, streptomycin, and methoxazole. (Beaber *et al*., 2003). The emergence of bacterial antibiotic resistance as a consequence of the wide-scale use of antibiotics has resulted in a rapid evolution of bacterial genomes. Furthermore, mobile genetic elements have played a key role in spreading antibiotic resistant genes amongst bacterial populations and contribute to multiple antibiotic resistance by bacterial pathogens (Salyers and Shoemaker, 1994; and Witte, 1997). Therefore, there are risks associated with the spread of antibiotic resistance genes amongst soil bacteria or to the human gut bacteria, even when there is no selection for the transgenic construct per se (such as selection for kanamycin resistance). The main concerns regarding GMOs containing antibiotic resistance maker genes is that HGT will spread antibiotic resistance genes amongst disease-causing microorganisms.

The antibiotic kanamycin is still used world-wide in operative procedures of colon and rectum and to treat ear infections and has also been found to be effective against E coli 0157 as well as important tropical disease of developing countries such as Tuberculosis

(TB) (Ishikawa *et al*., 1999, 5, 86-90, Hehl *et al*. 1999, Yelon J, *et al*. 1996, Ito *et al*. 1997). The fact that there is cross resistance to B- aminoglycoside antibiotics means that the spread of kanamycin resistance will also increase the spread of resistance to other of B-aminoglycosides that are invaluable in treating important tropical disease such as Tuberculosis (TB). The World Health Organization estimates that there are 9.4 million new TB cases and 1.7 million deaths annually. Coinfection with HIV and the emergence of resistant strains has reaffirmed TB as a global public health threat. Multidrug-resistant *Mycobacterium tuberculosis* (MDR-TB) strains are resistant to rifampin and isoniazid, the two first-line TB drugs; extensively drug-resistant *M. tuberculosis* (XDR-TB) strains have, in addition, acquired resistance to any fluoroquinolone and to any one of the three injectable second-line anti-TB drugs (amikacin, kanamycin, or capreomycin) (Jassal and Bishai 2009, Onaolapo 1994, and Mikkelson *et al* 1999).

Practically every medical organization that has looked at GMO crop safety has expressed concern with the use of antibiotic resistance marker genes, including the American Medical Association, World Health Organization, UK Royal Society, United Nations Food and Agriculture Organization, Pasteur Institute, European Food Safety Authority, and the British Medical Association. Alerted to these risks, European Union (EU) decided to prohibit and phase out GMOs with antibiotic resistance genes after the 31 December 2004 (directive 2001/18EC and Revising Directive 90/220/CEE).The EU has taken a pragmatic approach, where antibiotic resistance genes are classed into three categories based upon how useful the respective antibiotics are in medicine (to treat disease). The *nptII* is class1 that may still be used (class 2 and 3 is to be phase out and not allowed). Although the B-aminoglycoside antibiotics (such as kanamycin) have limited use in highly developed countries for treating diseases, they are important in less developed countries, such as South Africa, because they are used to treat diseases like TB. Therefore, the use of *nptII* carries different biosafety risks in South Africa. With the cross-resistance of B-aminoglycoside antibiotics and the spread of multiple resistance genes between microorganisms it can be expected that the use of *nptII* will compromise out ability to treat disease. This is very relevant in South Africa, since cross-resistance of B-aminoglycoside antibiotics is well recognized and sprectromycin and kanamycin is used to treat diseases such as TB (Heifets, L. B. 1991, Onaolapo J. (1994) and WHO 1997).

To conclude, the release of transgenic plants containing antibiotic resistance genes into the environment will increase the spread of antibiotic resistance amongst microorganisms compromises our ability to treat disease and, therefore, it is in our interest to limit the spread of antibiotic resistance.

The risk assessment states that "Except for the introduced trait, MON 87460 is equivalent to conventional maize." There is no data to back this claim up. In SANBI's investigation of MON810, researchers investigated protein expression and regulatory RNA expression for unintended effects for a specific variety grown in a particular environment. The study concluded that "GM plants grown in the same environment as the near isogenic-parent (non-GM counterpart), respond differently to the same environmental conditions, as shown by the differences in protein expression, for a number of proteins"[xxi].

The study recommended that further research is needed to understand what types of proteins are expressed differently in different varieties of GM and non-GM plants under different environmental conditions. It also recommended that, "Due to the unpredictable nature of these unintended, unwanted effects, it is essential to monitor and identify such

effects in field-based baseline studies in several growing conditions, and with several genetically modified varieties"[xxii].

The SANBI study also called into question the common practice of testing Bt protein engineered in bacteria rather than in the maize host, concluding that, "the CryIAb protein expressed in bacterial and maize hosts differ in protein size, and hence are likely to differ in other structural 'protein folding' characteristics. …. The differences in size and possible bioactivity between maize expressed and bacterially expressed CryIAb '*Bt*' proteins suggest that the practice of using the bacterial version as a replacement for maize versions of the same transgenic protein in safety testing should be re-evaluated. Further characterization work is necessary to determine the actual differences in composition that may be related to the size differences detected, and to confirm whether the computer simulations of changes in bioactivity accompanying secondary structure differences exist in bioactivity assays. Regulators may wish to re-examine policies of the use of bacterial versions in place of maize versions, as suggested by at least one expert body"[xxiii].

Lack of monitoring

Given the uncertainties in the biosafety risks of releasing of transgenics into the environment, careful design of field trials and a proper monitoring programme is required. The details of the trial-site design were not provided (i.e. Appendix B omitted) making independent assessment of the biosafety risks impossible. In one study, out-crossing of maize was <0.01% at 500m and no out-crossing was detected at 750m and 2 week of temporal separation (Halsey *et al*. 2005). This indicates a considerable isolation of maize is required to prevent transgene escape and the hybridization and out-crossing with non-GMO varieties and maize landraces. The details of the trial site, including the experimental design, have been considered CBI, and therefore these risks cannot be independently assessed. Furthermore, no data has been presented to assess the seed viability and dormancy to assess the weediness potential compared to the non-GMO counterpart.

Also of great concern, the applicant expects farmers at the trial site and on neighboring farms to identify and report problems such as the escape of MON 87460 beyond the field trial. Page 8:

> "The environment immediately surrounding the trial sites includes soya beans, natural veld and maize. Therefore, to a large extent, the environment directly surrounding the trial sites is continuously monitored through day-to-day activities by the local farmers and/or residents."

Given that there are no phenotypic (observable) characteristics MON 87460 compared to many other non-GMO maize varieties, the escape of MON 87460, and hybridization with non-GMO maize may go unnoticed until tested using a sensitive molecular technique. This molecular testing will likely only be carried out if transgenic maize is exported (transboundary movement requires such testing under the Cartagena Protocol on Biosafety), but should be part of the field trial monitoring program. A sensitive PCR detection method is available (http://gmo-crl.jrc.ec.europa.eu/summaries/2012-01-27_MON87460_validated_Method.pdf) but the applicant does apply this to a monitoring programme.

There is also a lack of monitoring for unintended effects on biodiversity with no details being provided as to whether this will form part of the field trial studies. Indeed the field trials seem to be focused on testing agronomic performance. There is no proposal to monitor any of possible unintended effects (mentioned above) which contravenes South Africa's obligations under the Cartagena Protocol on Biosafety, National Environmental Management Act (1998) and the and GMO Act (1997) (failure) to monitor changes in biodiversity as well as monitor GMO transboundary movements.

Socio-economic impacts

The WEMA project specifically aims to uplift smallholder farmers with this technology. As such, socio-economic impacts must be outlined and evaluated. Questions that must be asked include:

- If this technology is to be adopted, how will small holder farmers access finances to afford seed that must be bought annually and needs external inputs for a successful crop?
- How will they access markets to sell their produce to service loans?
- What about the erosion of open pollinated varieties and cultural practices?
- How will the adoption of this technology impact on small-holder diverse cropping systems that are used to mitigate risk and supply dietary variety or other services such as animal fodder?
- Will the adoption of this technology result in onerous management obligations?
- Will training and contracts be done in languages that smallholder farmers can understand?

The table below has been developed by CIMMYT to guide farmers in their choice of hybrid versus open pollinated variety. In many instances, the very type of farmers that WEMA hopes to support, would be advised to cultivate open pollinated varieties.

Farmers' checklist on when to grow a hybrid or OPV[xxiv]

When to grow a hybrid	**When to grow an OPV**
The farmer expects to harvest more than2 tons/ha (15 bags per acre) of maize grain.	The farmer does not expect to harvest more than 2 t/ha of maize grain.
The costs of hybrid seed will be recovered from its yield advantage. Hybrid seed costs about 10 times the price of grain, and therefore the yield advantage of the hybrid should be at least 250 kg/ha.	The costs of hybrid seed may not be paid for by its yield advantage over the OPV.
The farmer is located in a high potential environment and can afford inputs such as fertilizer and pesticides	The farmer is located in a low potential environment and cannot afford extra inputs.
Hybrids adapted/suitable for local conditions are available.	No locally adapted/suitable hybrids are available.

There may be several consequences of gene escape and hybridisation with other maize varieties or landraces. Maize has undergone many generations of breeding and natural selection to create numerous varieties suited to South Africa (adapted for increased resistance to soils, drought, pests etc.). This forms part of the indigenous knowledge systems and unique seed banks of maize varieties and landraces. Since GMO maize will freely cross-pollinate, hybridise and outcross with non-GMO maize, there are risks of contamination of South African landraces and loss of South Africa's unique maize seed diversity and the spread of patented-genes to landraces. The mixing of transgenes with South African landraces may also incur liability to other farmers that have not intended to grow MON 87460 since these transgenes are patented and the intellectual property of Monsanto.

Since GMO maize will freely cross-pollinate with non-GMO maize (wind pollinated over distances of 1km), contamination is practically inevitable. Globally, the loss of genetic diversity in agricultural crops is of serious concern. The diminishing number of crop varieties and patenting of seed makes the farmer dependent on external inputs and more susceptible to external shocks. For example, the saving of seed and selection of horizontal resistance was largely responsible for saving maize production from destruction in tropical Africa after the unintentional introduction of the fungal disease, Pucinia polysora, or tropical rust.

A lack of segregation of GMO with non-GMO maize can result in rejection of maize from importing countries such as the EU. Other African countries are also major importers of South African maize, many of which are yet to finalise their biosafety regimes. The comingling of GMO varieties in bulk shipments that may or may not have approval in their destination countries can also jeopardise trade. Indeed, South Africa is no longer importing bulk shipments of GMO maize from Argentina or Brazil since 2010, due to un-segregated bulk shipments that contain GM events that have not been approved in South Africa[xxv]. As noted earlier in this submission, American farmers who buy this technology will be obliged to commit to ensuring only on-farm and domestic consumption of their product, for this very reason.

Lack of biosafety capacity in South Africa

Independent analysis of these trials has been challenging for the ACB, not least due to lack of information. As noted in our previous submission, the original decision by the South African regulatory authority to permit field trials of MON87460 has not been made publicly available through the Biosafety Clearing House (BCH) in terms of Article 20 of the Cartagena Protocol. (South Africa became a party in August 2003.) Details on the gene construct of MON87460 for this submission had to be gained from the EU Compass website and the Appendices (A and B) in the application that provide details and reports on the findings from trials since 2009, were not provided with the current dossiers. Due to this gross omission of data and evidence, independent assessment cannot be carried out. The consequences are that many of the statements provided by the applicant cannot be substantiated and the Biosafety assessment becomes and farcical rubber stamping approval process. The ACB has formally alerted the Minister of Agriculture about this non-compliance with the Cartagena Protocol on at least 3 occasions. Since 1999, SA GMO

authorities have granted well over 2000 permits, however, there are only 13 decisions posted to the BCH, which was last updated in 2009. The Department of Agriculture, Forestry and Fisheries (DAFF) has been in the process of developing a South African BCH on their own website since 2005. While the link appears on the site, it still does not work. This calls into question whether the resources and capacity within the DAFF are optimally geared to ensure thorough and complete assessment of applications for the introduction of GMOs into the environment.

In terms of post-harvest monitoring, it is apparent that a similar lack of capacity constrains those mandated to ensure biosafety. The South African National Biodiversity Institute (SANBI) confirms this in their first study on the impacts of GMOs, saying that "The fast development and adoption of biotechnology in South Africa has not been adequately supported by a comprehensive biosafety research focus". This study comes thirteen years after the introduction of GMOs into our environment and assesses one of 15 GMOs granted general release status in South Africa.

In addition, labelling legislation still hangs in the balance, with consumers insisting on the right to know what is in their food while the food industry claims that creating Identity Preservation systems and ensuring meaningful labelling is impractical.

Regulating authorities have yet to come to grips with the herbicide tolerant and pest resistant GMOs growing in SA's fields. We question their capacity to deal with a completely novel GMO with no history in the environment and which is likely to pose new and unknown risks.

Conclusion

We reiterate our concerns with regard to this GM maize varieity, that:

1. Current data suggests that yield benefits will at best be modest, in severe drought conditions there will be no benefit whatsoever. The risks of exposing the environment, the public and environment to such a product cannot be justified within this context. Many viable alternative already exist.

2. No details on the experimental or trial-site design were given, making informed assessment impossible. Data from the past 5 years of trials has also not been made available to us.

3. The trials are focused on agronomic performance with no attention being paid to monitoring for unintended impacts. Lack of monitoring is problematic and the expectation that farmers will report unintended effects is unrealistic.

4. Despite Monsanto's assurances, the use of ARMG remains controversial and problematic, especially in South Africa where kanamycin is still in use.

5. GMO monitoring and administration is lagging behind permits granted and cannot cope with a new event.

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.

We do not believe that WEMA is taking the right approach with smallholder farmers and indeed, that their approach could ultimately undermine food security and agrodiversity. Given the lack of full characterisation of MON 87460 and an effective monitoring programme being in place, and given the fact that less risky and more efficient alternatives exist, it is recommended that the application for the extension of files trial should not be granted.

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