AFRICAN CENTRE FOR BIOSAFETY

Safe Food Coalition

BIOWATCH SOUTH AFRICA

SAFeAGE: The South African Freeze Alliance on Genetic Engineering

10 May 2004.

To; The Hon. Thoko Didiza
Minister of Agriculture.
The Hon. Dr. Manto Tshabalala Msimang
Minister of Health.
Union Buildings
Pretoria
0001

Dear Honourable Madam Ministers,

This letter serves as cover to a full setting out of our reasons overleaf, as to why **the National Department of Agriculture should ban the import of Bt176 maize and also call for a public enquiry into the safety of GMOs.** This enquiry must review the health, environmental and regulatory implications of this product, without delay.

This genetically modified insect resistant maize variety has been withdrawn from use in both the EU and the USA. Although these reasons differ, we set out in the attached letter our reasons and rationale why we should follow suit with this international decision of best practice of regarding the management of GMOs.

Besides examining the aforementioned concerns we also set out our obligations under international agreements and protocols to which we are party, such as the Cartegena Biosafety Protocol and the UNFAO/WHO Codex Alimentarius.

Sincerely

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Minister of Agriculture and Land Affairs
Hon. Thoko Didiza
Fax: (012) 321 8558

Minister of Health
Hon. Dr Manto Tshabalala Msimang
Fax: (012) 325 5526

RE: DEMAND FOR A BAN ON IMPORTS OF BT176 AND FOR A PUBLIC ENQUIRY INTO SAFETY OF FOOD DERIVED FROM GENETICALLY MODIFIED CROPS.

Dear Honourable Madam Ministers

We wish to bring your attention to the decision taken by the Spanish government on the 29th April 2004, to ban Syngenta's genetically modified (GM) Bt176 maize for commercial cultivation on the grounds that it may confer resistance to ampicillin. (*EIEstado espanol retirara un OGM a instancias de la UE. El maize Bt 176 Podrian provoca resistencisas a los antibioticals, GARA*). According to Richard Lopez de Haro, Spain's Office of Crop Varieties, Spain's food safety authority banned Bt 176 after the European Food Safety Authority (EFSA) published its report on the utilisation of antibiotic resistance market genes in GM plants. (http://www.efsa.eu/int/press_room/press_release/386_en.html).

We also point out that even the United States, the world's largest grower and exporter of genetically modified organisms (GMOs) does not allow for the growing of Bt176. Although the US government's Environmental Protection Agency (EPA) approved Bt176 in August 1995, in January 2000, the EPA stated "no sales of Event 176 should take place after January 2000" (US Environmental Protection Agency (EPA). *Amended Revised Response to EPA's Data Call-In Notice Concerning the Potential for Adverse Effects of Bt Corn on non-target Lepidopterans*. Agricultural Biotechnology Stewardship Technical Committee).

Several European countries including Austria, Luxembourg, France, Norway and the United Kingdom have expressed grave concerns about antibiotic genes in GM products. As a result, the EU has decided to prohibit GMOs with antibiotic resistance genes after the 31st December 2004.(Directive 2001/18EC) (Revising Directive 90/220/CEE).

The National Department of Agriculture (NDA) approved Bt 176 as safe for food, feed and processing in South Africa several years ago. Indeed, the NDA has issued a large number of import permits for bulk shipments of tens of thousands of tons of GM maize from Argentina, containing several GM maize events, namely MON810, T25, Bt11 and Bt 176. According to your department, these bulk shipments of GM maize are imported from Argentina for animal feed by the animal feed industry in the Western Cape because it is cheaper for them than to purchase maize on the South African market.

We remind you, Madam Ministers, that the purpose of biosafety legislation is not to enable industry to source the cheapest maize on the global market, but to protect the public from the risks posed by GMOs, based on the precautionary principle.

## 1. Risk of the antibiotic resistance gene in Bt176

Bt176 contains the *bla* marker gene that confers resistance to ampicillin, an antibiotic group widely used in animal and human medicine. Ampicillin belongs to the penicillin group of antibiotics. These antibiotics are used for the treatment of several serious diseases, such as pneumonia, bronchitis, and diphtheria.

The appearance of resistance to certain antibiotics in pathogen bacteria is a huge concern for medicine today. The introduction of GMOs containing antibiotic resistance genes into the food chain enhances the risk of worsening the problem as DNA can survive in animal and human gastro intestinal tract. There is scientific evidence that GM food can transfer its antibiotic resistance genes to bacteria in the gastro intestinal tract or to bacteria in the environment. (e.g. *Evaluating the risks associated with using GMOs in human foods.* New Scientist: January 30, 1999). According to the British Medical Association "*There should be a ban on the use of antibiotic resistance marker genes in GM food, as the risk to human health from antibiotic resistance developing in micro-organisms is one of the major public health threats that will be faced in the 21st Century. The risk that antibiotic resistance may be passed on to bacteria affecting human beings, through marker genes in the food chain, is one that cannot at present be ruled out.*" (British Medical Association. *The impact of genetic modification on agriculture, food and health. Recommendations.* May 1999).

The risks associated with antibiotic resistance are totally unacceptable, especially in South Africa where ampicillin and related antibiotics are used to treat opportunistic HIV and AIDS infections.

## 2. Fundamental Flaws in South Africa's regulatory system

### 2.2 Single approvals for import of multiple GM events

1. The South African government grants approval to importers in a single application for the import of several GM events for use in South Africa as food, feed and/or processing. This approach is contrary to international sound biosafety norms and standards. The international trend is for a single application for approval to be made for a specific event for a specific purpose. Norway for instance, which has a major farmed salmon industry is even examining distinctions between fish and land animals, and hence the safety parameters/requirements for GE feed.

Single approval for the import of multiple GM events reduces the liability by those responsible, in the event of a mix-up occurring as it did in the Starlink case. Moreover, such approval does not make it possible for South Africa to fully comply with the outcome of negotiations under Article 18 of the Biosafety Protocol (see below for further details of this).

***The granting by the NDA of one permit to importers for the import of multiple GM events must be urgently reviewed.***

### 2.2 Segregation, unique identification and labelling

The South African government does not require that GM maize be segregated from non-GM maize during production, processing, distribution etc. The risk of contamination by way of co-mingling of GM animal feed imported into South Africa with maize milled and distributed for human consumption is thus extremely likely, as has already occurred with Starlink maize. **It is thus extremely likely that GM maize imported from Argentina into South Africa that may contain Bt 176 enters the South African human food chain directly.**

The South African government has also failed to establish an identity preservation system, whereby the unique identification of GMOs/GM events can be traced throughout the food chain, from farm to plate. Thus, in the event that GM maize imported into South Africa from Argentina adversely affects animal and/or human health, it will be almost impossible for anyone to trace the offending GM event, and hence, the offending biotechnology company. **There is no reason why the South African government should shield the biotechnology industry in this way.**

The Department of Health promulgated labelling regulations for GMOs and GM food on the 16 January 2004. These do not require mandatory labelling, but at the same time, do not preclude voluntary labelling. It is our respectful view, that food producers who may wish to label GM products or products that may contain GMOs, may be severely impeded from doing so, especially if such producers wished to provide the consumer with full details of the GMO in question, in particular, information of the GM construct; the GM event, the transgenic line and trait etc.

## 2.3 Substantial Equivalence

The South African government has granted approved Bt176 as safe for use as food, feed and processing, some years ago. It has done so, principally because it considers Bt176 to be "substantially equivalent" to its conventional counterpart. 'Substantial equivalence' has been severely criticised as being a pseudo-scientific concept, because it is seen as a commercial and political judgement masquerading as it if were scientific. It is also viewed as a barrier to further research into possible risks of eating GM foods. ( *Millstone, E. et al Beyond 'substantial equivalence' Nature, Vol. 401, 7 October 1999*). A recent major literature review of food safety issues has shown a dearth of actual published scientific papers on which a reliable database of safety could be established. (Domingo, J.L. (2000) *Health risks of genetically modified foods: many opinions but few data*. Science 288). There is virtually nothing known about the potential hazards for human health from GM foods, if any.

The analysis of selected dossiers including Bt 176, Bt 11, CHB 351, GA21 etc were submitted to the EU in a project commissioned by the **Austrian Federal Environment Agency** came to the following conclusion:

*"No direct testing of potentially allergic properties of GMP (genetically modified plants) and products derived there from was carried out. The absence of allergenic properties was justified solely in an either argumentative way and/or by giving rather indirect evidence (e.g. digestion studies, sequence homology comparisons).* ***Some quotations of literature intended to confirm the safety of the GMP in the dossiers are cited wrongly or are outdated or are even suspected to be selectively quoted****…..* (emphasis added). ( "Toxicological and allergrological safety evaluation of GMOs" by Spoek, A., et al, 2002)

Below are some extracts from the English summary of the 2002 monograph:

"Toxicological and allergrological safety requirements are not determined in detail in [EC] directives and related documents. Consequently, the margins for putting safety evaluation into practice are rather wide." (page 1).

Note: This applies to all national laws, which rarely provide detailed requirements such as is the case with the South African GMO Act.

On toxicology:

"Data on the toxicity of the whole GMP (GM plant) are not provided in any dossier. Toxicological acceptance is often justified by three arguments: low toxicity of the gene product, substantial equivalence of the GMP to their conventional counterparts, and low exposure. Potentially toxic effects resulting as a secondary effect from the gene insertion are not considered in any case." (page 3).

"GMP are very often declared as being safe just by assumption based reasoning. Furthermore these assumptions are sometimes not easily or not at all verifiable. Risk assessment procedures which are carried out in a systematic way consisting of a hazard assessment of the GMP on one hand and of analysis of exposure on the other hand, are lacking in the dossiers."

On allergology:

"No direct testing of potentially allergic properties of GMP and products derived therefrom was carried out. The absence of allergenic properties was justified solely in an either argumentative way and/or by giving rather indirect evidence (e.g. digestion studies, sequence homology comparisons). **Some quotations of literature intended to confirm the safety of the GMP in the dossiers are cited wrongly or are outdated or are even suspected to be selectively quoted**….. (emphasis added)

Each of [the] arguments and their underlying assumptions has to be questioned in the light of recent scientific data. Furthermore, unintended secondary effects possibly caused by the gene insertion, such as the possible unregulated expression of other allergens through insertion and expression of the foreign gene in the GMP, are not considered at all. A safety evaluation which is based exclusively on the [approaches in the dossiers] is insufficient." (page 3).

***The substantial equivalence approach in the dossiers was also criticised (pages 3-4). Again, the specific analysis conducted by the Austrian project on the GA21 application would be very helpful for GMAC.***

**It is thus our respectful opinion that more science and not less science is needed. Innovative scientific methods are required to interrogate the compositional, nutritional/toxicological and metabolic differences between GM and conventional crops. In addition to assessing the safety of health, it is imperative that feeding studies are employed in order to assess changes in tissue structure and metabolic functions of organs etc.**

## 2.4 Monitoring

The South Africa's GMO Act does not require that the effects of antibiotic resistance genes on the digestive flora of animals eating the GM feed be monitored. In any event, such an endeavour cannot realistically take place, because there is no segregation of GM maize during processing. Monitoring is also not a priority for the South African government because its labelling regulations promulgated on the 16 January 2004, does not require mandatory labelling of GM food or food that may contain GMOs, let alone the mentioning of the trait.

## 3. South Africa's rights and duties under the Cartagena Protocol on Biosafety

## 3. 1. Review of decision and the Precautionary Principle

As a Party to the Cartagena Protocol on Biosafety (the Biosafety Protocol), the South African government is entitled to ban the import of Bt176 maize from Argentina. It may do so in terms of Articles 12 and 11(8) of the Biosafety Protocol.

Article 12 of the Protocol allows South Africa to review its decision on imports of GMOs in the light of new information or circumstances about the risks to the environment, biodiversity and human health. Scientific information regarding the negative impacts of Bt176 on human health that may not have existed or may not

have been known by the South African government at the time a decision was taken. These now clearly exist and it is incumbent upon the South African government, as a Party to the Protocol, to review its approval for Bt176, and impose an outright ban.

Moreover, it is imperative that the government review its decision, based on the precautionary principle set out in Article 11(8) of the Protocol.

The precautionary principle demands a rigorous scientific approach and ensures democratic decision-making in regard to the acceptance of risks. It also requires the seeking and considering of sustainable alternatives precisely because it explicitly considers uncertainty and ignorance.

We also expressly point out that the onus is on the proponent of GMOs-in this case, Syngenta, - to discharge the burden of proof that GMOs are safe, which it has clearly failed to do.

It is not required that those who raise objections to GMOs or voice concerns, should provide proof of adverse effects. The demand either by industry or regulators of proof of harm before action is taken can lead to ‘paralysis by analysis'. ( Harremoes, P. et al *The Precautionary Principle in the 20th Century: late lessons from early warnings.* London: Earthscan.)

## 3. 2. Unique Identification

The First Meeting of the Parties (MOP), Kuala Lumpur, Malaysia 23-27 February 2004, adopted an important decision on the documentation that accompanies bulk shipments of GMOs imported for food, feed and processing. In this regard, the MOP decided that in regard to GMOs imported for direct use as food, feed and processing, the documents should clearly identify that the shipment **may contain LMOs for direct use as food, feed or for processing and not intended for direct introduction into the environment.**

The documents should include the **common, scientific and commercial names of the LMOs, the transformation event code or its unique identifier code to establish clearly the identify of the LMO and any unique identification.**

It is thus incumbent upon the South African government to urgently establish a sound unique identification system in order to come in line with the imperatives of the Protocol. A good unique identification system will greatly facilitate access to full biosafety information and risk assessments; can help enable traceability, surveillance, post-market monitoring, risk management, remedial actions and assignment of liabilities in cases of contamination of damage. (Lim Li Ching *Unique Identification and the Cartagena Protocol.* Third World Network and Institute of Science in Society Doc. TWN/Biosafety/2004/E).

However, we point out that the current method of approval by the NDA, namely, the issue of one import permit for several GM events to be imported in one shipment, will not allow South Africa to fully utilise the outcome of either MOP 1 or the ongoing negotiations under Article 18 of the Biosafety Protocol. This situation has far-

reaching implications for food producers in South Africa who may wish to label their products, as already pointed out above.

### 4. Codex Alimentarius.

As members of the United Nation's Food and Agriculture Organisation (FAO) and World Health Organisation (WHO)'s Codex Alimentarius, South Africa must also take into account the recommendations of Codex concerning especially, risk assessment of GMOs.

Non-scientific elements also are consistent with the Codex mandate such as the need to deter deceptive practices, including the selling of GM foods to consumers without informing them of the alteration, even though surveys have consistently shown that the large majority of consumers in South Africa want this information. Indeed, the Codex Commission has recognised that there are "Other Legitimate Factors" than those purely based on science, and that these are still a valid basis for regulations.

## In the light of the above-we appeal to the Minister of Agriculture and Land Affairs and the Minister of Health to take immediate action to:

1. Immediately ban all imports, use, growing of Syngenta's Bt176;
2. Hold an urgent public enquiry into the food safety of GMOs, including GM food and feed, irrespective of whether transgenic material is detectable in GM food, feed or products of GMOs;
3. Fully comply with South Africa's obligations under the Biosafety Protocol and adhere to the recommendations of the Codex Alimentarius (taking into account that these are minimum standards and that the highest level of biosafety must be attained); and
4. Impose an immediate moratorium on the import, use and release of all GMOs into the environment, until a comprehensive independent review has taken place of the and risks to human health, the environment and biodiversity has taken place.

Signed

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