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26 September 2012

Dear Dr. Pakishe Aaron Motsoaledi

Re: Request for investigation into genetically modified maize and associated chemicals

We write to you from the African Centre for Biosafety (ACB), a non-profit organisation based in Johannesburg. The ACB has a respected record of evidence-based work in contributing to the GMO decision-making process; and protecting our genetic diversity, traditional knowledge and seed sovereignty that is built upon the values of equal access to and use of resources and support for the growing Agroecological farming movement.

Introduction

South Africa is the only country that has allowed the genetic modification (GM) of its staple food – maize. Elsewhere in the world this crop is grown primarily for the global livestock sector. However, in South Africa some 77% of our maize production is genetically modified[1] and provides the nation with their daily intake of carbohydrates. The debate on the long term health impacts of GM foods has raged around the globe for almost 2 decades now and to date there is no scientific agreement on their safety. The United Nation's Cartagena Protocol on Biosafety is based on the Precautionary Principle in recognition of this lack of scientific knowledge and agreement. Our own GMO regulations, paraphrasing the Precautionary Principle set out in the 1992 Rio Declaration on the environment and development, stipulate that a lack of scientific knowledge or scientific consensus shall not be indicative of an absence of risk. Our GMO Act also allows the Executive Council to revise any decisions made in the light of new scientific evidence.

Scientific evidence of serious health impacts from GMO maize

Last week a study on Monsanto's RoundUp Ready Maize (NK 603) was published in the peer-reviewed journal of Food and Chemical Toxicology. The study was led

by Professor Gilles-Eric Séralini of the University of Caen, France. Up until now animal feeding trials, which regulators the world over rely on for GMO risk assessment, have typically been industry sponsored and only go as far as 90 days. This gives no indication of the long term effects of consuming GM food; with no data there is simply no way to verify this. However, the new study led by Professor Séralini, which lasted for 2 years, is a first in this regard. (The study is attached herewith.) These results must be taken very seriously by your department as our nation is consuming this food daily as a large portion of our diet:

- All groups fed on GM maize diets had higher mortality rates (up to 50% of males, and 70% for females) than the control groups fed on non-GM equivalents (30% and 20% for males and females respectively)
- In female groups, there were 2 -3 times more premature deaths in all groups fed on GM diets than the non-GM control groups.
- By the beginning of the 24th month of the study, 50-80% of females fed GM diets had developed tumours, compared to 30% in the female control group.
- In males, liver congestion and premature cell death were 2.5 – 5.5 times higher than in the control groups.
- Further, groups fed water with traces of Roundup formulations below officially set safety limits displayed severe disturbances in the liver, kidneys and mammary glands.

These long term feeding studies show that GM maize may pose major long term threats to human health and indicate an urgent need for the South African government to reassess the decision to grant approval for this variety. The Roundup Ready maize variety used in the study (also known as NK 603) was approved for human consumption ten years ago in South Africa. After a slow uptake by farmers it has, for the last two seasons, been planted on nearly 1 million hectares. This trend looks set to continue, as over 660,000 kg of NK 603 seed has been imported this year[2] for multiplication and planting. To re-iterate, a maize variety that accounts for 40% of our national crop has just been shown to cause tumours and liver and kidney damage in laboratory rats. If this was a drug, it would never receive regulatory approval, and certainly should not be allowed in the general food supply.

Industry Response to the French Study

This is not the first time that shocking results have been published about the possible impacts of GMOs. The response from the biotechnology industry has always been to rubbish the studies rather than to follow up the warning signals to ensure that their products are indeed safe. Monsanto has very speedily responded to the study and its criticisms include[3]:

- Research protocol does not meet OECD standards;
- Source and quality of corn used is unclear;
- Critical details on diet preparation and dietary intake are absent;

- Complete lack of data pertaining to assertions of liver or kidney histopathology, liver function tests, and cytochrome activity;
- Lack of any statistical analysis for mortality or tumour incidence endpoints;
- Mortality rates and tumour incidence in all groups fall within historical norms for this strain of laboratory rats, which is known for a high incidence of tumours;
- Data presented is highly sporadic, using different methods for male and female animals, and is not sufficient to support conclusions drawn; and
- There is a lack of dose-response relationship throughout the study.

Predictably Monsanto conclude that there is no plausible mechanism for the results reported with genetically modified maize, and that the results are inconsistent with an extensive body of experience and scientific study. With regards to results on glyphosate, Monsanto claims that the "study does not provide information which calls into question the extensive safety evaluations of glyphosate or Roundup herbicides"[4].

However, according to Professor Charles Benbrook, a highly respected agricultural scientist from the United States (and former executive director of the US National Academy of Sciences) who has carried out many environmental studies with regard to GM related pesticides in the United States, "the study is actually more carefully designed and has the same sample size as the original study conducted on behalf of Monsanto and submitted to regulatory agencies in support of the approval of the tech in the first place". He states that the study sounds an alarm bell and recommends that it should be "followed up by much more careful studies with larger sample sizes, more than one species of lab animal and conducted by people that have no dogma on the side, haven't done research in the area and don't have an opinion in area"[5].

In addition, according to UK based GMWatch, an independent organisation specialising in genetically modified crops, the OECD guidelines that Monsanto refers to were "designed by industry and government representatives with the aim of creating an internationally harmonised system of tests that industry would do on its products in support of regulatory approval. The OECD protocols mean that industry only has to do one set of tests to gain approval in any OECD member country. While the OECD protocols make things easier and cheaper for industry, they have been criticised by independent scientists for being outdated, inflexible, and insensitive - in other words, they are likely to miss important toxic effects"[6].

The South African government cannot ignore studies showing possible harm to our population. Professor Séralini has raised some serious red flags and the South African government, the only government in the world that has seen fit to allow our staple food to be modified, must as a matter of extreme urgency, investigate these findings to the fullest extent and ensure that the population is eating safe and nutritious food. Already Russia has announced that it will

suspend imports of NK603 while its Institute of Nutrition assesses the results of this study. France and the European Commission have ordered a review of the study; with France stating that it will defend its right to ban GMOs within the EU should the study be verified[7]. We have written to the Minister of Agriculture, Forestry and Fisheries requesting that South Africa place an immediate ban on the cultivation, import and export of RoundUp Ready maize. (The letter is attached as well as the names of the organisations and individuals that support the call for an immediate ban).

Review of Decisions

It is within South Africa's power to revoke the decision to allow the cultivation, import and export of Mon NK 603. Article 12(2)(b) of the Cartagena Protocol allows for a country to review such decisions when new scientific information comes to light. The Executive Council of the South African GMO Act is also given the power to review decisions under Article 5(2)(g) of the GMO Act (1997) as amended, if the Council receives new and relevant scientific or technological evidence. Additional relevant scientific or technical information has become available. The Department of Health sits on this Council.

Requested Action

We urgently request the Department of Health to take the following actions:

- Initiate an investigation by relevant directorates of the Department of Health to consider classifying GM maize as Hazardous Substances and potentially harmful food. This should include herbicide tolerant GMOs as well as those that manufacture their own pesticide within the plant (insect resistant GMOs).
- Initiate an investigation by relevant directorates of the Department of Health into the pesticides associated with GM crops, notably glyphosate, to review their registration and toxicity as well as the lack of monitoring and testing of pesticide residues in our food , as has already been noted by the ACB in our publication, "How much glyphosate is on your dinner plate: SA food safety compromised by lack fo testing." [8]
- Request the Medicines Control Council (or its successor body the South African Health Products Regulatory Authority) to regulate these foods and associated chemicals.
- Initiate a process to review the Government's decision to approve NK 603.
- Initiate a process to review GMO risk assessment procedures under the GMO Act as these do not appear to be robust enough and have not kept up with current scientific findings. A report published by the SANBI on the impacts of GM maize has already flagged the need to review risk assessment procedures in light of their findings, which indicated that GMO crops are not substantially equivalent to their conventional counterparts[9].

Signed

African Centre for Biosafety

1 African Centre for Biosafety. 2012. **Hazardous Harvest. Genetically Modified Crops in South Africa 2008-2012**. http://www.acbio.org.za/images/stories/dmdocuments/Hazardous%20Harvest-May2012.pdf Accessed 13 September 2012

2 www.nda.agric.za 2012 Permits Issued. Accessed 25 September 2012

3 Monsanto Comments: Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. September 2012 http://www.monsanto.com/products/Documents/ProductSafety/seralini-sept-2012-monsanto-comments.pdf

4 ibid

5 Peeples, L. 21.09.2012. **GMO debate heats up: critics say biotech industry manipulating genes, and science**. Huffington Post. http://www.huffingtonpost.com/2012/09/21/gmo-proposition-37-study-funding-re Accessed 25 September 2012

6 GMWatch. 24.09.2012 **Response to Monsanto's rebuttal of Seralini study** (1). http://www.gmwatch.org/latest-listing/51-2012/14226-response-to-monsantos-rebuttal-of-seralini-study-1 Accessed 25 September 2012

7 Enserink, M. 21.09.2012. **France and European Commission Order Review of Controversial GM Study in Rats.** http://news.sciencemag.org/scienceinsider/2012/09/france-and-european-commission-o.html

8 http://www.acbio.org.za/index.php/publications/gmos-in-south-africa

9 Environmental Affairs, Republic of South Africa. **Monitoring the environmental impact of GM maize in South Africa. The outcomes of the South Africa-Norway Biosafety Cooperation Project (2008-2010)**. http://www.sanbi.org/sites/default/files/documents/documents/sanbimaizereportlr.pdf Accessed 14 September 2012.