African Centre for Biosafety

Setting the record straight on the Séralini GM maize rat study

Why the SA government must urgently intervene

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The African Centre for Biosafety (ACB) is a non- profit organisation, based in Johannesburg, South Africa. It was established to protect Africa's biodiversity, traditional knowledge, food production systems, culture and diversity, from the threats posed by genetic engineering in food and agriculture. It has in addition to its work in the field of genetic engineering, also opposed biopiracy, agrofuels and the Green Revolution push in Africa, as it strongly supports social justice, equity and ecological sustainability.

The ACB has a respected record of evidence based work and can play a vital role in the agro-ecological movement by striving towards seed sovereignty, built upon the values of equal access to and use of resources.

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Acronyms

ABIC	Agricultural Biotechnology International Conference
Bt	bacillus thuringiensis
CBI	Confidential Business Information
CRIIGEN	Committee for Research & Independent Information on Genetic Engineering
BBSRC	Biotechnology and Biological Sciences Research Council (UK)
EFSA	European Food Safety Authority
ENSSER	European Network of Scientists for Social and Environmental Responsibility
EPA	Environmental Protection Agency (USA)
GBH	Glyphosate based herbicide
GDARD	Gauteng Department of Agriculture and Rural Development
GMO	Genetically Modified Organism
HT	Herbicide Tolerance
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
OECD	Organisation for Economic Co-operation and Development

Introduction

On the 26th of September 2012 Professor Gilles-Eric Séralini, and his research team at the University of Caen, published the findings of a two year study in which laboratory rats were fed Monsanto's GM maize variety NK603 and its associated herbicide, glyphosate. The results, which are summarised below, are deeply troubling, though unsurprising to many who have been following the biosafety debate for several years. The reaction of the biotechnology industry, and those sections of the scientific community who are aligned with it, has been as vitriolic as it was expected. Since the peer-reviewed article went public a host of so called 'independent scientists' have responded with indecent haste to denounce it, with some going so far as to call it fraudulent. AfricaBio, a biotechnology lobby group based in South Africa, falls firmly into this category. Indeed, in response to our recent letters to the Ministers of Health and Agriculture calling for a ban on NK603, AfricaBio went so far as to call our letters 'deceitful', and peddled out a list of apparent shortcomings in the Séralini study, which they call "fraudulent".

In this briefing we respond to the main criticisms of the study (which have been appearing *ad nauseum* in the world's mainstream media); provide some background as to the importance of the NK603 GM maize to the biotechnology industry (and hence the scale of their reaction); and place the attacks on Séralini in the context of previous experiences of those whose research has uncovered some inconvenient truths about the nature and risks of genetically modified organisms (GMOs).

What is NK603 GM maize?

NK603 is variety of maize that has been genetically modified (GM) to confer tolerance to glyphosate-based herbicides (GBH). This GM maize is commonly referred to by its trade name, 'Roundup Ready maize'. The herbicide tolerant gene, or 'trait', is the bedrock of the global biotechnology industry. It accounts, either in the form of a single 'trait' or combined (or 'stacked' to use biosafety parlance) with the insect resistance 'trait', for 85% of all GM crops grown world-wide.[1] Though precise figures are almost impossible to come by, it is common knowledge within biotechnology circles that Monsanto's 'Roundup Ready' crops (including maize, soya and cotton) are the most frequently grown herbicide tolerant GM crops. When one considers that Monsanto, originally a chemical company, held exclusive patent rights on glyphosate-based herbicides from 1974 until 2001, the importance of this particular crop becomes even more apparent.

NK603 was first approved for commercial cultivation in the United States in 2000, and has since been approved for cultivation in 10 other countries, including Brazil (2008) and Argentina (2004), the world's second and third largest GM crop producers behind the United States. A further 10 countries have approved it for import in the form of food and feed, including the European Union[2], China, Japan, Taiwan and South Korea;[3] the world's largest maize importing markets.[4]

NK603 in South Africa

Though initially insect resistant (Bt) maize (Monsanto's 'Mon810' variety) was the principle GM crop grown in South Africa, Monsanto's NK603 maize is now extensively planted. NK603 was approved for environmental release in 2002. This was followed by the approvals of stacked events MON810 x NK603 in 2007, and MON8934[5] x NK603 in 2010.[6] By 2007/08 these single or stacked varieties

accounted for 29% of the total area planted with GM maize (24% as a single event, and another 5% stacked with Bt). However, in 2010/11 and 2011/12, NK603 was grown, either by itself or stacked with Bt, on over 50% of our GM maize area. This applied to both yellow maize, which is generally not consumed directly by humans, and white maize, which is our national staple food.[7] It should also be noted that from 2008 to 2012, the number of GM maize varieties registered for plant breeders' rights that contain the HT gene nearly trebled.[8]

This rapid increase of NK603 cultivation looks set to continue. During 2012, a staggering 90% of all GM maize seed imports have been for NK603, while it has accounted for 69% of all GM maize seed imports since 2008. In September this year, Pioneer Hi-Bred were granted approval to conduct field trials with a 2 further varieties of GM maize that contain NK603.[9]

South African imports of NK603 seed, 2008 - 2012* (tons)

Year	NK603	Mon810	Mon810 x NK603	Other	Total	NK603 as % of total GM seed imports
2008	626.00	4 105.00	1 082.00	0.80	5 813.80	**11**
2009	110 772.00	40 882.00	5 020.00	3.90	156 677.90	**71**
2010	1 181.00	324.90	1.20	62.60	1 569.70	**75**
2011	151.20	42.60	60.10	43.51	297.41	**51**
2012*	702.00	76.00	0.04	0.40	778.44	**90**
Total	113 432.20	45 430.50	6 163.34	111.21	165 137.25	**69**

Source: GMO permit lists, DAFF. *to end of September 2012

It should also be noted that South Africa has been actively involved in exporting both the seed, and the grain of NK603. Over the period covered in the table above more than 22,000 tons of NK603 seed has been exported to the Philippines.[10] A quick look at the GMO permit list for 2012 alone reveals that hundreds of thousands of tons of GM maize shipments, NK603 included, have been exported from South Africa.[11]

Séralini's study only looked at event NK603, and not the stacked events[12] that are grown on a much larger area. Our regulatory system requires that each stack in an event (variety) must be subject to a safety assessment in terms of the Genetically Modified Organisms Act (GMO Act).[13] Hence, the findings from the Séralini study could have implications for a number of other stacked GM events that have either been approved for commercial cultivation or are undergoing field trials.

This rapid spread of Roundup Ready maize has been a great boon for Monsanto; as it has dramatically expanded its market for its Roundup herbicide brand. Though in theory farmers can use generic GBHs on Monsanto's Roundup Ready maize, by doing so they forfeit any rights to compensation should they experience problems with the seed. By its own admission, Monsanto now supplies 60% of glyphosate based herbicides (GBH) in South Africa.[14] Interestingly, since 2006, overall glyphosate consumption in South Africa has increased from 12 million litres annually, to 20 million litres annually at the present time, while from 2007 – 2011 imports of glyphosate increased by 177%.[15]

The Séralini Study

On the 26th of September 2012 Professor Gilles-Eric Séralini, and his research team at the University of Caen, published the findings of a two year study in which laboratory rats were fed Monsanto's GM maize variety NK603. The study built on previous work done by Professor Séralini and his team when he reviewed 19 GM maize and soya animal feeding studies. The necessary raw data to enable such a study was only obtained from Monsanto through legal action. This data revealed significant effects of GM diets on the animals tested, particularly to the liver and kidneys. Further, the researchers concluded that 'the 90 day long tests are insufficient to evaluate chronic toxicity' and suggested that studies should be 'improved and prolonged'.[16] The rationale behind the present study was to replicate the 90 day toxicology study over the lifetime of the animal (2 years in the case of laboratory rats), and hence gain a better insight into any potential chronic effects of consuming NK603 and traces of the Roundup herbicide that is used in conjunction with it.

Two hundred rats (100 male, 100 female) were divided into groups of 10. For each sex, one control group of ten rats was given access to plain water and a standard diet from the closest isogenic non-GM maize variety. Six groups were fed with 11, 22 and 33% GM NK603 either treated or not treated with Roundup herbicide (to simulate the presence of Roundup residues that are found in the maize). The final three groups were fed with the controlled diet and had access to water supplemented with 0.2 ppb Roundup (a contamination level found in some tap water samples), 0.09% Roundup (the US maximum residue level of glyphosate in some animal feeds) and 0.5% Roundup (half of the minimal agricultural dilution).

Summary of results:

- Control males survived an average of 624 days, control females averaged 701 days. In the control group, 3 males (30%) and 2 females (20%) died.
- In groups fed GM maize, 50% of males and 70% females died prematurely, before the average life expectancy. Mortality rates were not dose-dependent on the concentration of genetically modified maize in the diet.
- As early as 24 months, that is to say at the end of their lives, from 50% to 80% of females fed GMOs had developed tumours (fibroadenomas and keratoacanthomas) as against only 30% fed the GMO-free diet.
- In females, mammary tumours (93% of tumours) and pituitary tumours developed earlier than in the control rats.
- In males, the majority died of liver or kidney problems. "We found progressive chronic kidney disease in greater numbers in rats fed GM corn, especially in the males," says Dr Spiroux, co-author of the study.
- Males who received GM maize did not have more tumours than controls. However, the authors state that in the three groups of males who received the transgenic maize, tumours, or kidney and liver pathologies appeared as early as the 4th month and exploded in the 11th and 12th months. For the control group, the tumours occurred mainly at the end of life, in the 23rd month and 24 months.
- The authors state that the results are similar in terms of tumour incidence and mortality in animals fed NK603 without Roundup and those fed NK603 with Roundup.

Responding to criticisms of the study

As predicted, the biotechnology industry's response to the study's findings has been as swift as it has been belligerent. The following criticisms are taken from AfricaBio's media statement which was posted to its website on the 5th of October, 2012.[17]

Criticism: **The statistical analysis is questionable or incorrect. The sample size is too small – the control group is inadequate to make any deductions. The maize only diet of the rats is dubious and unrealistic. No food intake data or growth data is provided.**

In 2010, CRIIGEN acquired external funding to investigate the signs of toxicity seen in experimental data provided by Monsanto. Thus, a toxicology trial was designed in accordance with OECD guidelines (OECD guideline 408). The authors did not apply the relevant methodological guidelines for carcinogenicity tests (which require 50 rats)[18] as the authors had no intention at the outset to conduct a carcinogenicity study. The intention was to carry out a toxicological test over an extended period.

The authors have acknowledged that the number of animals used is too low to apply statistical tests regarding the tumours and mortality, and therefore provided the raw data of each individual rat. In the Séralini study, food was offered ad *libidum* (at one's pleasure), which is consistent with many-industry based feeding studies. The Monsanto study that was used as the basis for approval of NK603 (Hammond et al, 2004) did not measure daily food intake either.[19] Furthermore, the biosafety dossiers presented by Monsanto to the European Food Safety Authority (EFSA) for food and feed approval of GM maize MON88017 and MON89034 both state "Each diet was presented ad libidum for approximately 90 days to 20 male and 20 female Sprague-Dawley [Crl:CD®24 (SD)] rats". (We have requested access to Monsanto's application in SA and assume that Monsanto provided similar information to the SA regulators).

Criticism: **The report does not suggest that the effects are caused by genetic modification.**

The study was specifically designed to test for potential adverse effects of the GM trait in NK603: Three groups of rats were fed with 11, 22 and 33% of NK603 treated with Roundup herbicide, while three groups were fed with NK603 not treated with Roundup. A further three groups were fed the closest conventionally bred counterpart maize variety, each being fed water with differing concentrations of Roundup added. Finally, the control group was fed on the closest conventional variety and water without Roundup. The impacts of NK603 alone and combined with Roundup, and Roundup alone, all had similar effects

Criticism: **The choice of rat type is incorrect and deeply questionable. This type is very prone to mammary tumors particularly when food intake is not restricted. The report does not mention that up to 86% of male and 72% of female rats of this type spontaneously get cancer at the age of 2 years.[20]**

This is the same strain of rat that is used in numerous industry sponsored GM feeding trials, including 90 day feeding studies provided by Monsanto as the basis for the approval of NK603 maize and other GM crops (Hammond et al., 1996, 2004, 2006; MacKenzie et al., 2007). This strain of rat was chosen specifically to keep the experimental design as close to Monsanto's as possible.[21]

Aside from being used in GM animal feeding studies, Sprague Dawley rats are also widely used in general toxicological studies. For example, The National Toxicology Programme of the U.S. Department of Health and Human Services uses this strain in its 2-year studies. An initial literature search conducted by the European Network of Sciences for Social and Environmental Responsibility (ENSSER)[22] revealed that the same rats were used in toxicology studies in:

- A 36 month study by Vos et al. (2005);
- 24 month studies by Hack et al. (1995), Klimisch et al. (1997), Minardi at al. (2002), Soffritti et al. (2006) and Gamez et al. (2007);
- An 18 month study by Lee et al. (2010); and
- 12 month studies by Perry et al. (1981), Conti et al. (1988), Morcos & Camilo (2001), Flamm et al. (2003) and Gutiérrez et al. (2011).

Criticism: **There was no proper control group of test rats; without those additional controls "these results are of no value".**

Dr. Michael Antoniou, a reader in molecular genetics at Kings College, University of London, commenting on criticism of the size and composition of the control group says:

> "The key is that there were both quantitative and qualitative differences in the tumours arising in control and test groups. In the former they appeared much later and at most there was one tumour per animal, if at all. In the latter case, the tumours began to be detected much earlier (4 months in males; 7 months in females), grew much faster and many animals had two or even three tumours. Many animals in the test groups had to be euthanised for welfare legal reasons due to the massive size of the tumours; none of the control animals had to be euthanised but died in their own time. One should not ignore these biological facts."[23]

Criticism: **The French team's claim to be the first to test for the animal's whole lifespan is incorrect. The report does not refer to the hundreds of existing reports, as is good scientific practice.**

This is the first long term feeding study for this particular variety of GM maize. A recent literature review (Snell et al, 2012) lists 24 long term GM feeding studies, though none of them were for NK603. Interestingly, the authors of this review were of the opinion that 'the studies reviewed here are often linked to an inadequate experimental design that has detrimental effects on the statistical analysis as far as the most frequently used statistics are concerned.'[24] A similar paper (Séralini et al, 2011) reviewed 19 animal studies of animals fed GM maize and soya. The only study on NK603 lasted for 90 days.[25]

Criticism: **The data has not been made available. From a scientific point of view this is questionable and suggests there is something to hide. The paper is supposed to have been reviewed by other scientists before it was allowed for publication, but the French team refused to allow journalists to show the paper to other scientists before the news reports were published.**

Firstly, the paper underwent the standard peer-review process to scrutinise the scientific process that is applied to all papers published in the journal.

Secondly, it is hardly surprising that there was an embargo on the paper given the previous experiences of scientists who have published research that has raised concerns about GM crops. In

1998 Dr Arpad Pusztai, who was the world's leading expert on plant proteins known as lectins, had just completed a three year rat feeding study with a GM potato variety. His team had been awarded the GBP 1.6 million project having been selected from 28 other research institutions around Europe. The project methodology had also been reviewed and passed by the Biotechnology and Biological Sciences Research Council (BBSRC), the UK government's main funding body for biological sciences.[26]

Towards the end of the study (before it was published) Dr Pusztai had appeared on UK television, talking about the ill effects he and his team had observed in the rats fed GM potato. Within days, Dr Pusztai became the victim of an elaborate smear campaign, orchestrated by the top echelons of the UK government and the UK Royal Society. In February 1999, for example, nineteen fellows of the Royal Society placed a highly critical letter in a national newspaper. Three months later the Royal Society published a partial 'peer-review' of Pusztai's then unpublished research; an act described by The Lancet's editor, Richard Horten, as 'a gesture of breathtaking impertinence to the Rowett Institute Scientists who should be judged only on the full and final publication of their work'.[27]

Undeterred, Dr Pusztai and his co-researcher, Prof Stanley Ewen, submitted their final paper to The Lancet. It was sent to six reviewers, double the normal number, and a clear majority were in favour of its publication. This initiated a second round of attacks, extending to include the journal's editor, Richard Horton. Horten has stated that before the article's publication he received a phone call from Peter Lachman, former vice-President of the Royal society, calling him 'immoral' for publishing something he knew to be 'untrue'. The attacks continued, with Lachman's successor as Biological secretary of the Royal Society, Patrick Bateson, telling readers of the British Association's journal Science and Public Affairs that The Lancet had published Pusztai's article 'in the face of objections by its statistically competent referees', again over-looking the fact (in a manner eerily reminiscent of current reaction to the Séralini paper) that it had gone through the peer-review process.[28]

Dr Ignacio Chapela experienced a similar 'scientific' backlash when research he was conducting with a graduate student of his, David Quist, revealed that native Mexican land races of maize had been cross-pollinated with GM maize from the United States, and that the transgenic DNA had randomly fragmented into the genome of the native maize varieties.[29]

Professor Séralini himself has previously been the victim a biotechnology industry campaign to undermine his scientific credentials, after publishing seven peer-reviewed scientific papers on the potential side effects of glyphosate and glyphosate tolerant maize on human and mammalian health. He had also provided biosafety expertise on GM Brinjal to the Indian government, which formed the basis of their decision to stall its commercial release. In 2010 the French Fondation Sciences Citoyennes and the European Network of Scientists for Social and Environmental Responsibility launched a public letter of support for Séralini that contained the signatures of over 250 scientists based in 20 countries.[30]

Criticism: **The French researcher has long been opposed to GM crops – often producing "pseudo-science" as one scientist said. The group has conflicts of interest – funded by large French retailers, and anti-GM NGOs, and with close links to Greenpeace and the organic movement and others in national and European politics with dubious political motivations.**

For AfricaBio to accuse another organisation of conflicts of interest represents a dazzling level of hypocrisy. Since its creation in 1999, AfricaBio has been a long-time advocate and lobbyist for the biotechnology industry in South Africa, and aims to 'provide one strong voice for lobbying the government on biotechnology and ensuring that unjustified trade barriers are not established

which restrict its members'.[31] CropLife International, 'a global federation representing the plant science industry', lists AfricaBio as one of its 8 member 'biotech associations'. CropLife's member companies include: BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto and Syngenta.[32]

In 2009 AfricaBio received $270,000 from the Bill and Melinda Gates Foundation to 'identify the most effective means of raising public awareness of biotechnology issues in Sub Saharan Africa'. The Gates Foundation has already ploughed nearly $90 million into research on GM maize, cassava and sorghum. Earlier this year Bill Gates was on record as saying 'countries can embrace modern biotechnology and genetic modification or their citizens will starve'. Strangely enough, he omitted to mention that during 2010 the Gates Foundation invested nearly $23 million in shares in the world's largest purveyor of GM seeds, Monsanto.[33]

In September 2011, AfricaBio, together with the Gauteng Department of Agriculture and Rural Development (GDARD), hosted the Agricultural Biotechnology International Conference (ABIC).[34] The keynote speakers at the event included none other than Dr Clive James, the founder and chair of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).[35] Among the ISAAA's main donor organisations are Bayer CropScience, CropLife International, Monsanto, the United States Department of Agriculture, the U.S. Soybean export council and USAID.[36]

AfricaBio has also been actively involved in policy debates around GMOs in South Africa. It was vehemently opposed to moves towards the labelling of GM food, and made submissions to Parliament to this end.[37] AfricaBio also contributed to the GMO Amendment Bill hearings in 2006, where its position was presented by Mr. W de Greef[38], general secretary of EuropaBio. While AfricaBio may be sanguine about its links to the biotech industry, EuropaBio has no such qualms, calling itself 'the voice of the European Biotech industry'. Its members include: BASF, Bayer, Dow AgroSciences, Monsanto, and a host of other biotech companies.[39]

Finally, if there was still any doubt as to AfricaBio's 'neutrality' on this matter; consider that among the new board members elected at its recent AGM in Pretoria are representatives from Bayer Cropscience, Pioneer Hi-Bred and Monsanto.[40]

Criticism: **The process of first releasing data to the media, prior to the article, in a highly organized and coordinated fashion, all organized by a PR closely linked with the organic movement, suggests the intention is not to produce good science, but to scare people and media into forming negative opinions of GM. The combination of the report launch with the publication of an anti-GM book by MEP Corinne Lepage is dubious. "Is this science or is this political campaigning?"**

See above

Criticism: **The inclusion of emotionally distressing photos in the article suggests that the authors have other intentions in mind than scientific data. Rather the interest was to create uproar.**

The report writes that 'All data cannot be shown in one report and the most relevant are described here'. This is a form of scientific cherry picking that is not good scientific practice. In that sense the report is "sub-standard" and should not have gotten through peer-review.

Transparency and access to information are two issues that cut to the heart of the GM debate, though complaints about this are rarely heard from the promoters and developers of biotechnology.

These are problems that are overwhelmingly experienced by independent scientists and members of civil society.

In 2009 a group of 26 entomologists submitted a statement to the United States Environmental Protection Agency (EPA) warning that "no truly independent research can be legally conducted on many critical questions" around genetically modified seeds. The majority of these scientists are not inherently opposed to genetically modified seeds, but to the extremely restrictive agreements they must sign with seed companies to conduct research.[41]

This is consistent with the experiences of the African Centre for Biosafety, which since its inception in 2004, has submitted comments on over 30 GMO permit applications lodged with the Registrar: GMO Act. Unfortunately, those not directly involved in the development of GM crops are not privy to the full safety dossier that is submitted, only a highly sanitised non-confidential business information (CBI) version. While in theory it is up to the regulatory bodies to decide what is confidential, in practice the applicant (Monsanto or Dow for example) prepares their own non-CBI version, thus dictating what is confidential and what is not. This example from our latest comments, on Dow's application for commodity clearance of GM soybean DAS-68416-4, could be applied to any one of the comments we have previously submitted:

"Of general concern is the data that is required for independent assessment (and should not be considered CBI) have not been included e.g. [2009a-Attachment A [CBI-DELETED: Section 68(a), (b) and (c)ii of the Promotion of Access to Information Act] and many others in the dossier. It is increasingly difficult to independently assess an application when the scientific data is withheld."[42]

In response to the accusations of 'scientific-cherry picking', it would be indicative to bring up a few further examples. Dow assures us (and our regulators) that 'an acute oral toxicity study...was conducted in mice' and that all the animals had survived, gained weight and that 'no clinical signs were observed' by the time the study was terminated after 15 days. No information on the size and composition (male or female for example) was provided, neither was an explanation given as to why the study only lasted 15 days. Even the much maligned European Food Safety Authority (EFSA) required at least 28 days for an acute toxicology test.[43] Of course, as we were only presented with the non-CBI version, these facts may have been omitted, though it is hard to reconcile information about rat sample sizes being confidential, particularly when there has been such an emphasis on this by the biotech industry in response to Séralini's study.

Similarly, Pioneer Hi-Bred's recent application for general release of GM maize event TC1507, "a toxicity study consisting of feeding rats with the PAT protein (0, 5000 and 50000 mg/kg body weight) has been carried out (Pfister et al., 1996; Health Canada, 1997) and the results showed that food consumption and body weight were not influenced by the PAT treatment with no occurrence of mortality." Again, no details as to the size and composition of the study are given. Even more worryingly, the statement is unclear as to whether the rats were fed the actual GM maize variety, or a bacterially produced surrogate PAT protein.[44] Another non-CBI dossier we received earlier this year, for Syngenta's application for commodity clearance of GM maize event 3272 x Bt11 x MIR604 x GA21, makes reference to a broiler feeding study, the details of which can be found in appendix 36, which was deemed confidential, and therefore not included in the non-CBI dossier we received.[45] These are only examples from dossiers we have received this year.

Conclusion

NK603 has been on the market for over 10 years, including in South Africa. The seed itself, and the herbicides it is sold with, are crucial revenue streams for the biotechnology industry. In light of this, the ferocity of 'scientific' attacks on Professor Séralini and his team come as little surprise. As has been illustrated above, the attacks on both the scientific methodology of the study, and on the researchers themselves are erroneous and unsubstantiated. That the criticisms levelled against the Séralini study have not been applied equally to those studies that industry has used to justify the safety of GM crops smacks of hypocrisy of the worst kind. That scientists and organisations, who benefit directly from the spread of GM crops globally, then question the character and motives of the researchers speaks volumes as to who has truly benefited from this technology.

We reiterate our call on the South African government to:

- Urgently review the decision to approve RoundUp Ready maize NK603 and ban the use of this maize;
- 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 of testing."
- 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 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.[46]

Annex 1: World-wide Approvals for NK603

Country	Environment	Food	Feed
Argentina	2004	2004	2004
Australia		2002	
Brazil	2008	2008	2008
Canada	2001	2001	2001
China		2005	2005
Columbia	2008	2004	2004
El Salvador		2009	2009
European Union		2004	2004
Honduras	2008		
Japan	2010	2010	2010
Malaysia	1998	1998	1998
Mexico		2002	
Philippines	2005*	2003	2003
Russian Federation**		2002	2003
Singapore		2006	2006
South Africa	2002	2002	2002
South Korea		2002	
Taiwan		2003	2003
Thailand		2002	2002
Uruguay	2011	2011	2011
USA	2000	2000	2000

* This approval was renewed in 2010

** Following the publication of the Seralini study, Russia temporarily suspended the importation pending the outcome of an investigation by the Russian Academy of Medicinal Sciences[47]

Source: Compiled from James (2010) and CERA GM Crop database.[48]

Annex 2: Maize plantings by trait in South Africa, 2005/06 – 2011/12 (as percentage of total area of GM maize planted)

Production Year	Trait	white	yellow	total
2005/06	IR	79	61	72
	HT	21	39	28
2006/07	HT	16	28	20
	IR	84	72	80
2007/08	IR	71	69	71
	HT	22	27	24
	stacked	6	4	5
2008/09	IR	66	63	64
	HT	17	18	17
	stacked	19	19	19
2009/10	IR	81	49	70
	HT	10	23	14
	stacked	9	28	16
2010/11	IR	50	39	46
	HT	9	21	13
	stacked	41	41	41
2011/12	IR	46	44	45
	HT	10	20	14
	stacked	44	36	41

Source: Esterhuizen (2012).

References

1 James, C (2011). **Global Status of Commercialized Biotech/GM Crops: 2011**. *ISAAA Brief No. 43*. ISAAA: Ithaca, NY.

2 In the EU approvals for the import of food and feed are granted on an EU (27 country) wide basis, whereas environmental releases are still approved at the national level (though there has been a recent concerted push orchestrated by the biotechnology industry to apply to same EU wide logic to environmental release approvals)

3 James, Clive. (2010). **Global Status of Commercialized Biotech/GM Crops: 2010**. *ISAAA Brief No. 42*. ISAAA: Ithaca, NY.

4 ACB (2010). **The dirty politics of the global grain trade – GM maize farmers face ruin in SA**. ACB briefing paper no. 21.
http://www.acbio.org.za/images/stories/dmdocuments/SA_GM_farmers_in_crisis.pdf

5 MON8934 is another insect resistant maize variety

6 http://www.nda.agric.za/doaDev/sideMenu/biosafety/doc/General%20Release%20Approvals.pdf

7 Esterhuizen, D. (2011). **South Africa – Republic of. Agricultural Biotechnology Annual**. USDA Foreign Agricultural Service.
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