OBJECTION TO MONSANTO’S APPLICATION FOR CONFINED FIELD TRIALS WITH (1) NK603 AND (2) MON89034 X NK603 MAIZE IN NIGERIA (MULTI-SEASON)

BY

HEALTH OF MOTHER EARTH FOUNDATION

(HOMEF)

AND

ENVIRONMENTAL RIGHTS ACTION/ FRIENDS OF THE EARTH NIGERIA (ERA/FoEN)

March 2016
Local Partner organisations supporting this objection

This memorandum is supported by the following organizations:

1. All Nigeria Consumers Movement Union (ANCOMU)
2. Committee on Vital Environmental Resources (COVER)
3. Community Research and Development Centre (CRDC)
4. Ijaw Mothers of Warri
5. Rice Farmers Association of Nigeria (RIFAN)
6. Host Communities Network of Nigeria (HoCoN)
7. OilWatch Nigeria
8. Green Alliance, Nigeria
9. African Centre for Leadership, Strategy & Development
10. Institute of Human Rights and Humanitarian Law (IHRHL)
11. Women Environmental Programme (WEP)
12. Persons with Disabilities Action Network (PEDANET)
13. Students Environmental Assembly of Nigeria (SEAN)
14. Centre for Environment, Human Rights and Development (CEHRD)
15. Ogoni Solidarity Forum (OSF)
17. Federation of Urban Poor (FEDUP)
18. Community Forest Watch (CFW)
19. The Young Environmentalist Network (TYEN)
20. Women’s Rights to Education Program (WREP)
21. Community Action for Public Action (CAPA)
22. Peoples Advancement Centre (ADC) Bori
23. Social Action
24. SPEAK Nigeria
25. Urban Rural Environmental Defenders (U-RED)
26. Gender and Environmental Risk Reduction Initiative (GERI)
27. Women’s Right to Education Programme (WREP)
28. Foundation for Rural/Urban Integration (FRUIT)
29. Community Action for Popular Participation
30. Torjir-Ager Foundation (TAF)
31. Civil Society on Poverty Eradication (CISCOPE),
32. Jireh Doo foundation
33. Advocate for Community Vision and Development( ACOVID)
34. Initiative for empowerment for vulnerable(IEV)
35. Women Right to Education Programme (WREP)
36. Kwaswdo Foundation Initiative(KFI
37. Environment and Climate Change Amelioration Initiative) ECCAI
38. Manna Love and care Foundation (MLC)
39. Okaha Women and children development Organisation(OWPDO)
40. JODEF-F
41. Glorious things ministry.(GTM)
42. Gaughters of Love Foundation
43. Medical Women Association of Nigeria (MWAN)
44. Community Links and Empowerment Initiative(CLHEI)
45. Gender and Environmental Risk Reduction Initiative (GERI)
46. Nigerian Women in Agriculture (NAWIA)
47. Osa foundation
48. Initiative for Improved Health and Wealth Creation (IIHWC)
49. Peace Health Care Initiative (PHCI)
50. Ochilla Daughters Foundation (ODF)
51. African Health Project (AHP)
52. Artists in Development
53. Ramberg Child Survival Initiative (RACSI)
54. Global Health and Development initiative
55. First Step Initiative (FIP)
56. Ruhujukan Environment Development Initiative (REDI)
57. The Centre for Environment, Human Rights and Development (CEHRD), Nigeria
58. CEEHOPE Nigeria
59. Next Generation Youth Initiative (NGI)
60. AIRGO
61. Rural Action for Green Environment (RAGE)
62. United Action for Democracy
63. Campaign for Democracy
64. Yasuni Association
65. Egi Joint Action Congress
66. Green Concern for Development (Greencode)
67. Kebetkache Women Development & Resource Centre
68. Kebetkache Ahoada Women Farmers Cooperative
69. Ahoada Uzutam Women Farmers Cooperative
70. Ogboaku Ahoada Farmers Cooperative
71. Gbobia Feefeelo women
72. Ovelle Nyakovia Women Cooperative
73. Rumuekpe Women Prayer Warriors
74. League of Queens
75. Emem Iban Oku Iboku
76. Uchio Mpani Ibeno
77. Rural Health and Women Development
78. Women Initiative on Climate Change
79. Peoples’ Centre
80. Citizens Trust Advocacy and Development Centre (CITADEC)
81. Center for Environment Media and Development Communications
1. ABOUT US

Health of Mother Earth foundation (HOMEF) is an environmental/ecological think-tank and advocacy organisation. HOMEF works to bridge the yawning gap between policy/decisions made by governments and the actual needs at the grassroots. HOMEF recognises that policies are often top down and actions based on such can distort the possibilities of meeting actual needs.

We recognise that the global crises the world is experiencing have impacts on our nation and that these manifestations have systemic roots. Pressures on nations manifest in pressures on the environment and the current paradigm of development and growth based on competition will lead to the critical destruction of biodiversity and continued destructive extraction of natural resources, disrespect for Mother Earth as well as dependency on risky technologies.

More about HOMEF at www.homef.org

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The Environmental Rights Action/Friends of the Earth Nigeria (ERA/FoEN) is a Nigerian advocacy non-governmental organization founded on January 11, 1993 to deal with environmental human rights issues. ERA/FoEN is the Nigerian chapter of Friends of the Earth International (FoEI), the world environmental justice federation campaigning to protect the environmental and to create sustainable societies.

ERA/FoEN is co-coordinating Friends of the Earth International Food Sovereignty Program and also Coordinates the Friends of the Earth Africa’s (FoEA) Food Sovereignty Program and is the premier winner of the Sophie Prize, the international award in environment and development.

More about ERA/FoEN at www.eraction.org

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2. INTRODUCTION

We hereby place on record our objections to the application made by Monsanto Agricultural Nigeria Limited on behalf of Monsanto Company, 800 North Lindberg Boulevard, St-Louis, Missouri 63167, USA to the National Biosafety Management Agency (NABMA), Abuja, Nigeria for Confined Field Trials with the events NK603 and MON89034xNK603 in Nigeria (multi-season).

The application is marked “MONSANTO COMPANY CONFIDENTIAL”. Though the location of field trial sites, personnel in-charge as well as measures to ensure isolation of trial crops has been included, the involvement of the National Biotechnology Development Agency (NABDA) and her officers, the former a flagship agency saddled with the responsibility of developing biotechnology raises potential conflict of interest issues and should effectively disqualify this application. NABMA should do this to help redirect the attention of this agency to what her responsibilities are. The National Biosafety Management Agency Act, 2015 in Part IX - Risk Assessment and Management, Section 32 states that ‘No person, shall be involved in a risk assessment review by the Agency in respect of a subject matter in which:
(a) he has direct or indirect interest of any kind; or
(b) there is likely to be conflict of interest as a result of his participation in the risk assessment process.’
Moreover, NABDA is a member of the Governing Board of NABMA and this may also raise indirect conflict of interest issues.

NABDA has clearly shown that it has interest in bringing genetically modified organisms (GMOs) to Nigeria and they should definitely not be the ones conducting trials as they already have a vested interest. It has apparently left the business of developing cutting edge biotechnology suitable for our agro-ecological systems and instead has entered the realm of helping companies to propagate the product of a technology that is suspect and which has several negative implications for our environment and health system. NABDA, instead of developing technology, now appears to be marketing the product of a technology she did not develop, giving the false impression that the product is safe for our environment by her involvement ab initio.

The technology being promoted has failed and has been roundly rejected by our neighbouring African countries. South Africa and Burkina Faso referred to in the application are battling the effect of these products both on their environment and health.

At the moment Burkina Faso has ordered the phasing out of all Bt cotton in the country. The Government took a bold step in doing so. Citing Burkina Faso’s experience as a reason to introduce GMOs cotton into Nigeria is a clear refusal to acknowledge the fact that the technology failed in that country, has brought misery to farmers and is being phased out there. The truth is that instead of becoming rich as proclaimed by promoters of the technology, farmers in Burkina have come to the realisation that the Bt Cotton brought them less productivity and less income than their traditional cotton varieties. We emphasise the fact that the Burkina Government has now taken the bold step to ban GM Cotton in Burkina Faso. This is a clear indication that Nigeria cannot afford to gamble with this clearly failed path. (See Burkina Faso dumps GM Bt cotton - GM Watch http://www.gmwatch.eu/news/latest-news/16219-burkina-faso-dumps-gm-bt-cotton and West African Country Dumps Monsanto’s GM Cotton, Seeks Compensation. Joining the
expanding list of GMO rejections: http://naturalsociety.com/west-african-country-dumps-monsantos-gm-cotton-seeks-compensation/

Most worrisome is the fact that should commercialization be eventually granted for this product, the end result will be a likely increase in the use of glyphosate in Nigeria, a chemical that the World Health Organization’s (WHO) International Agency for Research on Cancer in 2015 has classified as a “probable human carcinogen”. Recent studies have linked glyphosate to health effects such as degeneration of the liver and kidney, and non-Hodgkin lymphoma. That NABMA is considering giving us this “trojan horse” gift is indeed unfortunate knowing the low level of use of protective gears by our rural farmers and communities living close to farms.

References used in support of claims made by Monsanto are too old and none referred to the two GM maize events specifically but are general references for normal maize research. This may be due to the lack of thorough scientific peer-reviewed research carried out in support of the claims made in the application or is a deliberate effort at hiding information.

We note that no details of feeding studies whatsoever were provided by the applicant.

No data is given on the safety of the chemicals to which the events are resistant, namely glyphosate and glyphosate-based herbicides (GBHs). In fact, no information on experiments carried out has been made available. It is impossible under these circumstances for us to provide full and informed comments.

The application is of extremely poor quality. The application ends on page 50 without comprehensive information on insect pest resistance, which is a critical aspect of the information required to justly appraise the application in relation to the insect-resistance trait and in particular to purpose 3 of the field trials to evaluate the efficacy of the MON 89034 × NK603 against certain Lepidopteran pests.

Regardless of the incomplete information available to us, and on the basis of the documents we were able to access, our comments on the events are outlined below.

3. SUMMARY OF CONCERNS

A thorough and rigorous independent scientific assessment of this application has been impossible due to the omission of detailed information relevant to purpose 3, in particular on insect pest resistance. The information on gene flow is also scanty. Other important information, such as the description of the detailed genetic modification of the single events NK603 and combined event MON89034 x NK603 and resultant phenotypic modifications, was not provided as Monsanto provided only scanty information on page 10 of her application on phenotypic changes. It is necessary that this is provided in more detail to
allow better and informed comments.

Throughout the application, Monsanto asserts that NK603 and MON 89034 × NK603 are equivalent to conventional maize. The theory of ‘equivalence’ is a worn out argument that has been discredited by independent science, including in a joint South Africa – Norway biosafety project published in 2011. (See SANBI (2011). Monitoring the environmental impacts of GM maize in South Africa: The outcomes of the South Africa – Norway biosafety co-operation project (2008 – 2010). Department of Environmental Affairs. http://www.sanbi.org/node/1958/reference)

“The genetic modifications used to generate NK603 and MON 89034 were not meant to alter the reproductive biology of maize. MON89034 x NK603 was obtained by traditional breeding and therefore no new genetic modification was used”

The above is Monsanto’s assertion on page 10 of the application, ignoring completely the unintended consequences that may arise from the effect of the events’ and gene interactions (epistasis). The lack of attention to the potential unintended consequences of the interactions appears to also conform to the claim that because MON 89034 × NK603 was produced by the conventional breeding of single GM varieties, safety assessment of these individual parent varieties, and not MON 89034 × NK603 itself is satisfactory for risk assessment. However, the best practice is for such stacked GM plants to be themselves subject to risk assessment, as exemplified in the Cartagena Protocol on Biosafety ‘Guidance for Risk Assessment of Living Modified Organisms’ and in various jurisdictions, including the European Union. This is due to the potential unintended effects of “subsequent conventional breeding of the recombinant-DNA plant” as highlighted by the Codex Alimentarius Commission in its Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.

There is a dearth of information regarding the description of the GM maize varieties throughout the application. For example, no reference is made to southern blot analysis, this is not shown anywhere in the application, not allowing for independent verification. No mention is made of other characterization techniques, such as polymerase chain reaction (PCR). Numerous studies have noted that a combination of Southern blotting and polymerase chain reaction (PCR) should be used in GMO risk assessment. This has not been done.

“The conclusion of safety to humans of these proteins was based upon the following considerations:

The proteins have a demonstrated history of safe use;
The proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
The proteins do not exert any acute toxic effects to mammals.” Page 13 of application by Monsanto.

In addition, the rapid digestibility in simulated digestive fluids provide additional assurance for their safety. It is therefore highly unlikely that CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins would cause any toxic effects on human or animal health. (Page 13)

The CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins were also assessed for their potential allergenicity according to the recommendations of Codex Alimentarius Commission (page 13). The proteins are from non-allergenic sources, lack structural similarity to known
allergens, are rapidly digested in simulated gastric fluid, and constitute a very small portion of the total protein present in the grain of NK603 or MON 89034 x NK603. Taken together these data lead to the conclusion that these proteins are unlikely to have any allergenic potential, and NK603 and MON 89034 x NK603 are as safe as conventional maize regarding the risk for allergenicity (page 13 of application).

The above shows that evidence of the lack of risk to human and animal health is totally scanty. In fact, it is almost non-existent as reliability is placed on history not on empirical evidence from any study carried out by the applicant, as details are not provided. Vague reference is made to an animal feeding study, but no information is given to the study’s duration, the number of animals used, or any information about control groups or the control group’s diets.

“None of the genetic elements inherited from MON 89034 and NK603 encode toxic, allergenic or other proteins harmful to men or the environment (except for the targeted insect pests), or influence the reproduction, survivability, persistence or dissemination of the host plant.

Cry1A.105 and Cry2Ab2 proteins are toxic to certain lepidopteran insect pests but have been demonstrated not toxic to mammals and non-target organisms” (Page 12 of application)

‘The proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals’;

It is claimed on page 12 of the application as above that the Bt proteins present in these GM maize varieties have “no structural similarities to known toxin or other biologically active proteins that could cause adverse effects in humans or animals, and that the Bt proteins themselves are not toxic to humans, animals or non-target organisms”. This claim is not true at present. We cite multiple peer-reviewed articles that undermine these assertions, including a recent study in which pigs (their digestive systems are closer to that of man) fed GM maize and soya suffered severe stomach inflammation compared to pigs fed the non-GM equivalents (Carman et al. 2013).

No discussion of the potential risks to human and animal health and the environment from glyphosate is made in the application, even though this GM maize variety has been engineered for the express purpose of being sprayed with this chemical as seen below:

“to evaluate the selectivity of two glyphosate formulations when applied to MON 89034 × NK603 compared to an unsprayed hand weeded treatment; to evaluate the weed efficacy of two glyphosate formulations when applied on MON 89034 × NK603 in comparison to a local standard and hand weeding” page 14 of Monsanto application.

Two out of the four trial purposes are on glyphosate selectivity yet no information on environmental or health effects of glyphosate is provided.

We cite a number of studies that show that this technology has increased herbicide use and
that glyphosate is associated with so many health risks, including evidence from the USA and Europe that glyphosate has found its way into public water resources, and has been detected in people’s urine. We note that glyphosate has been classified as a “probable human carcinogen” by the WHO due to the health risks.

Monsanto’s application on page 12 claims that the “CP4 EPSPS, Cry1A.105 and Cry2Ab2, proteins exhibit toxicity towards certain lepidopteran insects but not toxic to mammals and non-target organisms”. A number of peer-reviewed articles that contradict these claims are referenced. No mention at all is made of any environmental risk from glyphosate nor the rapid emergence of insect populations resistant to Bt crops, and weed species resistant to glyphosate.

Monsanto does not adequately nor specifically describe measures to prevent cross-pollination during field trials, other than to say that adequate temporal and/or spatial isolation measures will be provided and that the trial sites will be allowed to have physical barriers of 5 m fallow and 6 border rows with conventional maize as buffer zone. This is inadequate as the trial sites cover all Nigerian agro-ecological zones and dire consequences are expected in the event of contamination. Contamination of Nigerian maize crops could impact negatively on farmer’s livelihoods and the national maize market including maize products in Nigeria. We cite peer-reviewed sound scientific records to prove that 5 m is too short a distance. It cannot prevent gene flow.

Should the GM maize events be eventually approved for commercial use, there are potentials implications for our farmers that will need to be seriously considered, even at this early stage. The oft-repeated claim that small-scale farmers will benefit from the adoption of GM seeds is not borne out by independent research. For example, small-scale farmers will not be allowed to share seeds as in traditional Nigerian settings. Stacked GM maize seed varieties, such as MON89034 x NK603, are typically more expensive than their single trait counterparts. If the adoption of single and then stacked GM maize seed in Nigeria expands, our traditional and native hybrids will be eroded and eventually lost and dependence will be placed on Monsanto seeds making Nigerian farmers subservient to corporate interests. Experience from South Africa has shown this to be so. Maize seed prices in South Africa have continued to rise, prompting concern among commercial agricultural organizations. Small scale farmers do not have nearly as much representation, however, expert testimony to the Competition Tribunal in 2011 in South Africa stated that maize seed price increases would make it impossible for small scale and subsistence farmers to continue farming (SANBI, 2011).

Finally, there is a clear notable lack of capacity within Nigeria to adequately monitor the potential human and environmental risks of GM crops and their associated herbicides. NABMA may claim to the contrary but we will challenge a public display as we have records of all laboratories in Nigeria and their REAL capabilities. There is also virtually no testing of any food material and products in Nigeria presently for residues of glyphosate or other pesticides, or to monitor their presence in the environment or our water resources. It is
unacceptable for government oversight to lag so far behind research, development and administration, while continuing to allow ever more controversial and complex events into our food chain and environment. Our authorities can and must set the pace to ensure safety.

This application has failed to adequately show that NK603 and MON89034 × NK603 are safe for human, animal and environmental health. Our submission points to a number of areas of scientific uncertainty that pose serious risks and require further research. The Precautionary Principle both obliges the NABMA and accords it the right to halt the introduction of these events into our environment until this research has been satisfactorily carried out. In addition, we do not believe that single or stacking genes to deal with insect and herbicide resistance is a reasonable response to these problems. It is clear that this strategy will lead to a cycle of further stacking, further resistance and increased use of agrochemicals to deal with the problem. We show that alternative weed and insect management systems exist and are proving to be effective while in no way undermining agricultural yield. Our biodiversity is our strength. About 75% of Nigerians depend on it for survival. Introduction of these GM crops will not just lower their quality but eventually eliminate them. In all areas of the country where glyphosate has been applied for the past three years spear grasses no longer exist, for example (Aguoru, et al. 2015). In several rural communities in Nigeria including the Director General of NABMA’s village it is a raw material for the well cherished traditional thatched houses. Caution, adequate care and accountable actions must prevail.

4. BACKGROUND

This is an application by Monsanto Agricultural Nigeria Limited on behalf of Monsanto Company, 800 North Lindberg Boulevard, St-Louis, Missouri 63167, USA for a trial release (field experiments) of the single event NK603 and two-event stack, MON 89034 × NK603 maize, in the Federal Republic of Nigeria. MON 89034 × NK603 has been produced by crossing MON 89034 and NK603 maize lines using conventional breeding methods. This event is a two-trait maize that incorporates previously established genetically engineered traits of herbicide tolerance (to Roundup/Glyphosate) and insect resistance, produced by crossing these maize lines through conventional breeding.

Purpose of Application

This application concerns field trials with NK603 and MON 89034 × NK603 maize (Zea mays). NK603 was genetically modified via the particle acceleration method to be tolerant to glyphosate. MON 89034 x NK603 was obtained by traditional breeding of MON 89034 (genetically modified maize protected against certain lepidopteran insect pests) and NK603 (genetically modified maize tolerant to glyphosate).

The purposes of these field trials are:

- To evaluate the selectivity of two glyphosate formulations when applied to MON 89034 × NK603 compared to an unsprayed hand weeded treatment;
To evaluate the weed efficacy of two glyphosate formulations when applied on MON 89034 × NK603 in comparison to a local standard and hand weeding;

To evaluate the efficacy of MON 89034 × NK603 against certain lepidopteran insect pests; and

To demonstrate that NK603 and MON 89034 × NK603 are equivalent to their conventional counterpart under Nigerian conditions during 2016-2017 growing season.

**Previous Applications or approvals**

According to the applicant, NK603 and MON 89034 x NK603 have been field tested extensively since 1997 and 2006, respectively and are approved for commercial release in several countries since 2000 and 2010, respectively.

(Also, both NK603 and MON 89034 x NK603 are being tested in Burkina Faso (2015 cropping year).

**This application is new for NK603 and MON 89034 × NK603 in Nigeria.**

The respective traits are conferred to the stacked event (MON 89034 x NK603) by contributions of two recombinant maize lines as follows:

1. MON 89034: Maize resistant to Lepidoptera (cry1A.105, modified cry2Ab2)
2. NK603 CP4 EPSPS, 5-enolpyruvylshikimate-3-phosphate synthase (*Agrobacterium tumefaciens* CP4) for glyphosate herbicide tolerance.

**5. CASE BY CASE RISK ASSESSMENT AND EQUIVALENCE**

Throughout the application, Monsanto asserts that NK603 and MON 89034 × NK603 are equivalent to conventional Nigerian counterpart maize. They also claim the descriptions of the genetic modification of the single events and resultant phenotypic modifications as provided in the application are fully applicable to the combined trait product.

“NK603 was genetically modified to express the glyphosate-tolerance trait. MON 89034 x NK603 was obtained by traditional breeding of MON 89034 and NK603. Therefore, MON 89034 x NK603 expresses the lepidopteran protection trait inherited from MON 89034 and the glyphosate-tolerance trait inherited from NK603. The genetic modifications used to generate NK603 and MON 89034 were not meant to alter the reproductive biology of maize. MON 89034 x NK603 was obtained by traditional breeding and therefore no new genetic modification was used. (p. 10)”

There is no way for us to verify this statement as there is also no peer reviewed material on this gene construct cited by the applicant in this section.

**Equivalence**

Research published by the South African National Biodiversity Institute (SANBI)\(^1,2\) on MON810 has highlighted that long-held assumptions about substantial equivalence are false. SANBI carried out the first government research project on the environmental impacts of the single trait variety MON810 from 2008 to 2010, to fulfil their mandate as laid out in the National Environmental Management Biodiversity Act (NEMBA) (Act no. 10 of 2004). While Monsanto safety data claims MON810 to be substantially equivalent to conventional...
maize, SANBI found in their study 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.” This is at odds with the assertion that MON810 and the near isogenic parent are the same in every respect except for pest resistance conferred by Cry1Ab. The reasons for this are as yet unknown and the researchers 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” (SANBI (2011)², Roush, W.B. & Tozer, P.R. (2004)⁸.

One of the purposes of these trials is to prove equivalence of NK603 and MON 89034 × NK603 to their conventional counterparts. As the SANBI research shows, equivalence is actually not demonstrated for GM and non-GM plants.

MON810 has been growing in the South African environment and has been introduced into the South African food system for 12 years based on the false assumption that it is “equivalent” to its conventional counterpart. The assumption of equivalence has allowed GM producers to get away with dangerously scant safety testing. Unfortunately, public research tends to lag very far behind corporate research and development, so this is only coming to light now. (Kohli, A., et al. 2003; Mehlo, L., et al. 2000)⁴,⁵.

The application under consideration is asking for permission to release into our environment for trials, a combination of two traits and another with one trait. We have hardly begun to understand the environmental implications of the insertion of just one trait and leaping forward to combined threats simply heightens the risk factors.

Assessment of stacked varieties

Monsanto has not provided sufficient information for each individual event in MON 89034 × NK603. It is important to note that a number of scientists, institutions and regulatory bodies hold the view that assumptions on molecular characterizations and potential harm cannot be made without full assessment of the new combined or stacked event in question. According to GenØk - Centre for Biosafety (the national competence centre for biosafety of Norway), “the issue of combinatorial and/or synergistic effect of transgene proteins either with endogenous host proteins or with other inserted GM traits (e.g. “stacked” events) is an area of nascent scientific inquiry and must be carefully considered in the development and risk assessment of combined/stacked event GMOs with respect to the implications on biodiversity and evolutionary consequences for crop genetic diversity. This will be an important area of investigation for risk research, as combined/ multi-trait (stacked) GMOs are poised to replace the current generations of GM crops used in global agriculture. More research in this area is needed”. (Impact assessment of maize hybrid MON 89034 x MON 88017 from Monsanto (EFSA/GMO/BE/2009/71). See http://genok.no/wp-content/uploads/2013/03/genok_raad_jan2010_h71.pdf)

Under the Codex Alimentarius ‘Guideline for the conduct of food and safety assessment of foods derived from recombinant-DNA plants’ (2003)¹⁰, paragraph 14 states:
“Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through the subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a rDNA plant would have an unexpected, adverse effect on human health.”

We are very concerned about the assumption of equivalence, compounded by the fact that the synergistic effects of breeding the single events into the combined trait product are not taken into account. It is assumed that there will be no unintended or undesirable changes to endogenous or introduced traits and functions. This assumption is clearly untenable.

We cite research that has found unexpected and unwanted effects due to gene stacking under human and animal health as well as environmental impacts. (Kohli, A., et al. 2003; Mehlo, L., et al. 2000).

We stress that the safety of MON 89034 x NK603 should not be assumed because parent lines may have been assessed individually and found to be safe. MON 89034 x NK603 must be assessed as a new event and fully assessed. Evidence of peer-reviewed documentation needs to be provided before this trial in Nigeria where we have little or no capacity to deal with unintended effects.

6. DESCRIPTION OF THE GENETIC AND RESULTANT PHENOTYPIC MODIFICATIONS OF THE GMO

Stability of the integrated DNA inserts for each individual event in the combined event under question (MON 89034, and NK603) is not demonstrated by reference to either southern blot analysis or polymerase chain reaction (PCR) nor a combination of the two which is recommended for the application. Without this, it is impossible for an independent reviewer to verify stability. Three tables were merely provided on pages 11-12 of the application indicating size and intended function of each constituent fragment of inserted DNA, without reference to their stability nor to the actual genetic sequences post-modification. The applicant does not show any sense of seriousness or readiness for rigorous tests and this is absolutely unacceptable.

Further, it is not clear from the application whether the applicant has made use of other procedures for profiling the rDNA before and after modification. Numerous studies have noted that a combination of Southern blotting and polymerase chain reaction (PCR) should be used. Verifiable information on stability has to be provided. The applicant has not done so.

For example, in their commentary on detecting the many small and/or complex products of multiple insertion sites, Kohli et al. said: "Mehlo et al. (2000) studied seven transgenic maize lines with multicopy transgene loci and found that every line showed some form of transgene rearrangement in at least one copy. Importantly, some of these rearrangements could be detected by sequencing and/or PCR, but were too subtle to be picked up by Southern blot analysis, the predominant technique used to characterize transgene loci. The authors speculated that undetected 'minor' rearrangements might be extremely common...However, sequencing and PCR analyses by themselves would provide an incomplete picture of transgene organization because, depending on the location of the
sequencing and PCR primers, some major rearrangements might not be detected. Therefore, PCR, sequencing and hybridization provide complementary information regarding locus structure." None of these have been shown in the application as uploaded online by NABMA.

7. ANIMALS AND HUMAN HEALTH

Details pertaining to the human health, animal health and environmental safety of NK603 and MON 89034 × NK603 have not been submitted with the application. While the application is for a confined field trial and exposure to humans from ingestion is unlikely, it is still pertinent for us to raise human health issues in the case that confinement measures are not strict enough and the GM maize event may inadvertently enter the food chain, and also due to exposure of humans (including those who are carrying out the trials) to the herbicide that is used in conjunction with the herbicide-tolerant trait. Furthermore, the applicant sought to justify safety to humans via assumptions and assertions that are not backed by evidence, and we have sought to respond to these.

**Natural Bt is not necessarily equivalent to Bt expressed in plants**

“The conclusion of safety to humans of these proteins was based upon the following considerations:

- The proteins have a demonstrated history of safe use;
- The proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;
- The proteins do not exert any acute toxic effects to mammals.”

In addition, the rapid digestibility in simulated digestive fluids provide additional assurance for their safety. It is therefore highly unlikely that CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins would cause any toxic effects on human or animal health.

The CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins were also assessed for their potential allergenicity according to the recommendations of Codex Alimentarius Commission.

The proteins are from non-allergenic sources, lack structural similarity to known allergens, are rapidly digested in simulated gastric fluid, and constitute a very small portion of the total protein present in the grain of NK603 or MON 89034 x NK603. Taken together these data lead to the conclusion that these proteins are unlikely to have any allergenic potential, and NK603 and MON 89034 x NK603 are as safe as conventional maize regarding the risk for allergenicity (page 13)

**WE NOTE THAT THE ABOVE ASSERTIONS ARE NOT VERIFIABLE AS NO PEER REVIEWED REFERENCE IS CITED AND DETAILS ARE NOT AVAILABLE.**

We assert that the risk assessment should be backed with bioinformatics analysis, because no risk assessment would be complete without bioinformatics analysis. Though we assert as in the preceding sentence that the applicants should also note that in silico approaches are limited to identified proteins and to epitopes that are not influenced by post-translational modification (PTM). Bioinformatics of this type also cannot provide insight into
unanticipated or unintended changes that introduce new allergens. Moreover, the databases are limited to those proteins known to be allergens. These databases are growing rapidly, but it cannot be concluded that they are comprehensive. In the case of toxins, the search results are dependent upon those annotating the databases to recognize that the proteins are toxins. These methods also heavily rely on the algorithm used and guesses about protein folding, which are far from strong.

Natural Bt toxin is not necessarily the same as the Bt toxin expressed in GM plants; the Bt toxin in GM plants may be truncated or otherwise modified. For example, there is a 40% difference between the toxin in Bt176 maize and the natural Bt toxin. Further research into the safety of genetically engineered Bt is necessary as it cannot be assumed safe based on the safe use of pesticides derived from naturally occurring Bt.

THE CONCLUSION BY THE APPLICANT BASED ON THE ABOVE INFORMATION PROVIDED ON PAGE 13 OF THE APPLICATION IS THEREFORE WRONG.

Hematotoxicity of Bt

Published studies carried out on Swiss mice (Mezzomo BP, Miranda-Vilela AL, Freire IdS, Barbosa LCP, Portilho FA, et al. (2013))\textsuperscript{11,12,13} showed that the “Bt spore-crystals genetically modified to express individually Cry1Aa, Cry1Ab, Cry1Ac or Cry2A can cause some hematological risks to vertebrates, increasing their toxic effects with long-term exposure”. The researchers concluded, “taking into account the increased risk of human and animal exposures to significant levels of these toxins, especially through diet, our results suggest that further studies are required to clarify the mechanism involved in the hematotoxicity found in mice, and to establish the toxicological risks to non-target organisms, especially mammals, before concluding that these microbiological control agents are safe for mammals.” The applicant and NABMA need to take note of the above.

Immune effects

“Taken together these data lead to the conclusion that these proteins are unlikely to have any allergenic potential, and NK603 and MON 89034 x NK603 are as safe as conventional maize regarding the risk for allergenicity (page 13)”

In GenØk’s assessment of MON 89034 x 1507 x NK603, they point out that: “Published mouse experiments have demonstrated that Cry1Ac raises specific immune reactions, and also possesses adjuvant properties by increasing the immunogenicity of proteins intermixed with feed products.\textsuperscript{11a,11,13}

Published data also suggest that Cry proteins may inhibit development of mucosally induced suppressive immune mechanisms referred to as "oral tolerance" against innocuous food proteins\textsuperscript{12}. In investigations with Cry1Ab protein, (12) did not find a similar type of adjuvant effect elicited against peanut proteins as with Cry1Ac, yet instead found evidence of Cry1Ab acting as an adjuvant leading to early phase production of leukotrienes and increased Th2 and Th17-cytokine production in bronchoalveolar lavage fluids after airway exposure. The implication of possible effects of Cry1Ab to produce allergen-induced cytokine responses is an area of investigation warranting further inquiry.”
It is as yet unknown if the risk of food allergy increases with the presence of intestinal localized Cry proteins. The use of maize containing multiple Cry proteins, brings up a concern whether there will be a higher incidence rate for food allergy, especially when eaten as a staple by infants, adults, the sick and elderly. In addition, “since Cry proteins possess adjuvant activity there may be enhanced inflammatory processes. Combinatorial or synergistic effects of recombinant proteins acting as adjuvants to immunostimulatory effects, or as potential allergens are areas of important coming scientific inquiry”.

This concern was also raised by experts of the Norwegian authorities in the context of the market authorisation of MON89034xNK603 in the EU. (EFSA 2009c): “Assessment of allergenicity of the whole GM plant or crop Scientific studies, also very recent ones, have shown that the Cry1Ac protein is a potent systemic and mucosal adjuvant, which is an enhancer of immune responses. The GMO Panel of the Norwegian Scientific Committee for Food Safety find it difficult, based on the available data, to assess whether kernels from maize MON89034 may cause more allergenic reactions than food and feed from unmodified kernels. As the different Cry proteins are closely related, and in view of the experimental studies in mice, the GMO Panel finds that the likelihood of an increase in allergenic activity due to Cry1A.105 and Cry2Ab2 protein in food and feed from maize MON89034 cannot be excluded.”” (quoted in p. 14, Testbiotech 2013). (Ref: Testbiotech, 2013. Analysis of the data submitted by Monsanto to the Indian authorities on genetically engineered maize MON89034 x NK603)

Researchers have found that further research into allergenicity is still needed and that “further studies are needed to determine the amount of allergen that sensitises and elicits allergic events” (FAO/WHO 2001). With regard to allergies in general, they noted that "Severe reactions can take place after intake of minute amounts of the offending food, and a safe threshold level below which reaction will not occur has not been defined” ”(FAO/WHO 2001 – Evaluation of Allergenicity of Genetically Modified Foods. http://www.fao.org/3/a-y0820e/y0820e04.htm)

**Protein digestibility**

Monsanto states that “the rapid digestibility in simulated digestive fluids provide additional assurance for their safety. It is therefore highly unlikely that CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins would cause any toxic effects on human or animal health (page 13).

The correlation between resistance to digestion by pepsin and a protein’s potential to be an allergen is in doubt because some allergens are readily digested and some non-allergens are resistant to digestion. Industry-independent observers note that "later work, however, cast some doubt on the usefulness of this test since few of all known food allergens demonstrate resistance to simulated gastric fluid (SGF-containing pepsin) or to simulated intestinal fluid (SIF) comprising pancreatin (a mixture of five enzymes: amylase, trypsin, lipase, ribonuclease, and protease). An explanation for the lack of correlation between SGF digestibility and nonallergenicity may be that both children and adults may have naturally or iatrogenically increased ventricular pH for extended periods." (Poulson 2004)
Criticism also arises from the apparent lack of correlation between digestibility and percentage of allergenicity (i.e., major allergens are not more stable than minor ones). Furthermore, digestibility of a protein in SGF does not seem to correlate with digestibility in SIF. The digestibility of the vast majority of allergens (there are more than 1000 in databases), has not been determined. (Bannon and Ogawa, 2006)

Apart from questions about the validity of the assumption that stability and allergenicity are linked, several experimental factors are of concern, mainly arising from the fact that the assay is not standardized. First of all, the interpretation of obtained data can vary greatly between different studies as there is no agreed on definition of "stability". Astwood et al. (1996), for example, defined "labile" as digested after 30 sec, while "stable" proteins were detectable for more than 30 sec and up to 60 min, the maximum time of the experiment. Other studies used different frames, e.g., defining a protein detectable for 30 min as stable or discounting fragments that were stable for the maximum time of the assay, even though the whole protein was not (reviewed e.g., in Bannon, and Ogawa, 2006). Different studies have shown that a variety of factors can profoundly influence the result of the assay, leading to false negative results (that is, suggesting that the protein is less stable than it actually is). Factors that can influence the results include: the enzyme to test protein ratio, pH, purity of the test protein used, and the detection method.

Given the above, there is little assurance that the applicant’s assertions on the digestibility of the CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins are any confirmation of their safety.

**New evidence of stomach inflammation in pigs fed GM maize and soya**

A thorough, long-term toxicology study (for 22.7 weeks, being the normal lifespan of a commercial pig from weaning to slaughter) on pigs in a USA commercial piggery was carried out in order to compare the effects of eating either a mixed GM soya and GM maize diet, or an equivalent diet with non-GM ingredients. The maize used in the study contained 90% DK 42-88 RR YG PL (a triple stack of NK603, MON863 and MON810 genes) with the remainder being equal quantities of Pannar 5E-900RR (containing NK603), Pannar 4E-705RR/Bt (a double stack of NK603 and MON810) and Producers 5152 RR (containing NK603) (Carman et al. 2013).

The results of Carman et al. 2013 showed that the GM diet caused gastric and uterine differences in pigs. GM-fed pigs had uteri that were 25% heavier than non-GM fed pigs. GM-fed pigs had a higher rate of severe stomach inflammation with a rate of 32% of GM-fed pigs compared to 12% of non-GM-fed pigs. The severe stomach inflammation was worse in GM-fed males compared to non-GM fed males by a factor of 4.0, and GM-fed females compared to non-GM fed females by a factor of 2.2.

The researchers highlight the importance of this study, saying that,
“Our findings are noteworthy for several reasons. First, we found these results in real on-farm conditions, not in a laboratory, but with the added benefit of strict scientific controls that are not normally present on farms.

“Second, we used pigs. Pigs with these health problems end up in our food supply. We eat them.

“Third, pigs have a similar digestive system to people, so we need to investigate if people are also getting digestive problems from eating GM crops.

“Fourth, we found these adverse effects when we fed the animals a mixture of crops containing three GM genes and the GM proteins that these genes produce. Yet no food regulator anywhere in the world requires a safety assessment for the possible toxic effects of mixtures. Regulators simply assume that they can’t happen.

“Our results provide clear evidence that regulators need to safety assess GM crops containing mixtures of GM genes, regardless of whether those genes occur in the one GM plant or in a mixture of GM plants eaten in the same meal, even if regulators have already assessed GM plants containing single GM genes in the mixture.” (Evidence of harm in pig study, http://gmojudycarman.org/new-study-shows-that-animals-are-seriously-harmed-by-gm-feed/, accessed 18 June 2013).19

This study is of extreme concern to us due to the fact that GM maize, and increasingly stacked varieties of GM maize, are what are being considered for our nation. No tests have been carried out to understand the effects the diet from these GM maize event may have on our health. We believe that the claim by Monsanto of GM maize being safe is false and we cite numerous studies in this objection to support our concerns. We are baffled why our regulators continue to have faith in non-peer reviewed, producer-generated safety data that claim safety, while turning a blind eye to an ever-mounting body of independent peer-reviewed science that are raising red flags.

Furthermore, a 2-year study of rats fed NK 603 maize and maize spayed with Roundup (glyphosate) found that female mortality was 2-3 times higher due to large mammary tumors and disabled pituitary function. Male rats on the NK603 and Roundup diet suffered liver congestion and necrosis, severe kidney nephropathies and large palpable tumours. The study attracted controversy; more than a year later and after a concerted campaign to discredit the study and under intense pressure, the journal retracted the study. However, the study was republished in 2014 in another journal, with extra material addressing criticisms of the original publication ((Séralini et al. 2014). The new paper presents the same results as before and the conclusions are unchanged. Moreover, it is the only paper showing effects in the long term, as most feeding studies are only 90 days in duration. (Reference: Seralini G.E., Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D and Spiroux de Vendomois J. 2014. Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Environmental Sciences Europe 2014.
Our trust in the Nigerian regulatory process is further eroded when a vast amount of information is not made available for independent oversight. Nigerians are being kept in the dark about the safety of their staple food and to make matters worse, may have no choice but to eat whatever they may find on the market shelves because no one protected them by carefully scrutinizing what they are exposed to. Something has gone horribly wrong when corporate interests are allowed to trump the rights of citizens, especially in a matter as intimate as the food we put into our bodies and with the risk that local varieties may be contaminated and eliminated through pollution by genetically modified varieties such as the ones Monsanto is here applying to introduce.

**Glyphosate safety**

No data is given on the safety of the two herbicides [Roundup®2 PowerMax (540 g a.e./l)(MON 79873) and Roundup® Turbo 450K (450 g a.e./l)(MON 79545)] that will be used on these crops. All the application says is,

“The purpose of these field trials is to evaluate the selectivity of two glyphosate formulations [Roundup®2 PowerMax (540 g a.e./l)(MON 79873) and Roundup® Turbo450K (450 g a.e./l)(MON 79545)] when applied to glyphosate tolerant maize and protected against certain lepidopteran insect pests (MON 89034 x NK603) compared to an unsprayed hand weed treatment in Nigeria during 2016-2017 growing season. To prove selectivity of the above mentioned, herbicides will be applied in single and double rates” (page 42).

This is all that is stated in the application on the herbicide – glysophate - to be used in conjunction with both NK603 and MON89034 x NK603. No safety data are provided on a chemical that WHO has recently classified as a “probable human carcinogen” and for which other parts of the world are moving toward banning. We are strongly opposed to any move to introduce the nation to more of its use. (See, for example, “Widely Used Herbicide Linked to Cancer”. March 25, 2015. [http://www.scientificamerican.com/article/widely-used-herbicide-linked-to-cancer/](http://www.scientificamerican.com/article/widely-used-herbicide-linked-to-cancer/))

Research carried out in the United States has found that genetically engineered crops have led to an increase in overall pesticide use, by 404 million pounds (7%) from the time they were introduced in 1996 through 2011. Of that total, herbicide use increased over the 16-year period by 527 million pounds while insecticide use decreased by 123 million pounds (Benbrook 2012)\(^20\). Similar increases have been observed in Latin America. For example, between 1996 and 2011 the amount of glyphosate used in Argentina increased 11 fold, to 237 million litres. The volume of pesticides sold in Brazil increased by 360% between 2000 and 2009 (Vargas et al, 2012). In South Africa, annual glyphosate use has increased from 12 million litres in 2005 to 20 million liters, while from 2007 to 2011 glyphosate imports increased by 177%. Over a similar period, herbicide tolerant soya cultivation rose from 165,000 ha in 2008 to 472,000ha in 2012 (ACB, 2012).\(^21\)

The development of resistant weeds has played a large role in this massive increase in use of herbicides in the USA. The fact that Monsanto and the University of Pretoria at the present have a collaborative research programme into glyphosate resistant weeds indicates that this
issue is anticipated in Nigeria. (See: http://web.up.ac.za/default.asp?ipkCategoryID=21534&subid=21520&ipklookid=11&parentID=20987, accessed 24/06/2013). The omission of information regarding the problem of weed resistance in this application and plans on mitigating the risk is disturbing. Instead, Monsanto may intend to fix a problem they may create with yet another of their products, which will in turn create further problems for them to fix, all at the expense of our health and environment.

Glyphosate, which is the ingredient of Roundup, is one of the world’s most ubiquitous agrochemicals, and is the most traded active ingredient in the global herbicide market. It is a broad-spectrum herbicide that works by inhibiting the enzyme enolpyruvylshikimate-phosphate-synthase (EPSPS), which is a catalyst for the production of three essential amino acids: phenylalanine, tyrosine, and tryptophan. Though Monsanto’s application states on page 13 that there is “no harm expected from EPSPS enzymes” there is no reference at all to the safety of glyphosate or glyphosate-based herbicides. The agro-chemicals industry has claimed glyphosate is benign to humans and animals, but a good number of studies have shown otherwise:

• Glyphosate formations can induce cell death in human umbilical, embryonic and placental cells. The same study further added that ‘adjuvants in Roundup are not inert’ (Nora Benachour & Gilles-Eric Seralini (2009).23
• In order to improve the efficacy of glyphosate as a herbicide, it is combined with other chemicals (called adjuvants) when sold commercially (such as under Monsanto’s Roundup brand). These adjuvants are claimed to be benign, and not always listed on the packaging of the herbicide (under the guise of commercial confidentiality). However, research carried out on nine commercial formulations of glyphosate based herbicides (GBHs) revealed that one of these adjuvants, POE-15, was actually more toxic to human cells than glyphosate itself. (Mesnage R., Bernay B., Séralini G-E. (2009).23
• Cell exposure to glyphosate can trigger programmed cell death (to prevent the growth of tumours, for example). Research has revealed that Bt toxins (produced by the other significant GM trait on the commercial market) can impair this process in human embryonic kidney cells. (Mesnage, R. Clair, E. Gress, S. Then, C. Szekacs, A. Seralini, G.E (2009).23 This could have severe implications, as ‘stacked’ GM crops, which contain both traits, are becoming more and more prevalent. MON 89034 x NK 603 is one such stacked GM crop.
• In Ontario, Canada, glyphosate use has been associated with an increased risk of spontaneous and late abortions among farm-workers (Tye E. Arbuckle, Zhiqiu Lin, and Leslie S. Mery (2001).24 Similar evidence has emerged from Argentina (Antoniou, M. Robinson, C. Fagan, J (2012).25

According to the EU regulations in force, a compound will be classified as a carcinogen category 1B (“presumed human carcinogen”) if the evidence shows “an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different
protocols” (Regulation 1272/2008, p. 104).

In the case of glyphosate, five mouse studies and two rat studies have been identified that show a statistically significant increase in tumour incidences. In addition, mechanistic evidence exists as documented and analysed in the IARC monograph demonstrating the biological significance of these findings in relation to humans. (The 31 August 2015 Addendum to the Renewal Assessment Report on Glyphosate A critical analysis by Peter Clausing, PAN Germany)

In addition, a growing number of studies have shown the environmental impacts of glyphosate, including negative impacts on aquatic systems (see next section).

8. ENVIRONMENTAL IMPACTS

Impact of Bt proteins on biodiversity and non-target organisms

Monsanto’s application claims that the “Cry1A.105 and Cry2Ab2 proteins exhibit toxicity towards certain lepidopteran insect pests but have been demonstrated not toxic to mammals and non-target organisms” (p.12). No information on their degradability in soil, deleterious effects on soil and aquatic organisms or on non-target organisms was provided. We therefore provide the following information.

Various meta-analysis studies dispute this theory of no toxic effect to non-target organisms: (Lövei, GL, Arpaia, S, (2005))\textsuperscript{26,27} documented that 30% of studies on predators and 57% of studies on parasitoids display negative effects to Cry1Ab transgenic insecticidal proteins. Another review (Hilbeck & Schmidt, 2006) on various Bt-plants found 50% of studies documenting negative effects on tested invertebrates. Further meta-analysis of 42 field experiments has found GM Bt producing crops to have toxic effects on non-target insect populations, (Lovei and Arpaia 2005)\textsuperscript{26,27}, including butterflies (Losey et al, 1999; Jesse and Obrzycki 2000; and Lang andVojtech 2006)\textsuperscript{28,29,30} and beneficial predators such as ladybirds (Schmidt et al, 2009 and Hilbeck et al, 2012)\textsuperscript{31,32,33} and lacewings (Hilbeck et al, 1999).\textsuperscript{33} Bt toxin has also been found to impact bees’ learning behaviour, interfering with their ability to find nectar sources for food (Ramirez-Romero et al, 2008).\textsuperscript{34}

More recent research on aquatic environments has sparked intense interest in the negative impacts of Bt crops on aquatic invertebrates such as \textit{Daphnia magna} (Bohn et al, 2008)\textsuperscript{35} and caddisflies (Rosi-Marshai et al, 2007).\textsuperscript{36} These publications warrant future study, given the potential load of novel target proteins that may end up in agricultural runoff and eventually in aquatic environments. Douville et al. (2007)\textsuperscript{37} present evidence of the persistence of the transgenic insecticidal protein Cry1Ab in aquatic environments and suggest that sustained release of this potently bioactive compound from Bt maize production could result in negative impacts on aquatic biodiversity.

Impacts on soil microflora and fauna, including earthworms (Zwahlen et al, 2003),\textsuperscript{38}
mycorrhizal fungi (Castaldini et al, 2005) and microarthropods in response to Cry endotoxins have also been reported. (Griffiths et al, 2006 and Wandeler et al, 2002).

**Environmental impacts of glyphosate**

Again, Monsanto does not deem it necessary to consider the potential impacts of glyphosate on the environment. This is in keeping with the biotechnology industry’s very narrow definition of potential ‘stressors’ in GM plants; that only the novel ‘trait’ (e.g. the CP4 ESPS enzyme) is to be assessed, and not the chemical that the trait has been expressly created to be used with (Hilbeck, 2012). A more holistic approach to biosafety should consider the impacts of glyphosate (and glyphosate-based herbicides) in addition to the CP4 ESPS enzyme, which could include the following:

- Research analyzing the impact of Roundup formulations and glyphosate itself has shown it to have an inhibitory effect on microbial growth at lower concentrations than those recommended in agriculture. The toxic effect of glyphosate was amplified by its formulation adjuvants (Clair et al, 2012).

  - Glyphosate is generally considered to rapidly ‘bind’ to soil particles following application in the field, therefore minimising the risk of it leaching from the soil into nearby water. However, glyphosate’s ability to bind to soil particles can vary depending upon specific chemical properties (such as soil pH levels). It is also known that phosphate (which is used extensively in chemical agriculture as a fertiliser) plays a particularly important role in this, though further study will be needed (Helander et al, 2012).

  - Various studies have found glyphosate to: impair water intake and use efficiency, and biomass production in plants (Zobiole et al, 2010); interfere with the uptake of calcium, magnesium, iron and manganese in non HT soybeans (Cakmak, et al, 2009); and contribute significantly to incidences of fungal disease (Fernandez et al, 2009).

  - Glyphosate weed control programmes have been linked to increased incidences of over thirty plant diseases, in crops as diverse as apples, barley, canola, citrus, cotton, soybeans, tomatoes and wheat (Johal and Huber 2009).

  - Greenhouse studies have shown that glyphosate interferes with iron uptake even in glyphosate tolerant soybean plants (Bellaloui et al, 2009). A three year field study in the USA indicated that, at rates of 2.52 kg/ha, glyphosate inhibits nitrogen fixation and or simulation in glyphosate resistant soybeans (Zablotowicz and Reddy, 2007).

  - In greenhouse and growth chamber experiments, conventional and glyphosate tolerant soybeans were treated with glyphosate doses of 0.28 kg/ha, 1.12 kg/ha and 2.24 kg/ha. A dose of 2.24 kg/ha reduced the dry shoot and root weight of glyphosate tolerant soybeans by 25-30%. A repeated dosage reduced root growth, and reduced the nodule number by between 30% and 39%. (Reddy et al. See: http://www.ars.usda.gov/SP2UserFiles/Place/64022000/Publications/Zablotowicz/Reddyetal_00JNS.pdf)

- Glyphosate is toxic to earthworms (Antoniou et al, 2012).

- Glyphosate’s impact on plant (weed) diversity in areas it is used has knock-on effects...
further up the food-chain: The rapid spread of GM HT crops in the USA has contributed significantly to ‘the potential collapse’ of the ‘unique migration and overwintering biology of the eastern North American monarch butterfly’ (Pleasants and Oberhauser 2012). Studies from the USA have also linked its use to declining bird populations (similar results were observed in the UK – see below) (Santillo et al, 1989).

**Glyphosate in Water**

A study conducted by the US geological survey from 2001–2006 detected glyphosate and its breakdown product AMPA in 32% of 608 surface water samples collected. In areas with near continual applications (common in areas with HT crops), glyphosate and AMPA were detected ‘in almost every sample’ (Coupe et al, 2011).

- Other studies from the Mississippi river basin in the USA, revealed glyphosate and AMPA detection rates ranged from 60–100%. Its concentration in rain was found to be higher than any other high use herbicides in the area (Chang et al, 2010).
- In Catalonia, Spain, 140 ground water samples were analyzed from 2007–2010. Glyphosate was present above limits of quantification levels in 41% of samples, with the highest recorded sample at 2.5ug/L in one location (25 times the maximum level of pesticides permitted in water) (Sanchis et al, 2011).

It is also worthy to note that residues of glyphosate have also been found in groundwater in Canada, Denmark, the Netherlands, and USA. They have been detected in the marine environment off the Atlantic Coast of France; and in the rain in Belgium and Canada.

- A recent study carried out by Friends of the Earth Europe, in which volunteers in 18 European countries gave urine samples, found traces of glyphosate in people in every country represented. In Great Britain, Germany and Poland 70% of participants were found to have glyphosate traces in their urine. Disturbingly, all of the volunteers in the study lived in cities, and none had handled or used glyphosate products in the run up to the tests (FoE Europe, 2013). This study if conducted in Nigeria will be very interesting. We challenge NABMA to commission such work in Nigeria.

Glyphosate is highly soluble in water, giving it the capacity to be highly mobile in aquatic systems. (Riley et al, 2011) There is mounting evidence that, once glyphosate, GBHs and AMPA have entered surface water courses, they can cause considerable damage:

- Western chorus tadpoles exposed to the glyphosate product Roundup WeatherMax at 572 µg/L glyphosate acid equivalents (a.e.) resulted in 80% mortality, which the authors suggested resulted from a unique surfactant formulation. Exposure to WeatherMax or Roundup OriginalMax at 572 µg/L a.e. also lengthened the larval period for American toads (Riley et al, 2011).
- A study published in 2013 revealed that Roundup actually induced morphological changes in tadpoles. The author concluded that to his knowledge ‘this is the first study to show that a pesticide can induce morphological changes in a vertebrate (Relyea 2012).
- Scientists in Argentina exposed embryos of *Xenopus laevis* (African Clawed Frog) to
commercial formulations of GBHs. The embryos exhibited ‘highly abnormal with marked alternations in cephalic and neural crest development’, which are vital processes in cranial development (Paganelli et al 2010).  

- Rotifer (Brachionus calyciflorus) (microscopic aquatic animals) exposed to different concentrations of glyphosate had longer embryonic developmental time, longer durations of juvenile and reproductive periods, shorter average lifespan, a reduced net reproductive rate and reductions in the intrinsic population growth rates (Riley et al, 2011).

At Rhodes University, research has been taking place into the impact of Roundup formulations on aquatic ecosystems, using Freshwater Shrimp (Caridina nilotica) as a biomarker. Roundup’s toxicity was tested in new born (up to 7 days after hatching), juvenile (7-20 days) and adult (over 40 days) freshwater shrimps. Though newborns were the most sensitive to Roundup formulations, all three age groups exhibited slow and erratic movements. The study concluded that even low levels of Roundup may adversely affect Caridina nilotica health and survival (Mensah et al, 2012). A study to assess oxidative tissue damage was assessed by determining lipid peroxidation (LPx). The results suggested that Roundup ‘exerts toxic effects related to oxidative stress (Mensah et al, 2012). (In human’s oxidative stress is thought to be involved in the development of many diseases or may exacerbate their symptoms, including cancer, Parkinson’s and Alzheimer’s disease) (http://en.wikipedia.org/wiki/Oxidative_stress).

The spread of herbicide resistance and resistance of insects to Bt toxins

Insect resistance

“The purpose of these field trials is to evaluate the efficacy of MON 89034 x NK603 maize against certain lepidopteran insect pests in Nigeria during the growing season of 2016-2017.” (Page 47)

The assumptions about multiple gene stacking to prove/ arrest resistance need to be interrogated.

In June 2007, Van Rensburg published a paper entitled “First report of field resistance by the stem borer, Busseola fusca (Fuller) to Bt-transgenic maize”. Two reasons were cited for the development of this resistance: 1) the lack of refugia inside irrigated plantings with farmers opting to use susceptible plantings provided under rain fed conditions in the immediate vicinity of irrigated plantings as refugia; and 2) continuous exposure of larvae of the second seasonal moth flight to sub-lethal levels of the toxin at late plant growth stages.

Monsanto should acknowledge the reality of the development of insect resistance and lay out their strategy to deal with it even at this early stage of a field trial application. At the very least, Monsanto should bring the issue to the attention of regulators in their application, owning up that resistance is already reported in other countries like South Africa (SANBI, 2011 and Tabashink et al, 2009).
Professor Cummins, Emeritus Professor of Genetics at the University of Western Ontario, has pointed to resistance monitoring data from five continents, reported in 41 studies that evaluated responses of field populations of 11 lepidopteran pests to four Bt toxins produced by Bt corn and cotton. After more than a decade since initial commercialization of Bt crops, most target pest populations remain susceptible, whereas field-evolved resistance has been documented in some populations of three noctuid moth species: *Spodoptera frugiperda* (J. E. Smith) to Bt corn in Puerto Rico, *Busseola fusca* (Fuller) to Cry1Ab in Bt corn in South Africa, and *Helicoverpa zea* (Boddie) to Cry1Ac and Cry2Ab in Bt cotton in the southeastern United States (Tabashink et al, 2009)⁶³. **Why try in Nigeria what has failed in other places?**

Studies have now also shown that increased resistance was observed in pest populations exposed to the concurrent use of pyramided plants (where two dissimilar Bt toxins are inserted to reduce the risk of resistance development) and single Bt events, as ‘exposed populations were given a “stepping stone” to develop resistance to both toxins’ (Tabashink et al, 2009).⁶³ Indeed, the multi-gene strategy might be responsible for increasing the pace of resistance rather than effectively dealing with it. MON 89034 produces two different insecticidal toxins. Cry1A.105 has never been used before – it is a newly synthesized toxin that has no variants in nature. **Cry2Ab2 has previously been used in Bt cotton, but – as far as we know – not in plants that are mainly used for food and feed production.** It is thus imperative to assess the potential toxic effects thoroughly, including for synergistic effects of the Bt toxins and for chronic long-term effects, as well as to consider whether the two-toxin strategy will effectively delay insect resistance or on the contrary, speed up resistance development.

**Herbicide resistant weeds**

“The purpose of these field trials is to evaluate the selectivity of two glyphosate formulations [Roundup® PowerMax (540 g a.e./l)(MON 79873) and Roundup® Turbo 450K (450 g a.e./l)(MON 79545)] when applied to glyphosate tolerant maize and protected against certain lepidopteran insect pests (MON 89034 x NK603) compared to an unsprayed hand weeded treatment in Nigeria during 2016-2017 growing season. To prove selectivity of the above mentioned, herbicides will be applied in single and double rates” (page 37).

GMOs expressing herbicide resistance and producing Bt-insecticidal toxins may have impacts in terms of non-target effects, the generation of multiple herbicide-resistant weeds and changes in soil biodiversity and function (Mortensen et al, 2012)⁶⁴. The over reliance on glyphosate herbicide in genetically modified (GM) glyphosate-resistant cropping systems has created an outbreak of glyphosate-resistant weeds, the severity of which has been enough to motivate hearings in the US Congress to assess the problem. Biotechnology companies are now promoting second-generation GM crops resistant to additional herbicides as a solution to glyphosate-resistant weed problems. This approach will create new resistant-weed challenges, will increase risks to environmental quality, and will lead to a decline in the science and practice of integrated weed management (Mortensen et al, 2012)⁶⁴. **Why are we trying to prove right in Nigeria what has already been declared**
wrong even in the country of origin of the product? If the US Congress conducts a hearing on a matter, is it not enough for Nigeria with our limited capacity to be watchful and stay away from it?

Weeds in 14 countries have developed resistance to glyphosate. Most of this resistance has been caused by the repeated use of glyphosate in GM crops and no-till agriculture. Some have resulted from a gradual evolution of exposed weed species, and some from gene flow from GM crops to weed relatives. The latter has been observed with sugar beet in France, canola in Canada, creeping bentgrass in USA, and also with corn and soybean. Now even Monsanto is recommending the use of other herbicides in addition to glyphosate in Roundup-Ready crops (crops genetically modified to be tolerant of Roundup), to slow the onset of resistance in weeds. (Pesticides Action Network Asia and Pacific Glyphosate: Addendum 2012: Prepared by Meriel Watts, PhD)

There is a dramatic rise in the number and extent of weed species resistant to glyphosate and a concomitant decline in the effectiveness of glyphosate as a weed management tool. The number and extent of weed species resistant to glyphosate has increased rapidly since 1996, with 21 species now confirmed globally.

Although several of these species first appeared in cropping systems where glyphosate was being used without a resistant cultivar, the most severe outbreaks have occurred in regions where glyphosate-resistant crops have facilitated the continued overuse of this herbicide. The list includes many of the most problematic agronomic weeds, such as Palmer amaranth (Amaranthus palmeri), horseweed (Conyza canadensis), and Johnson grass (Sorghum halepense), several of which infest millions of hectares.

The result of the extensive use of these herbicides over vastly expanded areas will likely create interrelated challenges for sustainable weed management. First, crops with stacked herbicide resistance are likely to increase the severity of resistant weeds. Second, these crops will facilitate a significant increase in herbicide use, with potential negative consequences for environmental quality, as well as for human health. Finally, the short-term fix provided by the new traits will encourage continued neglect of public research and extension in integrated weed management. Nigeria cannot afford this scenario.

9. GENE FLOW IN MAIZE

“Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and/or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology. Physical barriers (5 m fallow, 6 border rows with conventional maize as a buffer zone) will minimize pollen flow” (page 16).

The above is Monsanto’s claim in the application of how gene flow will be controlled. Though the 5 locations of contained trials are given, the above statement is not detailed enough for informed comment on control of gene flow. These “other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology” hasn’t been fully provided by the applicant. It is therefore necessary that that information is provided in detail.
Monsanto has not adequately described measures to prevent cross-pollination, other than to say that adequate temporal and/or spatial isolation measures will be provided and that the trial sites will be fenced in the form of “5 m fallow, 6 border rows with conventional maize as a buffer zone”. We assert that this is not adequate for a wind-pollinated plant like maize especially keeping in mind the wind speed and velocity in the trial areas especially the drier areas of Northern Nigeria. There is no published work in Nigeria regarding the extent of gene flow in maize included in the submission of the applicant. Only work published in the USA has been cited in this submission.

Even South Africa, which has been cultivating GM crops, does not have published data on gene flow. Professor Viljoen of the University of the Free State says, “There are no published data regarding the extent of cross-pollination for maize in South Africa, even after a decade of commercialization of GM. … Despite a requirement for non-GM food, especially for export, there is no system for coexistence of GM and non-GM crop. Gene flow is a major contributor to commingling (Viljoen and Chetty, 2008).” His research showed that “the use of mean values of cross-pollination over distance may result in an underestimation of gene flow” and suggested that, “where stringent control of gene flow is required, for example, for non-GM seed production or for GM field trials under contained use, the high values of cross-pollination should be used to determine isolation distance. However, this may not be practical in terms of the isolation distance required.”

According to Viljoen, “based on the logarithmic equations of cross-pollination over distance, 45 m is sufficient to minimize cross-pollination to between <1.0% and 0.1%, 145 m for <0.1% to 0.01% and 473 m for <0.01% to 0.001%. However, compared to this, a theoretical isolation distance of 135 m is required to ensure a minimum level of cross-pollination between <1.0% and 0.1%, 503 m for <0.1% to 0.01% and 1.8 km for <0.01% to 0.001% based on high values of cross-pollination”. Yet Monsanto is recommending a paltry 5 m. How could this work?

“Anything but maize can be planted the following season to allow post trial monitoring.

The trial sites, including the 5 m fallow and 6 border rows with conventional maize as a buffer zone will be monitored for one year after harvest on a monthly basis for maize volunteer plants. Any volunteer plant that is found will be destroyed by uprooting the plant, leaving in the field to desiccate and burning at designated pits at the trial site. This activity will be recorded in the field notebook. The monitoring will be facilitated using the GPS coordinates of the four corners as measured at the beginning of the trial” (page 16).

This loose assurance of Monsanto on the issue of trial plant volunteers above cannot simply be accepted as it is inadequate (Viljoen and Chetty, 2008). In May 2013, the United States Department of Agriculture confirmed that instances of volunteer wheat, from trials that were discontinued in 2005, had been detected in farmer fields. This has resulted in the temporary loss of wheat exports to Japan, Korea and the European Union, threatening the US$8 billion wheat market (Reuter 31 May 2013). In addition, it has cast grave doubts on the control methods currently employed to control confined field trials of GMOs. People living in the vicinity of the trials or businesses in the vicinity should be apprised of the trials and their opinions solicited.

10. LACK OF STATE CAPACITY

It is stating the obvious that Nigeria does not have the capacity to monitor these GM crops. Not many Nigerians are aware of this application much less have access to it. Many persons
have an erroneous impression about GM crops being the solution to our problem of food security.

We have cited peer-reviewed thorough researched scientific publications that point out the health and environment problems associated with GM crops. Nigeria has no solutions to these problems, neither does she have the requisite capacity to contain them.

Added to lack of capacity for the health and environmental monitoring of GM crops, there is also a noticeable lack of public capacity for the monitoring of pesticide use in Nigeria’s food chain and the environment. Even in South Africa, a country far ahead of Nigeria in GM crops, this capacity is lacking: “In 2012, research from the ACB revealed that there was no testing for glyphosate residues in maize and soya products within South Africa, and no laboratories that could do this. There is also a barely believable eleven ‘food inspectors’ among the 3,264 environmental health practitioners registered with the Health Professions Council of South Africa (HPCSA). The Minister of Health, Dr Aaron Motsoaledi, appears to have recognised the severe potential risks of this, and informed us in October 2012 that the Department of Health was planning to undertake sampling runs to test for glyphosate residues in maize and soya meal products during 2012/13.”

There is also a distinct lack of environmental monitoring of pesticides (including glyphosate) in Nigeria. The right to a healthy environment and to sufficient and safe water is enshrined in the Nigerian Constitution the African Charter on Human and Peoples’ Rights and several other regulations by different agencies of government. It is worth noting that there are no water quality standards to protect the country’s freshwater systems, or indigenous freshwater organisms, from glyphosate based herbicides (GBHs). Neither is there a national maximum residue level (MRL) set for glyphosate in water sources. The National Environmental Standards and Regulations Enforcement Agency (NESREA) has several regulations but none is tied specifically to GBHs.

Glyphosate tolerant genetically modified (GM) crops should not be approved for field trials or for commercial release. Moreso because NABMA has no environmental monitoring project for these crops.

11. CONCLUSION

This application has failed to adequately show that NK603 and MON89034 x NK603 are safe for human, animal and environmental health. Our submission points to a number of areas of scientific uncertainty that pose serious risks and require further research. The Precautionary Principle requires commitment to the idea that full scientific proof of a causal link between a potentially damaging operation and a long term environmental impact is not required to take action in order to avoid negative effects on health and the environment. The Precautionary Principle supplies NABMA with a tool to halt further introduction of genetically modified crops, and especially combined/stacked varieties, due to the lack of information available in the scientific literature on genetic stability, expression of inserted proteins or immune effects as well as the stacked event of MON 89034 x NK603.

In addition, we do not believe that stacking genes to deal with insect and herbicide resistance is a reasonable response to these problems. It is clear that this strategy will lead to a cycle of further stacking, further resistance and increased use of agro-chemicals to deal with the problem. Alternative weed and insect management systems exist and are proving to be effective while in no way undermining agricultural yield.
We affirm that based on the data presented by Monsanto, no decision can be taken on the safety of the plants in regard to large scale field trials and their long-term impact once introduced into the Nigerian market. There are some substantial indications of risks for human health and the environment, which should trigger a high level of precaution in all further decision-making:

- Several publications show a reaction in the immune system of animals fed with genetically engineered plants that produce bacterial proteins.
- There are indications that feeding animals with genetically engineered plants such as Nk603 has a negative impact on organs such as the kidneys.
- Health risks due to residues from spraying with glyphosate formulations such as Roundup are a particular cause for concern.
- Large-scale cultivation of glyphosate tolerant crops is likely to cause emergence of resistant weeds, changes in soil microbial communities and losses in biodiversity.

This application is fraught with unverified claims and our objection to it has presented well-documented negative issues and lessons from elsewhere. We have also raised the issue of a conflict of interest concerning the interest of a government agency, NABDA, in the application.

It is our belief that if NABMA brings together all the organic agriculture research groups based in universities and other research centers in Nigeria, we shall find home-grown solutions to our problems rather than bringing in products with unclear consequences. Burkina Faso’s experience on Bt cotton should serve as a signal to us and we must tread with clear caution. Dowd-Uribe and Schunur 2016 reported the phasing out of Bt cotton in Burkina Faso due to the problems associated with it. We can certainly learn from our neighbour’s problems and decisions.

Monsanto’s application should be rejected for its inability to adequately address risks and concerns and for the protection of our biodiversity, our health and that of our environment.

REFERENCES

1 Safety Assessment of YieldGard Insect-Protected Corn Event MON 810
   bch.cbd.int/database/attachment/?id=10721 (accessed 11 June 2013)


52, 247–258.


18 Carman, A. et al. 2013. A long-term toxicology study on pigs fed a combined genetically


31 Schmidt JE, Braun CU, Whitehouse LP, Hilbeck A. Effects of activated Bt transgene products (Cry1Ab, Cry3Bb) on immature stages of the ladybird Adalia bipunctata in laboratory ecotoxicity testing. Arch Environ Contam Toxicol. Feb 2009; 56(2): 221-228.


http://www.ars.usda.gov/SP2UserFiles/Place/64022000/Publications/Zablotowicz/Reddyetal.00JNS. pdf
56 Sanchís, J. Kantiani, L. Llorca, M. Rubio, F. Ginebreda, A. Fraile, J. Garrido, T. Farré, M.

https://www.foeeurope.org/glyphosate-reasons-for-concern-briefing-130613


Tabashnik et al. 2009. Asymmetrical cross-resistance between Bacillus thuringiensis toxins Cry1Ac and Cry2Ab in pink bollworm. PNAS 106:11889-11894


