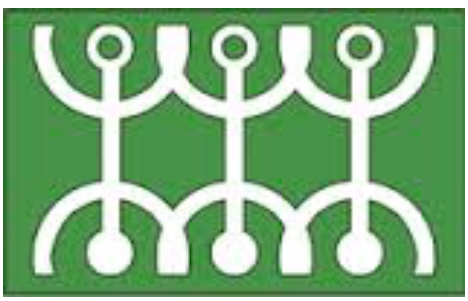
OBJECTION TO THE APPLICATION FROM MONSANTO AGRICULTURAL NIGERIA LIMITED ON BEHALF OF MONSANTO COMPANY, 800 NORTH LINDBERG BOULEVARD, ST. LOUIS, MISSOURI 63167, USA TO THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (NABMA), ABUJA, NIGERIA FOR THE RELEASE OF GENETICALLY MODIFIED COTTON MON 15985 AND ALL COTTON VARIETIES DERIVED FROM THIS EVENT IN ZARIA AND SOME TOWNS AROUND IT

SUBMITTED BY

HEALTH OF MOTHER EARTH FOUNDATION (HOMEF)
AND
ENVIRONMENTAL RIGHTS ACTION/ FRIENDS OF THE EARTH NIGERIA (ERA/FoEN)

March 2016

HOMEF
HEALTH OF MOTHER EARTH foundation



We gratefully acknowledge the work of civil society in Malawi, who faced a similar application for the commercial release of MON 15985 in their country and kindly allowed us to draw on their document for inputs into this objection.

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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)
16. KebetKache Women Development and Resource Centre
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. Host Communities Network
26. Urban Rural Environmental Defenders (U-RED)
27. Gender and Environmental Risk Reduction Initiative (GERI)
28. Women's Right to Education Programme (WREP)
29. Foundation for Rural/Urban Integration (FRUIT)
30. Community Action for Popular Participation
31. Torjir-Agber Foundation (TAF)
32. Civil Society on Poverty Eradication (CISCOPE),
33. Jireh Doo foundation
34. Advocate for Community Vision and Development(ACOVID)
35. Initiative for empowerment for vulnerable(IEV)
36. Kwaswdoo 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(OWCDO)
40. JODEF-F
41. Glorious things ministry(GTM)
42. Daughters of Love Foundation
43. Medical Women Association of Nigeria (MWAN)
44. Community Links and Empowerment Initiative(CLHEI)

45. Nigerian Women in Agriculture (NAWIA)
46. Osa foundation
47. Initiative for Improved Health and Wealth Creation (IIHWC)
48. Peace Health Care Initiative (PHCI)
49. Ochilla Daughters Foundation (ODF)
50. African Health Project (AHP)
51. Artists in Development
52. Ramberg Child Survival Initiative (RACSI)
53. Global Health and Development initiative
54. First Step Initiative (FIP)
55. Ruhujukan Environment Development Initiative (REDI)
56. The Centre for Environment, Human Rights and Development(CEHRD), Nigeria
57. Center for Children's Health Education, Orientation Protection (CEE Hope)
58. Next Generation Youth Initiative (NGI)
59. Akwa Ibom Information and Research Organisation (AIBIRO)
60. Rural Action for Green Environment (RAGE)
61. United Action for Democracy
62. Campaign for Democracy
63. Yasuni Association
64. Egi Joint Action Congress
65. Green Concern for Development (Greencode)
66. Kebetkache Ahoada Women Farmers Cooperative
67. Ahoada Uzutam Women Farmers Cooperative
68. Ogboaku Ahoada Farmers Cooperative
69. Gbobia Feefeelo women
70. Ovelle Nyakovia Women Cooperative
71. Rumuekpe Women Prayer Warriors
72. League of Queens
73. Emem Iban Oku Iboku
74. Uchio Mpani Ibeno
75. Rural Health and Women Development
76. Women Initiative on Climate Change
77. Peoples' Centre
78. Citizens Trust Advocacy and Development Centre (CITADEC)
79. Center for Environment Media and Development Communications
80. Center for Dignity
81. Peace and Development Project
82. Triumphant Foundation
83. Earthcare Foundation
84. Lokiakia Centre
85. Community Development and Advocacy Foundation (CODAF)
86. Citizens Center
87. Development Strategies
88. Rainforest Research and Development Center
89. Center for Environmental Education and Development (CEED)
90. Initiative for the Elimination of Violence Against Women & Children (IEVAWC)
91. Charles and Doosurgh Abaagu Foundation
92. Community Emergency Response Initiative
93. Society for Water and Sanitation (NEWSAN)
94. Shacks and Slum Dwellers Association of Nigeria
95. Atan Justice, Development and Peace Centre
96. Sisters of Saint. Louis Nigeria
97. Life Lift Nigeria

98. Community Research and Development Foundation (CDLF)
99. Environmentl rights Action Frineds of the Earth Nigeria (ERA/ FoEN)
100. Health of Mother Earth Foundation (HOMEF)

Contents

LIST OF ABBREVIATIONS AND ACRONYMS

ARMG	Antibiotic resistant market gene
AU	Africa Union
BCGA	British Cotton Growers' Association
CaMV	Cauliflower mosaic virus
CBD	Convention on Biological Diversity
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
GE	Genetically engineered
GM	Genetically modified
GMOs	Genetically modified organisms
Ha	Hectares
Indels	Insertions and deletions
Kb	Kilobytes
OAU	Organisation of African Unity
USA	United States of America
WHO	World Health Organization

1 Introduction

On Thursday 25th February 2016 NABMA placed a 21-day public notice in the Leadership newspaper announcing the public display of an application dossier by Monsanto seeking approval for environmental release and placing in the market of genetically modified (GM) cotton engineered to be pest resistant (MON 15985, known commercially as Bollgard II). This notice is a significant event for Nigeria, the west African subregion and indeed the continent, because to date very few African governments have permitted the commercial cultivation of GM crops. This application is the first of its kind in Nigeria[1].

GM crops have been the site of intense international debate since the 1970s when the technology "triggered major scientific, social and political controversies."[2] Genetic engineering "allows the intentional crossing of natural breeding barriers. The underlying molecular processes are qualified as sufficiently "new" so that they and the resulting organisms can be patented as inventions".[3] The proponents of genetic engineering (GE) claimed that the technology had great potential to address global food security concerns through increasing yields and nutritionally enhancing crops, through creating crops that would yield under environmental stress and that would impact on the environment positively through the reduction of pesticide use. However, the international community responded that conventional breeding was as effective in producing these results without the threat of corporate patents or scientific uncertainty about the long-term impacts these novel organisms might have on the environment and human and animal health. "The latter view prevailed in the international discussion and led to the establishment of regulations that should ensure biosafety in order to exploit the potentials of modern biotechnology in a safe and sustainable manner".[4]

The resulting Cartagena Protocol on Biosafety under the United Nations Convention on Biological Diversity (CBD) is based on the "Precautionary Principle" and sets minimum international biosafety standards for the transboundary movement of genetically modified organisms (GMOs). African leaders, aware of the socio-economic and cultural importance of agriculture on the continent, were particularly cautious about embracing this new proprietary technology and they played an important role in the shaping of international and African biosafety policy.

In addition, the African Model Law on Biosafety was drafted to guide African governments as they domesticated their biosafety regimes. The African Union adopted the Model Law in 2003 and the AU (then the Organization of African Unity – OAU) Executive Council urged the Member States to use the African Model Law on Safety in Biotechnology as a basis for drafting their national legal instruments in biosafety.[5] An updated Model Law was finalized in 2011[6] after the adoption of the the Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety and it was adopted at the Conference of African Ministers of Justice in 2014. The Model Law raises the bar for best biosafety practice, going far beyond the provisions of the Cartagena Protocol, thus reiterating African concerns about the potential impacts of this technology on African agriculture, which is the very basis for survival for the majority of Africans and is embedded in African culture and society.

Governments globally have been extremely cautious about the adoption of this technology over the past two decades and today almost 80% of GM crops are grown in just three countries – the United States of America (USA), Argentina and Brazil.[7] South Africa is the 8th largest producer of GM crops in the world, having grown 2.9 million hectares (ha) of GM maize, soya and cotton in 2013, which accounts for 1.66% of global GM crop plantings.[8] In 2008, Burkina Faso approved pest resistant GM cotton (known as Bt cotton) and according to unverified industry data, produced 0.5 million ha in 2013.[9] Sudan approved Bt cotton in 2012 and unverified industry data reports that 0.1 million ha were grown in 2013.[10] A number of African countries have instituted bans or restrictions on GMOs,

for example, in 2012 the Kenyan Parliament placed a ban on imports of GM foods,[11] the Seed Act of Mozambique does not allow the importation of GM seed and Burkina Faso is currently phasing out Bt cotton. European consumers remain staunchly opposed to GM crops and they are strictly regulated and restricted in the vast majority of European countries. In the European Union, only one GM event is cultivated (MON 810 maize), mostly in Spain. The same event, however, is banned in eight European countries on environmental grounds.[12] The Burkina Faso Government took a bold step in 2016 to phase out Bt Cotton in the countrty[13] when Nigeria is struggling to introduce it. Can't we learn a lesson and avoid the pit fall?

2. Summary of the Civil Society Objection to Monsanto's Application for the General Release of MON 15985 Cotton in Nigeria

The civil society organizations that have endorsed this submission have formulated a position in response to the public notice that was published by the NABMA DG regarding the "Application for the environmental release and placing in the market of genetically modified organisms" in Zaria and surrounding towns, a cotton zone that produces 60-65%[14] of the cotton needs of Nigeria. Several main areas of concern have been identified regarding the objection to the release of GMOs in this cotton zone of Nigeria, or more specifically, the requested approval of Monsanto's MON 15985 "Bollgard II" variety of Bt cotton. These areas of concern have been extensively laid out in this submission and are summarized as follows:

2.1 Socio-Economic Concerns

• The application by Monsanto has not sufficiently addressed the needs and concerns of other equally important actors in farming, such as the organic growers; protection of Nigeria's biodiversity and natural resources; promotion of sustainable agriculture and economic development for the benefit of both the present and future generations; promotion of gender equality and equity in biotechnology undertakings; promotion of traditional crops, animal genotypes and indigenous knowledge.

• No cost-benefit analysis has been carried out to support Monsanto's claims that this technology will benefit cotton farmers in the northern cotton zone and indeed the entire cotton zones of Nigeria. Experiences from Burkina Faso and South Africa have shown that the technology brings a high risk of indebtedness due to the exorbitant cost of the seed. Farmers must further risk the loss of markets where trading partners will not accept GM crops and traders might face increased costs and obstacles when transporting seed cotton that will be subject to the provisions of the Cartagena Protocol. Private-public partnerships that the Government of Nigeria may have entered into that do not allow the cultivation of GM cotton are also threatened by the introduction of Bt cotton. There is no clarity regarding liability and redress for farmers whose crops fail or who lose markets due to GM contamination. Furthermore, Monsanto has not clearly stated how she intends to control the spread of these Bt cotton seeds beyond Zaria and surrounding towns, despite being fully aware that the seed market in Nigeria is highly mobile.

2.2 Technical & Administrative Concerns

• The original notice placed by NABMA in the Leadership newspaper, calling for a 21-day period of public comment, included two display centres – one in Abuja and one in Zaria. For a country of 36 states and Abuja which is treated as a separate state, this is woefully inadequate. This indicates that effectively NABMA has given only two addresses for over 160 million Nigerians and for the 36 states even when Federal Ministry of Environment to which NABMA belongs has offices in the 36 states of the federation yet NABMA chooses not to use them, depriving Nigerians from full access to information. The inclusion of the dossier on the website of NBMA is also inadequate given that many Nigerians do not have access to the Internet. Worse still, the submission of

objection/comments has to be done through a Gmail address, NABMA knowing how epileptic Nigerian e-networks system is. In addition, the legal understanding regarding how to remedy the situations of grievances is yet to be clearly understood arising from the fact that the Biosafety Act of 2015 is still new and has not been tested in that regard. The Act also has a lot gaps. Moreover, we are not aware that NABMA has developed regulations arising from the Act for effective operation and implementation.

We also want put on record that the application was speedily uploaded onto the website after we had complained that it was not available on the website. We also note the inconsistencies and contradictions in the Public Notice of the application regarding the deadline for submission in the advertisement that was placed in the Newspaper on 25 February. Two different display dates are mentioned in the same advert: 29 February-28 March and 22 February–15 March. We have also not been able to resolve the puzzle as to why the deadline mentioned in the notice took effect from 22 Febuary but the advert was published on 25 February.

- We are really alarmed that the application is for an environmental release and placing on the market. This is coming so close after the dismal failures of Bt cotton in Burkina Faso. We are shocked to learn that it is already at the commercial release stage, when our Biosafety Act has only recently entered into force. What legislation was used to authorise the field trials in the first place?

- The National Biosafety Techinical Committee has evident technical capacity gaps that should be fully addressed before it can be deemed technically ready to assess an application of such specifications (being the first of its kind in Nigeria and for commercial release) and there are concerns regarding government capacity to monitor GM cotton for the development of insect resistance once it is released into the environment.

- We request that the field trial data be made available to us to review, and record our disappointment that the application does not refer to any of the specific field trial data from Nigeria. Public access to local field trial data on the use of MON 15985 in Nigeria, has remained inaccessible and out of the public domain. This is the case also for Zaria locality where approval for release is sought.

2.3 Molecular Concerns

- MON 15985 contains genes referred to as *cry2Ab2* and *cry1Ac*, which produce Bt toxins. These genes have been synthetically manufactured with no history of safe use in nature.

- The insertion of the *aadA* antibiotic resistant marker gene (ARMG) causes concerns regarding the potential transfer of antibiotic resistance to other living organisms. This concern, which is dismissed by the applicant, has been raised by a scientific panel of the European Food Safety Authority (EFSA) stating that this particular ARMG should be restricted to field trial purposes and should not be present in GM plants to be placed on the market.

- No information is included in the application regarding the specific locations and genetic context of where the insertions took place, or of specific primers necessary for the detection of the genetic insertions.

- There are several unexplained inconsistencies in the application with regard to the 'Southern Blot' and PCR tests used for molecular characterization, but no satisfactory clarification or explanation is made of these. Only general reference is made to ELISA.

- The applicant fails to provide information on the identification of novel production of ribonucleic acid (RNA) variants, a known occurrence with the terminator (NOS 3') used in MON 15985. The RNA variants have the potential to produce novel proteins with potential toxic or allergenic effects.

• MON 15985 also contains the 35S promoter from the cauliflower mosaic virus (CaMV). Recent scientific research has raised concerns regarding the consequences of a potential overlap between 35S and a viral gene VI. Such an overlap has not been tested for, nor ruled out, by the applicant.

2.4 Safety Assessment

• There are no baseline data regarding the quantity, spread and use of cottonseed meal/cakes/oil used for human or animal consumption in Nigeria, and therefore no foundation for the assessment of food and feed safety.

• The applicant states that the safety of newly produced proteins can be determined through the assessment of these proteins on an individual basis, but fails to take into account any combinatorial or cumulative effects. Therefore, safety tests should be conducted on the whole plant and not individual toxins.

• One component of the allergenic assessment of MON 15985 is based on comparison of its sequence similarity with an 8-amino acid segment of known allergens. A consultation from the Food and Agricultural Organization (FAO) and World Health Organization (WHO) has noted that the larger the peptide sequence used, the greater the likelihood of false negatives, and suggested the use of a 6-amino acid segment in assessing allergenicity. Research has also shown that when assessed using a 6-amino acid segment, both Cry1Ac and Cry2Ab toxins have shown similarities to known allergenic proteins. Further evidence is required to show that the two toxins, both separate and combined, will not cause allergenic effects.

2.5 Environmental Risk Assessment

• The treatment of the potential effects on non-target organisms (organisms other than the target pests) in the application is very superficial and is contrary to what has been demonstrated in the literature. No data is provided on the tests used to confirm the claim of no adverse effects, neither is there a demonstration that the specificity of ecological functional groups that are unique to Nigeria has been taken into account.

• Scientific models exist for assessing the environmental risks of the Bt toxins in a broader context of testing parameters, including the direct and indirect, cumulative and interactive effects. Such assessment models have been used in Kenya, Brazil and Vietnam and would yield more meaningful results if also applied in Nigeria.

• The ways in which organisms can come into contact with the Bt toxins of MON 15985 are referred to a "exposure pathways", and despite being very diverse are given very little attention in the application. Methods of exposure and potential transfer of toxicity include: consumption of lower-order organisms by higher-order organisms through the food web, wind dispersal of GM pollen, washing of plant matter into aquatic ecosystems, leaching of transgenic materials into the soil, leaching from root systems through fecal matter or through the release of decaying plant and animal matter. These exposure pathways should be described and understood in order to determine whether or not and to what degree non-target organisms come into contact with the plant and the Bt toxins.

2.6 Secondary Pests and Insect Resistance

• Secondary pests are populations of insects that can become a serious problem following changes in management practices or disruption of control by a natural enemy. The issue of secondary pests occurring, following the reduction in the target pest, is not considered at all in the application. Problems arising with secondary pest populations subsequent to the use of Bt crops have already been identified in several countries. Should secondary pests replace the target pests, this may necessitate increasing spraying of pesticides.

• Strategies for risk management and monitoring of GM crops are important and necessary according to the "Guidance on Risk Assessment of Living Modified Organisms" developed under the Cartagena Protocol on Biosafety, to which Nigeria is a party. Unfortunately, this application concludes that as no significant risks were identified compared to conventional cotton, therefore no risk management, i.e. post-commercial monitoring, beyond insect resistance management, is necessary. There is only a vague mention in the Fourth Schedule (page 3) of activities that will delay development of resistance.

• Insect resistance to Bt toxins has been documented in various parts of the world, including in Africa. Insect resistance to Bollgard I has already rendered it ineffective in several countries, and as such it is not marketed commercially anymore; hence the applicant's request for the approval of Bollgard II in Nigeria. Bollgard III, incorporating a third toxin, is already seeking application for use in some countries.

• The use of two toxin Bt crops is thought to be able to delay resistance development, however, several assumptions for the success of such a "pyramid" strategy have not been borne out. The possibility of insects developing resistance to MON 15985, despite it containing two toxins, cannot be excluded, nor can the possibility of cross-resistance developing be ruled out at this stage.

• Due to mounting global problems of insect resistance to Bt crops, a comprehensive resistance management plan would be essential for minimizing these risks. In this application, however, Monsanto has proposed a vague insect resistance management action plan without much detail of what is to be done. The applicant believes that use of structured refuges of non-Bt cotton and other approaches (for which no details are provided) could delay resistance. We posit that this approach has failed in other places and is therefore a waste of time and effort.

• There is also very little training envisioned in the application regarding local farmers' understanding and use of resistance management measures and refuges. It is also unclear who will bear the costs and responsibility of monitoring refuge implementation and compliance. The applicant only talked about unidentified stakeholders.

2.7 Conclusion

The concerns listed above have demonstrated that the basis of releasing MON 15985 cotton in Nigeria by the applicant is not justifiable and fails to comply with both national and international standard procedures of good practice. In response to the public notice published in the Leadership newspaper on 25th February 2016 by the NABMA DG, we object to the application 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 release of GM MON 15985 cotton in Nigeria (Zaria and surrounding towns).

3. Background

3.1 Background on the Cotton Sector in Nigeria

The British Cotton Growers' Association (BCGA) operated the cotton market in Nigeria until the formation of the marketing boards for cocoa, oil palm produce and cotton in 1949[15]. The cotton board was however, disbanded in 1986 with other commodity boards, as a result of the deregulation of the cotton market. The deregulation of the cotton market thus permitted private participation in the market and it was expected that it would afford both sellers and buyers of cotton a fair return on investment as compared to the days of commodity boards when there was unilateral fixing of prices by the boards. A major consequence of the market liberalization policy is that a new market structure has emerged because of the entrance of individuals, firms and cooperate organizations that now sponsor production and marketing of cotton in Nigeria[16]. This

we believe is what Monsanto wants to leverage on to penetrate the cotton zone of Nigeria.

In 1993, cotton output was roughly equivalent to the requirement of the textile industry (Andrae and Beckman 1987).[17] However, later cotton production in Nigeria could only account for 38% of the requirement of the textile industry while the remaining 62% was imported (Chukwendu 1993)[18]. According to Mshelia (1991), cotton production in the country has taken a downward trend as the gap between demand and supply is becoming wider and wider every year because the supply does not equate demand[19]. The current cotton production in Nigeria as reported by United States Agency for international Development (USAID) (2012) is 120,000 tons in the year 2012.[20]

According to Raw Material and Research Development Council (RMRDC) (2004), consumption of cotton lint by the textile industry in Nigeria is about 100,000 metric tons plus or minus 15%.[21] The cotton production areas in Nigeria are divided into three ecological zones, namely: the Northern cotton zone which comprises of Kano, Kaduna (**ZARIA**), Sokoto, Kebbi and Jigawa States. These States contribute 60-65% of the cotton produced in Nigeria. Also, there is the Eastern cotton zone which comprises of Adamawa, Bauchi, Borno, Gombe, Yobe and Taraba States. This zone contributes 30-35% of the total cotton production in Nigeria. The third ecological area known as the Southern cotton zone is made up of Kwara, Niger, Kogi, Oyo, Osun, Ondo and Edo States; it contributes 5% of the total cotton production in Nigeria (Anon 1995)[22]. A study by Adeneji (2011) revealed that cotton production in the Northern cotton zone is on the increase compared to other zones[23].

The Northern cotton zone comprises of Kano, Kaduna (**ZARIA**), Sokoto, Kebbi and Jigawa States. These States contribute 60-65% of the cotton produced in Nigeria.[24] ***This is the zone Monsanto is seeking to release the Bt cotton into, with little regard to the health, environmental or socio-economic risks for Nigeria and Nigerians alike.***

The international cotton market is highly competitive and notoriously erratic, made more challenging for developing countries by skewed trade subsidies (e.g. since the turn of the century cotton farmers in the USA have received over $27 billion in subsidies[25], Nigerian farmers have received nothing and may not likely do so in the near future[26]

Global prices impact significantly on Nigeria given that Nigeria imports part of her cotton needs[27]

The bulk of production is carried out by smallholders under contract farming for Afcot.[28]

3.2 Policy

The BCGA operated the cotton market in Nigeria until the formation of the marketing boards for cocoa, oil palm produce and cotton in 1949.[29] The cotton board was however, disbanded in 1986 with other commodity boards as a result of the deregulation of the cotton market. The deregulation of the cotton market thus permitted private participation in the market and it was expected that it would afford both sellers and buyers of cotton a fair return on investment as compared to the days of commodity boards when there was unilateral fixing of prices by the boards. A major consequence of the market liberalization policy is that a new market structure has emerged because of the entrance of individuals, firms and cooperate organizations that now sponsor production and marketing of cotton in Nigeria.[30] The cotton policy in Nigeria is therefore now a deregulated one. The introduction of this Bt cotton will definitely negatively affect the smallholders who "produce more than 90% of cotton needs in Nigeria."[31]

3.3 Background to the Event

Monsanto Agricultural Nigeria Limited on behalf of Monsanto Company, 800 North Lindberg

Boulevard, St-Louis, Missouri 63167, USA made an application to DG NABMA for the environmental release and placing in the market of GM MON 15985 cotton.

The release is intended for the entire cotton-growing region in Nigeria, although the notification specifically mentions Zaria and surrounding towns. MON 15985 is genetically engineered to be insect-resistant (i.e. target insect pests that eat it will die). The insertion of genes isolated from *Bacillus thuringiensis* (Bt), a naturally occurring soil-borne bacterium found world-wide, confers Bt crops such as this the ability to produce crystal (cry) proteins that are toxic to certain insect pests when digested. The target pests of MON 15985 are Lepidopteran insect pests. In Nigeria, the main target pest is the African bollworm, although MON 15985 would also be toxic to other Lepidopteran pests that occur in cotton in Nigeria, such as pink bollworm.

MON 15985 (trade name Bollgard II®) is a result of the retransformation of transgenic cotton line MON 531 (Bollgard I®). MON 531 was genetically engineered via *Agrobacterium tumefaciens* mediated transformation to express the *cry1Ac* gene. MON 531 was then genetically engineered again, using particle acceleration transformation, to express the *cry2Ab2* gene to give rise to MON 15947. MON 15985 inherits inserts from MON 531 and MON 15947 cotton. As a result, MON15985 expresses both the Cry1Ac and Cry2Ab2 insecticidal proteins.

The expression cassettes corresponding to the two cry genes consist of respectively: a *cry1Ac* coding sequence regulated by the e35S promoter from CaMV and the 7S transcript termination sequence derived from soybean (*Glycine max*); and a *cry2Ab2* coding sequence regulated by the e35S plant promoter from CaMV, the heat shock protein leader (Hsp70) from Petunia, the chloroplast transit peptide, designated ctp2 derived from the *Arabidopsis thaliana epsps* gene and the nos3' transcript termination sequence from *Agrobacterium tumefaciens*. Other genetic elements in MON 531 include the *nptII* coding sequence, isolated from the transposon Tn5 present in the enterobacteria *E. coli*; its regulatory genetic elements, 35S from CaMV and nos 3' from *A. tumefaciens*; and the *aadA* bacterial gene encoding an aminoglycoside- modifying enzyme, 3 (9)-O-nucleotidyltransferase from the transposon Tn7. Other genetic elements in MON 15947 include the marker cassette uidA, which codes for the GUS protein, from *E. coli* strain K12, and its regulatory genetic elements e35S from the CaMV and nos3' from *A. tumefaciens*.

MON 15985/Bollgard II® has been approved for environmental release in the USA (2003), South Africa (2003), Australia (2004), India (2006), Burkina Faso (2008) and Brazil (2009). Bollgard II®, containing two Bt toxins, was introduced as insects developed resistance to Bollgard I®; as such Monsanto does not market the latter anymore. Of note, Bollgard III® (expressing Cry1Ac, Cry2Ab and vegetative insecticidal proteins (VIP)) release is in the pipeline in other countries, although in Nigeria it is Bollgard II® release for which approval is being sought.

An assessment of the biosafety data provided by Monsanto for the application of environmental release and placing in the market of MON 15985 follows in the next four sections (Sections 4 to 7). The assessment does not address all the issues of concern, but focuses on key areas of particular relevance.

4. Molecular Characterization

4.1. Description of Recombinant DNA (rDNA) Before and After Modification

This section identifies and discusses hazard identification at the level of transgene creation and insertion/deletion, including how to characterise potential harms.

The genes of interest *cry2Ab2* and *cry1Ac* have been synthetically made, with no history of safe use in nature. It is therefore important to ask the applicant to clearly describe the synthetic modification performed on the original bacterial genes.

Among the genetic elements used in the transgene is the antibiotic resistant marker gene *aadA*, which confers resistance to the antibiotic streptomycin. The applicant states that:
"*For MON 15985, the origin of replication for plasmid maintenance at high copy number in E. coli, ori-322, was contained on the plasmids PV-GHBK04 and PV-GHBK11 used for transformation, but was not transferred into the cotton plant genome. Therefore, the nptII and aadA antibiotic resistance genes in MON 15985 cannot be mobilized by excision of the marker gene to create a functional plasmid. The DNA would have to be integrated into the recipient's genome or plasmid in order to replicate and be passed on through reproduction. Studies have addressed this potential for the horizontal transfer of antibiotic selectable marker genes and concluded the* ***probability*** *of this event occurring is essentially zero*
Conclusion

Taken together the low potential for the introduced trait to be transferred to other organisms (low outcrossing frequency, absence of sexually compatible wild relatives and feral populations and virtually no possibility for horizontal gene transfer to bacteria) and the absence of any possible harm that is not intended, it should be concluded that the risk for the environment of cultivating MON 15985 in Nigeria is negligible". (Page 15 third schedule risk assessment parameters)

While the applicant dismisses the risks of horizontal gene transfer by stating that "*for the horizontal transfer of antibiotic selectable marker genes and concluded the* ***probability*** *of this event occurring is essentially zero*" (p. 15 3rd schedule of application), an analysis by Heinemann and Traavik (2004) of antibiotic-resistant bacteria and of the sensitivity of current techniques for monitoring horizontal gene transfer from GM plants to soil microorganisms demonstrates that this claim cannot be supported.[32]

They concluded that horizontal gene transfer from GM plants to microbes could still have an environmental impact at a frequency approximately a trillion times lower than the current risk assessment literature estimates the frequency to be; and that current methods of environmental sampling to capture genes or traits in a recombinant are too insensitive for monitoring evolution by horizontal gene transfer.[33]

The Scientific Panel on genetically modified organisms (GMO Panel) of the European Food Safety Authority (EFSA) has evaluated the potential risks associated with specific antibiotic resistance marker genes (ARMGs) taking into account their current usage in clinical and veterinary medicine, the likely occurrence of horizontal gene transfer from GM plants to microbes and the potential impact of horizontal gene transfer where naturally occurring resistance to the relevant antibiotics exists in the microbial gene pool.[34] These factors will impact on the likelihood of any adverse effects on humans or the environment of ARMGs used in GM plants. With respect to clinical importance, the GMO Panel has categorised ARMGs into three groups with different potentials for compromising human health and the environment. The *aadA* gene found in MON 15985 is categorised into Group II, which contains antibiotic resistance genes that are widely distributed in micro-organisms in the environment (soil, plant, water and the mammal gut) and confer resistance to antibiotics that are used for therapy in defined areas of human and veterinary medicine, but will have minimal impact on human and animal health. However, the GMO Panel recommends that these ARMGs should be restricted to field trial purposes and should not be present in GM plants to be placed on the market. Experimental or field trial releases of GM plants are generally confined, being limited in time and space, and are not intended for use in foods or feeds.

This means that EFSA saw it fit to recommend limitations to the use of GM crops with the antibiotic resistant marker gene *aadA*, due to the risks that may be posed. Given that the application under consideration is for the environmental release and placement in the market of MON 15985, we recommend that the authorities in Nigeria seriously consider the risks related to antibiotic resistance posed by this event, and ask the applicant to furnish information relating to the clinical, veterinary and agricultural use of streptomycin in Nigeria, a widely used antibiotic at that.

4.2. Molecular characterisation of the indel

This section identifies and discusses hazard identification at the level of the genome, including how to find the locations and structures of indels (insertions and deletions), followed by a discussion on evaluating the stability of indels.

The molecular characterisation of MON15985 includes diverse genetic integrations; however, in the application the specific locations of these insertions and the information of the genetic context where the integrations took place are not described. There is also no information about the specific primers that could be used for specific detection (for example, primers that include sequence on the specific context of the integration).

Inconsistencies around Southern Blots

In the application there is no description of the sensitivity and stringency of the performed Southern blot tests. This information should be made available by the applicant for each of the blots for each probe. It is explained that unexpected bands in the blots are possibly caused by star activity, however there is no description on how this was confirmed and remediated (many actions can be performed to inhibit star activity). **The applicant should be asked to provide this information**.

All the purported figures describing southern blot result showed in the application third schedule (downloaded from the NABMA website) – fig 4 page 27; fig 5 page 28; fig 8 page 39; fig 9 page 40; fig 10 page 41; fig 11 page 42; fig 12 page 43; fig 13 page 46; fig 14 page 47; fig 15 page 48 – did not display anything. There are no images shown by them and therefore the claims made on them are unverifiable. ***The applicant should be made to present the images to enable independent assessment of the claims***.

Unreadable PCR figures

The purported PCR result images presented in figures 17 page 52 and 18 page 53 of the application (3rd schedule) downloaded from the NABMA website displayed no images and therefore could not be read. All the claims made under them are unverifiable due to lack of the images they are referring to. **The applicant should be made to provide them for assessment.**

4.3. Description and Characterization of Changes to the Transcriptome, Proteome and Metabolome

There is a complete lack of acknowledgement in the application of profiling techniques for the transcriptome, proteome and metabolome for testing, despite these techniques currently being used and appropriate for complete molecular characterization.[35] **The applicant should be asked to provide profiling results for MON 15985.**

There were also no studies performed on identifying novel production of RNA variants, an issue of particular importance since the genes of interest used a well-known terminator (NOS3'), which has shown this effect in the scientific literature.[36] The possibility of these novel RNA variants producing novel proteins with potential toxic or allergenic effects cannot be excluded. **The applicant should be asked to identify novel production of any RNA variants for MON 15985**.

4.4. Use of CaMV 35S Promoter

The use of the 35S promoter from the cauliflower mosaic virus (CaMV) in MON 15985 is a cause for concern. A recent 2012 paper on "Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used and the viral gene VI in transgenic plants" has generated a discussion on whether past approvals of GE events have overlooked key safety questions related to the use of the CaMV 35S promoter (P35S).[37]

The genetic organisation of the densely packed genome of the CaMV results in sequence overlap between P35S and viral gene VI, encoding the multifunctional P6 protein. In the article, the authors state that some P35S variants contain open reading frames that when expressed could lead to unintended phenotypic changes. It is not known if the P35S version inserted into MON 15985 overlaps with gene VI. If expressed, the fragments of gene VI could be substantial enough for them to be functional. **The applicant should therefore be required to study the presence of partial P6 protein and the possibility of chimeric proteins containing P6 fragments**. Failure to do so would mean that potential harm to the environment and human health cannot be ruled out.

5. Safety Assessment

Establishing the food and feed safety of MON 15985 is relevant as cottonseed oil and meal is consumed by humans and animals in Nigeria especially Zaria and its environs. There are however, no baseline data provided in the application on this issue. The applicant should be asked to provide baseline data on the quantity, spread and use of cottonseed meal/cakes/oil used for human or animal consumption in Nigeria.

Several assumptions are made regarding the safety assessment of MON 15985, which are questionable.

The applicant states that "*Therefore, the safety assessment of the newly produced proteins in MON15985 can be performed by assessing the safety of the proteins on an individual basis."* (Page 7 of third schedule).

It therefore does not consider any combinatorial or cumulative effects of the proteins acting together.

Combinatorial effects may occur due to interactions among the proteins and metabolites produced by the transgenes or endogenous genes of a pyramided GM plant such as MON15985. For example, the pyramiding of various insecticidal toxins in the GM cotton could have a synergistic effect on non-target organisms that could be broader than the sum of the effects of the individual toxins. Likewise, the evolution of resistance in target organisms (for example, insect pests) to the pyramided MON 15985 could happen faster than the development of resistance to the single-toxin Bt cotton.

The applicant should be asked to provide safety tests based on whole plant material, not on individual toxins.

The applicant cites studies with mice to ascertain toxicity of the proteins expressed in MON 15985. However, no details are provided. It would be also important to know if these studies were done with the bacterial or plant-expressed protein, as post-translational modifications in plants do not occur in bacteria, so the results of tests using bacterial proteins cannot be used to prove safety of the Bt cotton. **The applicant should be asked, if it has not done so, to submit tests based on the use of plant-expressed proteins**.

5.1 Bioinformatic Analysis for Allergenicity

Two bioinformatics tools were used in the assessment of allergenicity. The second tool, an eight-amino acid sliding window search (page 79 of third schedule), was used by the applicant to specifically identify short linear polypeptide matches to known or suspected allergens. The applicant notes that the Codex Alimentarius Commission (2003) recommends that the size of the contiguous amino acid searched should be based on a scientifically justified rationale, and chooses to use eight amino acids in its analysis.[38]

The 2001 FAO/WHO consultation on the assessment of possible allergenicity due to GM foods however had suggested moving from eight to six identical amino acid segment searches. Codex (2004) notes: "The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely the larger the peptide sequence used, the great the likelihood of false negatives, thereby reducing the utility of comparison" (footnote 8, p.23).[39] Using six amino acids for comparison would therefore be more precautionary, and in line with the thrust of our Biosafety Act and the Cartagena Protocol on Biosafety, to which Nigeria is a Party.

In addition, a research paper comparing six amino acids, found that Cry1Ac and Cry2Ab show sequence similarity with known allergenic proteins.[40] Cry1Ac, for example, shares two identical peptides, GNAAPQ and GSTGITI, with cedar pollen allergens. Further analysis however enabled the authors to conclude that "it therefore appears that no further testing would be needed".

Given that the Cry1Ac and Cry2Ab toxins show sequence similarity with known allergenic proteins, when comparing with six amino acids, **the applicant should be asked to provide further evidence that the two toxins, both separate and acting together, will not cause allergenic effects.** It should also be noted that bioinformatics should not be the only or major data for assuring safety. Spök et al. (2005) described that it is well known that non-allergenic isoforms of allergens exist which differ by only a few amino acids compared to their allergenic counterparts.[41] Moreau et al. (2006) have highlighted that allergenicity can be sometimes better predicted based on non-contiguous stretches of amino acids.[42]

6. Environmental Risk Aassessment

6.1 Assessment of Impacts on Non-Target Organisms

Testing procedures for the impact assessment of GM plants on non-target organisms largely follow the ecotoxicological testing strategy developed for pesticides. This is likely to be the case with the assessment presented by the applicant for MON 15985.

There are no details or data provided on the experiments on acute oral toxicity of Cry1Ac, NptII, Cry2Ab2 and GUS proteins. Were these proteins isolated from bacterial sources and used in the acute oral toxicity tests as has commonly been the case with most application dossiers submitted by the biotechnology industry? This presumes that any potential adverse effect of the MON 15985 and the plant-produced novel compounds can be extrapolated from testing of the isolated bacteria-produced novel compounds or can be detected in agronomic field trials, which is not necessarily the case. Moreover, the extrapolation from an isolated chemical surrogate (tested in the lab) to a complex living biological organism (in the field) can be called into question.[43]

While the assertion that the required quantities of protein are not easily obtained from plant material may have been more accurate some years ago, the development of protein isolation and purification technologies have dramatically improved the efficiency of these procedures in recent years. In addition, the proteins, including the Cry1Ab and Cry2Ac toxins are tested separately, and so ignore any potential combinatorial effects. **The applicant should therefore have no excuse not to use plant-produced proteins, which would provide a more accurate assessment of not only acute**

effects, but also of direct chronic effects and indirect effects. The applicant should be asked to submit data on tests using plant produced proteins and whole plant material.

No data is provided on the tests used to confirm the claim of no adverse effects to non-target organisms. The usual biotech industry practice is to use test species that are typical surrogate species based on the Organisation for Economic Cooperation and Development (OECD) protocols for environmental chemicals such as pesticides. However, these species are chosen from a list of universal standard species that are representative for trophic levels in general, rather than present in a given receiving environment and may therefore not be typically representative of the important ecological functional groups present in Nigeria.

A scientifically improved environmental risk assessment has been proposed that integrates a procedure for selection of testing organisms that, for one, do occur in the receiving environment and, secondly, have an important role for those ecological functions that are critical for a sustainable production of the particular crop.[44] Only those species that end up being ranked highest regarding their importance for fundamental ecological functions in that crop and that have the greatest likelihood of significant exposure will be subjected to testing. The aim is to test a reasonable set of species with greatest relevance to the receiving environment and an important ecological function in the given cropping system. Hence, observed adverse effects would constitute a biologically and ecologically meaningful result of concern that merits further investigation or surveillance. Further, since the GM plant is at the centre of the testing programme, all possible effects, direct and indirect, cumulative and interaction effects are considered.

This approach of broader environmental risk assessment that is system oriented with the GM plant at the centre and integrates a procedure for selection of testing organisms that do occur in the receiving environment, has been carried out in Kenya for Bt Maize,[45] Brazil for Bt cotton and Vietnam for Bt cotton.[46] It would therefore not be unreasonable to ask for a similar approach to be applied to the environmental risk assessment of MON 15985 in Nigeria, as it will yield much more meaningful results. The applicant should be asked to provide information and tests on priority non-target organisms representing ecological functional groups in cotton-growing areas in Nigeria, using plant-produced proteins and whole plant material.

6.2 Exposure Pathways

Unfortunately, the application does not give serious attention to the possible exposure pathways of MON 15985 and its products in Nigeria. Determination of the possible exposure pathways requires a solid characterization of the GM plant and the expressed novel traits and accompanying management systems.[47] Because GM plants can multiply and spread via pollen and seed flow, this exercise will differ significantly from an exposure analysis of chemicals.

Exposure of associated organisms to MON 15985 may be multi-fold and complex.[48] This is because the transgene products are integral parts of the Bt cotton and their expression is coupled to the physiology and metabolism of the plant. Exposure can be bitrophic via the Bt cotton, including any metabolites of the transgene products in residues, fluids (e.g. phloem) or secretions (e.g nectar, root exudates). Exposure of higher order consumers can occur through multi-trophic exposure routes when the transgene products move through the food web. Should there be movement and expression of the transgenes in other genetic contexts (e.g. wild relatives), an entirely different suite of organisms may come into contact with the novel transgene products. The same holds true after spread of the transgene products, such as the Bt toxins including any metabolites, away from the field of release of MON 15985, for example, embedded in wind-dispersed GM pollen or in GM plant residue washed into water systems like ponds, lakes, creeks and rivers, or leaching of transgene products into the soil.

Bt toxins from GM plants enter the ecosystem via many routes; embedded in living and decaying plant material, pollen or as toxin leaching and exudated from roots and in faeces from insects and animals that may be fed with Bt cotton seed cake. However, the bioactivity of such metabolites remains unknown to date. The impact of Bt crops on soil organisms also needs to be considered. Recent research has documented the input of transgene products or transgene DNA into aquatic systems, headwater streams and rivers and connected them to possible adverse effects on some aquatic organisms.[49]

The applicant should be asked to carry out a thorough analysis of the potential exposure pathways, including modelling exposure scenarios, of both the Bt toxins and MON 15985, in order to determine whether or not and to what degree non-target organisms come into contact with the plant and the Bt toxins.

6.3 Secondary Pests

A secondary pest is a pest that under normal conditions is not a big problem, but becomes a serious problem following changes in management practices or disruption of control by a natural enemy. The issue of secondary pests occurring, following the reduction in the target pest population, is not considered in the application. This is a serious omission, as evidence from around the world shows that secondary pests may replace the target pest, necessitating increased pesticides sprays.

For example, in relation to Bt cotton in China, Wu et al. (2002) warned that mirids had become key insect pests in transgenic cotton fields, and that their damage to cotton could increase further with the expansion of the area planted to transgenic cotton if no additional control measures were adopted.[50] By 2010, Lu et al. (2010) confirmed that mirid bugs had progressively increased population levels and acquired pest status in cotton and multiple other crops, in association with the regional increase in Bt cotton adoption.[51] A three-year study in 2005 identified the emergence of another secondary pest, leafhopper, as its populations on Bt cotton were consistently larger than those on non-transgenic cotton.[52]

There are also reports of secondary pest emergence in the USA in Bt cotton. For example, Farm Press in February 2006 claimed that lygus was "slowly moving to the front of cotton industry's pest problems", and in March 2008 that cotton insect pressure had shifted. According to Greenwire (17 May 2010), "modified cotton curbs one pest only to unleash another" (www.eenews.net/public/Greenwire/2010/05/17/3).

The applicant should therefore be asked to provide a report identifying the potential secondary pests of cotton in Nigeria, an assessment of the potential for pest replacement to occur in the event that MON 15985 is planted, and the necessary risk management steps to address this risk.

6.4 Lack of Risk Management and Monitoring

*"The conclusions on safety assessments of food, feed and the environment in the Second and Third Schedules show consistently that the release or placing on the market of MON 15985 poses negligible risk to human and animal health and to the environment. MON 15985 cotton is not different from conventional cotton in terms of its composition and its agronomic and phenotypic characteristics except for the introduced trait of insect protection conferred by the expression of Cry1Ac and Cry2Ab2. These proteins have been demonstrated safe for human and animal health and the environment. There is therefore no reason to believe that MON 15985 may behave differently from conventional cotton. In addition, cotton is not considered a dangerous plant. Considering these conclusions, no case-specific post-release monitoring actions would be required" (**page 3 fourth schedule)***

The applicant concludes as above that as no significant risks were identified compared to

conventional cotton, no risk management is necessary, i.e. no post-commercial monitoring (beyond insect resistance management) is necessary. This is at best foolhardy, as even though it might be possible that there is no identifiable risk (and note that this is Monsanto's assertion, not ours) that would require case-specific monitoring, there is still a need for general surveillance or general monitoring to account for effects that were not anticipated in the risk assessment.

Such an approach to monitoring is recognized in the "Guidance on Risk Assessment of Living Modified Organisms" (UNEP/CBD/BS/COP-MOP/6/13/Add.1) developed under the Cartagena Protocol on Biosafety, to which Nigeria is a Party. In case changes that could lead to an adverse effect are detected through general monitoring, possible causes for the observed changes are examined and, where appropriate, a more specific hypothesis is developed and tested to establish whether or not a causal relationship exists between a GMO and the adverse effect, and can be followed up by case-specific monitoring or further research.

The applicant should be asked to submit a detailed monitoring plan and information on the monitoring techniques (beyond insect resistance monitoring and management) to be employed, in accordance with the requirements of the Biosafety Act, which leans heavily on precaution. Indeed, sections 33 and 34 of the Act require risk management and monitoring.

7. Insect Resistance

The evolution of resistance by the target insect pests is the most serious threat to the continued efficacy of Bt crops. Insect resistance to Bt crops has been documented in various parts of the world. For example, the field resistance by stemborer in Bt maize (containing Cry1Ab) was first reported in 2007 in South Africa.[53] Resistant corn rootworm populations in Bt maize (containing Cry3Bb1) in the USA were reported in 2011, and as of 2014, resistance has been reported in four American states (see http:// www.businessweek.com/news/2014-06-10/war-on-cornfield-pest-sparks-clash-over-insecticide).

In the USA, the frequency of resistance alleles has increased substantially in some field populations of cotton bollworm, *Helicoverpa zea*.[54] Monsanto confirmed pink bollworm resistance to Cry1Ac expressed in Bollgard I, in four districts in Gujarat, India in 2010 (www. monsanto.com/monsanto_today/for_the_recor/india_pink_bollworm.asp). A 2010 survey by Zhang et al. (2011) showed field-evolved resistance to Cry1Ac of the major target pest, cotton bollworm (*Helicoverpa armigera*) (also targeted by MON 15985 in Nigeria), in northern China.[55] *H. armigera* has low susceptibility to Cry1Ab, which could hasten resistance development in this species. One possible explanation for the low susceptibility is the unexpected suppressive effect of the Cry1Ab toxin in the P450 genes of *H. armigera* larvae;[56] it is not known whether the response to other Cry toxins such as Cry1Ac and Cry2Ab2 is similar.

7.1 Use of Pyramided Toxins

MON 15985 is a pyramided event, containing two toxins (Cry1Ac and Cry2Ab2) that protect against the same Lepidopteran pests. The applicant states, "…combining the Cry2Ab2 protein with Cry1Ac in MON 531 will provide an additional tool to delay the development of resistance since these two protein classes have different modes of action…. In general, if the second insecticidal protein is sufficiently different in its mechanism of action from the first, and is itself highly efficacious against the target pest species, then insects would need to develop two distinct modes of resistance to survive both proteins, which is highly unlikely. Therefore, MON 15985 containing the genetic elements necessary to produce both the Cry1Ac and Cry2Ab2 proteins, provides added protection against the possibility of resistance developing in the primary target insect species and is expected to extend the effectiveness of this technology for the grower and prolong the overall benefits

already documented for MON 531" (p. 58 Second schedule).

While two-toxin Bt cotton is more efficacious than one-toxin Bt cotton, and Monsanto asserts that the presence of two Cry proteins with different modes of action is expected to reduce the occurrence of resistance-development significantly, the assumption for success of the pyramid strategy – that pests' resistant to the first toxin should survive on one-toxin plants, but not on two-toxin plants, because the second toxin should kill them (so-called "redundant killing") – have not been borne out. Brevault et al. (2013) found that on two-toxin plants (containing Cry1Ac and Cry2Ab), cotton bollworms (*Helicoverpa zea*) resistant to one toxin survived significantly better, contradicting the assumption.[57] Moreover, the concentration of Cry1Ac and Cry2Ab declined during the growing season, which would tend to exacerbate this problem.

In addition, the study analysed the results of 21 experiments in which strains of eight major Lepidopteran pests had been selected for resistance to a Cry1A toxin and subsequently evaluated for cross-resistance to Cry2A, or vice versa. The overall pattern in the 21 experiments considered together indicates significant cross-resistance between Cry1A and Cry2A toxins.[58] Previous studies had already found that in field-derived strains of *H. zea* and *Helicoverpa armigera* (the main cotton pest in Nigeria targeted by MON 15985), responses to Cry1Ac and Cry2Ab were genetically correlated, indicating potential cross-resistance. In pests with low susceptibility to Cry1A and Cry2A toxins, cross-resistance between Cry1A and Cry2A will generally hasten evolution of resistance. *H. armigera* is known to have low susceptibility to at least Cry1Ab;[59] it is not known whether the response to other Cry toxins such as Cry1Ac and Cry2Ab2 is similar.

The research team also found that inheritance of resistance to plants producing only Bt toxin Cry1Ac was not completely recessive,[60] which hastens resistance development and is expected to reduce the ability of refuges to delay resistance. Overly optimistic expectations of pyramided Bt crops have led the USA Environmental Protection Agency to greatly reduce requirements for planting refuges to slow evolution of pest resistance to two-toxin Bt crops; this may need to be revisited in light of the research findings.

7.2 Insect Resistance Management

The issues raised above could seriously impact the efficacy of MON 15985 in Nigeria. The issue of refuge requirement should be seriously considered in the insect resistance management plan for MON 15985. Monsanto has however previously stated elsewhere that refuge size requirements for dual mode of action crops can be reduced when compared to insect-protected transgenic crops expressing a single toxin.

This assumption needs to be revisited in light of the above research, as the serious possibility of insects developing resistance to MON 15985, despite it containing two toxins, cannot be excluded, and neither can the possibility of cross-resistance developing be ruled out at this stage. Insect resistance should instead be seriously planned for by incorporating a robust insect resistance management plan. This includes having the data of baseline susceptibility for the species targeted in Nigeria in order to confirm resistance.

As shown by the experience in South Africa, which was the first country to commercially produce Bt crops in Africa, and where African maize stem borer had evolved resistance to the Bt maize containing the toxin Cry1Ab very quickly resulting in its loss of efficacy, these issues cannot be taken for granted.[61] Many of the early warning signs that should have alerted regulators to the impending problems were ignored. Likewise, while such early warnings should have prompted intensive monitoring of resistance levels, as well as strict refuge compliance, this did not happen. In fact, between the first plantings of Bt maize in the 1998/99 cropping season and the first report of resistance in 2007, no systematic evaluation or monitoring for resistance was done.

The South African case highlights that for countries that may choose to plant Bt crops, insect resistance management should be a high priority, starting with appropriate monitoring subsequent to release of Bt crops, followed by accurate reporting and development of strategies to counter the problem as soon as it appears. If one waits until pest-induced yield losses start to occur, the level of resistance of the target pest to the Bt crop is most likely such that it cannot be corrected. Furthermore, the South African experience shows that the predicted rate of evolution of resistance in many instances was underestimated.[62]

Though Monsanto has provided an Insect Resistance Management (IRM) Plan for the deployment of MON15985 in Nigeria on page 3 of the fourth Schedule, this is not detailed enough. The applicant may need to clearly state who bears the cost and also clearly outline specific responsibilities for specific groups at the outset to avoid problems. A detailed IRM plan, more than what is presently presented is required. Monsanto therefore needs to take a more critical look at her IRM as currently stated and improve significantly on it, particularly given the issues raised in the previous section.

The applicant should therefore be asked to submit a comprehensive insect resistance management plan as part of the application.

8. Conclusion: Lessons from Bt Cotton Cultivation on the Continent

Monsanto's Bt cotton is currently grown in South Africa and Burkina Faso. A recently published paper explains how within 10 years of its introduction, most growers had abandoned Bt cotton altogether in Makhathini, South Africa, and why Burkina Faso has begun a complete phase out of Bt cotton, in spite of being Africa's top cotton producer (Dowd-Uribe and Schnurr, 2016).[63]

South Africa approved the commercialization of Monsanto's Bt cotton in 1997. Larger-scale, commercial growers readily adopted the crop. One year after its initial release, Monsanto launched a campaign to increase Bt cotton adoption among smallholder cotton farmers in the Makhathini Flats. Initial accounts were extremely positive, reporting gains in average yields and profits, as well as a significant reduction in pesticide applications.

However, the success did not last long. After only a few years of operation, the cotton company that operated the local gin and provided credit for the purchase of the more expensive Bt cotton seeds went bankrupt. A new company took over, but this scheme also failed after only a few years. It proved too difficult to transform a patchwork of smallholder producers into a more financially viable model, one that requires centralization, mechanization, and that revolves around cotton monocultures. Within ten years, most farmers had abandoned Bt cotton altogether. The total number of Bt cotton adopters in the 2014/15 season was below 5 percent of what it was in the peak production years that followed the introduction of Bt cotton.

Burkina Faso's conventional cotton traditionally had a stellar international reputation and commanded a premium price based on its high quality, namely, its high ginning ratio and long staple length. Both qualities have seriously declined with the GM cotton, seriously undermining the reputation and value of Burkinabè cotton on the international market and compromising the profits of Burkinabè cotton companies. The companies are reportedly demanding that Monsanto compensate them to the tune of USD 280 million for losses incurred due to declines in quality since 2010.

The Burkina Faso case points to the risks of unintended effects in GM crops, in this instance, the insertion of the Bt trait into the local variety appears to have interfered unexpectedly with some of its most important characteristics, affecting commercial value. Also the exclusive focus on pest mitigation contrasts sharply with the Francophone West African breeding programmes, which have spent decades successfully integrating a broad spectrum of adaptability (to local growing conditions) and fibre quality characteristics. While yields were high, the experience of Burkina

Faso demonstrates that focus on yield is not the defining factor of a crop's success.[64]

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