**REPORT OF THE NATIONAL BIOSAFETY COMMITTEE (NBC) ON ASSESSMENT OF THE APPLICATION BY THE INSTITUTE OF AGRICULTURAL RESEARCH ZARIA FOR CONFINED FIELD TRIAL OF MAIZE GENETICALLY MODIFIED FOR RESISTANCE TO STEM BORER INSECT AND FOR DROUGHT TOLERANCE, HELD AT BROOKVILLE HOTEL AND SUITES ABUJA ON THE 14-15TH OCTOBER, 2019**

## INTRODUCTION

In line with the National Biosafety Management Agency (NBMA) regulations, an ad-hoc National Biosafety Committee (NBC) was constituted by the DG/CEO, NBMA under the Chairmanship of Professor Celestine Aguoru, with the list of NBC members attached.

The Committee in expressing her opinion relied on the dossier submitted by the applicants, NBTS document, expertise of the members and other relevant documents with the aim of advising the Agency on the merits and demerits of the application.

**Mode of Assessment**

The application was assessed through an in-depth review of the submitted dossier

| S/No | | OBSERVATIONS | REMARKS/RECOMMENDATIONS |
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| 1. | **Administrative Information** | | |
| | Purpose of Application | The applicants propose a Confined Field Trial to test maize, (Zea mays L.) plants that have been genetically modified for resistance against stem borer insect pest and for drought tolerance. | This transformation was done through crossing events MON 87460 and MON 89034 |
| | Previous applications or approvals | No previous application has been made on this combination. The application is new. However, in 2016, a permit for a CFT of maize containing event MON 89034 was issued by NBMA, NBMA/CFT/001 | Combinations containing MON 89034 and MON 87460 have been issued for commercialization in USA and South Africa. Similar CFTs have been undertaken with MON 87460 combined with MON 810 in at least five countries that participate in the WEMA/TELA Maize project including, Kenya Uganda, Tanzania, Mozambique and Ethiopia. |
| | Applicant | Institute of Agricultural Research(IAR) Zaria | |
| | Contact Details of Principal Investigator | Contact Details of Principal Investigator: Name of Lead Scientist: Prof. Rabiu Salisu | The Curriculum Vitae of the Principal Investigator and the Trial Manager was not attached |

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| | | Adamu Address: PMB 1044, IAR/Ahmadu Bello University, Zaria, Nigeria Tel: +234 8028373464 Email: rsadamu@gmail.com | |
| | Proposed Location and Size of Trial | Location: IAR Research Farm Samaru-Zaria Size: Approx. 2Ha. GPS Co-ordinates: N $11^0$.18167 to N $11^0$.18093 and E $7^0$.61476 to E $7^0$.61601 with elevation of 100m.<br><br>Site Manager: Audu Gado, Agronomy technologist Address: PMB 1044, IAR/Ahmadu Bello University, Zaria, Nigeria Tel: +234 80 77187899 E-mail: gado40@yahoo.com | |
| | Proposed duration of Trial | Two Years. Expected starting date: November 2019 Expected termination date: October 2021 | Expected starting date to be determined by the NBMA |
| 2 | **Plant Information** | | |
| | Toxicity and Allergenicity | Comprehensive safety assessments on food, feed and | |

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| | | environment confirm the safety of the crop and are supported by regulatory approval for its commercial cultivation in many countries. The assessments included:<br>1) detailed molecular characterization of the introduced DNA;<br>2) safety assessment of the expressed Cry1Ab protein;<br>3) compositional analysis of maize grain and forage; and<br>4) environmental impact assessment of the maize plants. These assessments demonstrated that it is safe to humans, animals, non-target organisms, and beneficial insects.<br><br>Food induced allergic reactions to maize have not been reported and no known information on allergenic protein derived from maize | |

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| | | is available. The insertion of the genes and their expression have not introduced any | |
| | Describe the Intended Phenotypic Changes to the Plant. | Apart from being more resistant to Stem Borer infestation, and drought stress than its unmodified counterpart, no other phenotypic changes were introduced | |
| | Intended Reproductive Effects | The genetic modification that led to the events were not intended to affect the reproductive biology and has not done so | Maize does not have wild relatives in Nigeria |
| | What is the source of genetic material?<br>Is the source of genetic material likely to affect the safe conduct of a Confined Field Trial? If yes, how? | MON 87460 × MON 89034 maize was obtained by conventional breeding of two single maize event products: MON 87460 and MON 89034. MON 87460 expresses cold shock protein B (CspB) and neomycin phosphotransferase II (nptII), isolated from Bacillus subtilis.<br>MON 89034 was developed through | |

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| | | Agrobacterium-mediated transformation of maize cells to produce the Bt insecticidal proteins Cry1A.105 and Cry2Ab2, making use of a binary plasmid vector, PV-ZMIR245.<br><br>The transformed maize will be the same as the untransformed one except for the introduced genes which confer specific benefits. The source of the genetic material is therefore not likely to affect the conduct of the CFT. | |
| | Changes in Toxicity and Plant Composition | The protein products encoded by the three genes (CspB, Cry1A.105 and Cry2Ab2) involved in transformation have been rigorously characterized in the modified maize and were declared safe for the environment and for human consumption. | The safety of and products derived from *B. subtilis* for use in food has been confirmed consistently by numerous reviews: the US Food and Drug Administration (FDA), EFSA's Scientific Committee and the US Environmental Protection Agency (EPA). Other countries with history of safe use include Mexico, Ukraine, South Asia and China. |

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| | | Therefore, there are no intended changes in toxicity and plant composition. | |
| | Describe the features of the genetic construct? | The detailed information provided in the dossier on the genetic construct (plasmid PV-ZMIR245and PV-ZMAP595) is adequate. The restriction maps of the plasmids and their detailed description in tabular forms were provided. | |
| 3 | **Trial Description** | | |
| | Experimental Design | The 3x4 alpha lattice experimental design is conflicting with the number of entries(16) to be evaluated as provided in the dossiers by the applicant | Though the applicant picked alpha lattice design, split plot design may be more appropriate based on the number of treatments (water regime -optimum and managed drought stress) and artificial infestation using two species of stem borer insect pest |
| | Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial | Maize has no sexually compatible relatives in Africa. Therefore, no wild relatives in the vicinity of the trial. | |

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| | plants, resulting to viable seeds? | | |
| | Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial sites. | There will be isolation distance of 400m. The area will be fenced; there will be full security and monitoring at recommended intervals to prevent escape of genetic materials outside the vicinity. | |
| | Describe measures in place to control trial plant volunteers after termination of the trial. | The site will be put under irrigation to induce germination of all seeds that may have inadvertently lodged themselves into the soil. The site will be monitored for such volunteers weekly for five weeks during which all viable seeds that might be in the soil would have germinated. | |
| 5. | **Material confinement** | | |
| | Packaging | The information on packaging is adequate as the seeds will be packaged in a tough waterproof material carried in a plastic container | |

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| | | with a tightly-fitted screw lid | |
| | Harvesting, Transport and Storage | Though applicant stated at maturity, maize will be hand-harvested, threshed and data recorded at the CFT site, but details on how this will be carried out was not provided.<br><br>Applicants may need to move grains out of the CFT site | Applicants should provide detailed information on how to move harvested materials out of the CFT site, including their storage |
| | Disposal and Clean-up | Information provided is adequate but applicants need to comply with the NBMA guidelines on disposal and clean up | |
| | Site Security | Information provided on site security is adequate following its compliance with NBMA guidelines on site security | |
| 6. | **Records, Personnel and Planning** | | |
| | Other reports | In addition to the records the applicants have stated will be provided, the applicant will need to provide any other record as may be required by | |

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| | | the NBMA | |
| | Contingency Plans | Information on contingency plan is adequate | |
| | Recovery of materials | In addition to the security measures and contingency plans put in place, measures for the recovery of materials that may be inadvertently lost should be put in place | |

**RECOMMENDATION**

1. The Curriculum Vitae of the Principal Investigator and the Trial Manager should be provided.
2. A sketch map of the experimental site with the experimental layout should be provided.
3. Expected date of commencement and termination should be determined after approval by the NBMA.
4. All relevant regulatory agencies (Plant Quarantine, Customs, Seed Council etc) concerned with material transfer should be involved.
5. Applicants should provide information on how to move harvested materials out of the CFT site, including their storage.
6. The applicants may consider changing their experimental design from the alpha lattice to split plot design which may be more appropriate for the CFT
7. The NBC having gone through the document submitted by the applicant and the assessment and recommendation by the NBTS, hereby recommend to the NBMA to approve the application subject to correction of all the observations.

**NBC Members**

| NAME | SIGNATURE | DATE |
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| Prof. Celestine Aguoru | | |
| Dr. Barth Ugwu | | |
| Mrs. Kadiri Haleemat | | |
| Mrs. Loko Veronica E. | | |
| Dr. Ijeoma Akaogu | | |
| Mr. Zidafamor, Ebiarede Jimmy | | |
| Dr. Rose Gidado | | |
| Maishanu T. H | | |
| Abah Anthony O. | | |