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**REPORT OF THE NATIONAL BIOSAFETY COMMITTEE (NBC) ON ASSESSMENT OF THE APPLICATION BY NATIONAL BIOTECHNOLOGY DEVELOPMENT AGENCY (NABDA) ABUJA FOR CONFINED FIELD TRIAL OF GLYPHOSATE-TOLERANT SOYBEAN, AT DENNIS HOTEL, ABUJA, ON 18TH -19TH APRIL, 2018**

**Introduction**

In line with 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 P.C. Onyenekwe, with the following under-listed members.

The Committee was mandated to review the submission of the National Biosafety technical Sub-committee (NBTS) 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.

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| S/No | SS | Observations | Remarks/Recommendations |
| 1. | **Administrative Information** | | |
|  | Purpose of Application | While application is for both screening and introgression into commercial varieties, the names of commercial varieties to be used were not stated. | NBC recommends that the names of the commercial varieties into which transgene (s) will be introgressed be provided, to allow for proper monitoring by the NBMA. |
|  | Previous applications or approvals | While no such variety has been assessed or approved in Nigeria, this variety has been approved in other parts of the world. |  |
|  | Applicant | The qualifications of the Principal Investigator and Lead Scientist show they lack competence for their proposed roles. However all other personnel associated with the trial were deemed appropriate. | NBC recommends that the position of Principal Investigator and Lead scientist be given to scientists with required competence and experience in soybean breeding or related crop. |
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|  | Proposed Location and Size of Trial | Although the CFT at NABDA is large, its multipurpose use may have inherent problems arising from cross contamination. | NBC recommends that demarcated plots should be provided for each GM crop under field trial, soybean inclusive. |
|  | Proposed duration of Trial | The expected start and termination dates were observed to be infeasible. | NBC recommends that expected start date should be slated after approval and/or next cropping season. |
| 2 | **Plant Information** | | |
|  | Toxicity and Allergenicity | Observations were made that there is substantial equivalence between transgenic and non-transgenic varieties, as verified by several literatures. |  |
|  | Describe the Intended Phenotypic Changes to the Plant. | Information provided describing intended phenotypic changes was inadequate. | NBC recommends that a brief description of intended phenotypic changes should be provided by the applicant. |
|  | Intended Reproductive Effects | Information regarding intended reproductive effects was inadequate. | NBC recommends that the experiences of other nations should be shared. |
|  | What is the source of genetic material? Is the source of genetic material likely to affect the safe conduct of a confined field trial? If yes, how? | Although information was provided, no references were cited. | NBC recommends that relevant references should be cited. |
|  | Changes in Toxicity and Plant Information | Reference provided (1996) was very old and thus may be lacking in relevant information that have been obtained since then. | NBC recommends that recent references should be cited. |
|  | Describe the features of the genetic construct? | It was observed that information provided was adequate. |  |
| 3 | **Trial Description** | | |
|  | Experimental Design | Information provided on experimental design was deemed inadequate. | NBC recommends that information be provided regarding the following;   * definite number of varieties to be used, * the type and spraying regime of herbicide, * methodology of introgression to be employed, * methodology for screening, testing the stability and uniformity as well as the distinctiveness via a series of backcrosses. |
|  | Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting to viable seeds? | Observations were made to the fact that there are no wild species of soybean in the vicinity of the CFT. | Planting soybean as border roles. |
|  | Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial seeds. | Observations were made of plans to net the trial plots for only the first year of trial. | NBC recommends that trial plots be netted throughout the period of the trial. |
|  | Describe measures in place to control trial plant volunteers after termination of the trial. | Measures provided were deemed appropriate in controlling plant volunteers. |  |
| 5. | **Material confinement** | | |
|  | Material confinement | Although measures for confinement were stated, these would be ineffective without demarcated plots. | NBC recommends that demarcated plots be provided for each GM crop under field trial, soybean inclusive. |
|  | Packaging | Packaging description is not adequate. | NBC recommends that packaging labels should contain the names of the commercial varieties to be used. |
|  | Harvesting, Transport and Storage | Sentence concerning transporting harvested seeds to laboratories within the CFT is not factually correct. | NBC recommends that sentence should be re-casted to reflect the fact that GM pods will be transported in compliance with NBMA regulations. |
|  | Disposal and Clean-up | The opening phrase, ‘whenever possible’ provides no specifications on equipment that will be dedicated to trial. | NBC recommends that processes and/or equipment dedicated to the trial be identified. |
|  | Site Security | Although measures described were deemed appropriate for the application under review, it was observed that a more robust security measure was to have backup security staff, in case of unforeseen eventualities. | NBC recommends that a backup security plan should be adopted. |
| 6. | **Records, Personnel and Planning** | | |
|  | Other reports | Observations were made of a mix up concerning time-frames for oral and written reports on Incidence and Corrective report | NBC recommends that sentence be recasted to reflect correct time-frames (oral report-24hrs, written report-2 working days). |
|  | Contingency Plans | It was observed that reports were to be made to the Biosafety Registrar, a position that does not exist. | NBMA recommends that all reports be made to the DG/CEO of National Biosafety Management Agency. |
|  | Recovery of materials | Measures provided for the recovery of spilled seeds were deemed inadequate. | NBC recommends that all unidentified spilled seeds should be discarded and destroyed. |

**Recommendation**

Major recommendations as observed by the NBC are as follows:

1. The names of commercial varieties into which transgene (s) will be introgressed be provided, to allow for proper monitoring by the NBMA.
2. The position of Principal Investigator and Lead scientist be given to scientists with intellectual competence and proven experience in soybean breeding.
3. Demarcated plots should be provided for each GM crop under field trial, soybean inclusive.
4. The expected start date be slated after approval is obtained and/or next cropping season.
5. A brief description of intended phenotypic changes arising from transformation should be provided by the applicant.
6. Experiences of other nations should be shared as it pertains to the intended phenotypic changes in the plant as a result of this transgene.
7. Relevant recent references should be cited where applicable.
8. The trial description should be expanded to include type of herbicide, spraying regimes as well as introgression methodology to be employed.
9. Sufficient isolation distance of not less than 30-meter radius must be maintained from other crops as provided on this application.
10. Trial plots should be netted throughout the duration of the trial.
11. Packaging labels should contain the names of the commercial varieties to be used.
12. Processes and/or equipment dedicated to the trial should be identified.
13. A back-up security plan should be adopted for both this application and future applications.
14. All reports be made to the DG-CEO of National Biosafety Management Agency and not to the Biosafety Registrar.
15. All unidentified spilled seeds should be discarded and destroyed appropriately.
16. Compliance training must be given to all staff associated with trial. They must sign a document agreeing Tomball rules guiding the operations of the CFT.

**Final Recommendation of the NBC**

NBC having reviewed the application, taking into cognizance the recommendations of the NBTS recommends the application for approval subject to the revisions hereby stated.

**Names and Signatures of NBC members**

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| **NAME** | **SIGNATURE** | **DATE** |
| Prof. P.C. Onyenekwe (Chairman) |  |  |
| Dr. Chinwe Ezejiofor |  |  |
| Mrs. Agbaegbu E.Q.I |  |  |
| Awerikihi M. Blessing |  |  |
| Kadiri Haleemat |  |  |
| Okpala Emeka F. |  |  |
| Azosiri Chioma |  |  |
| Habiba U. Chime |  |  |
| Oyelade Adeola |  |  |
| Zidafamor Ebiarede J. |  |  |
| Olife Ifeyinwa C. |  |  |