

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY	
National Biosafety Committee	
DECISION DOCUMENT	
1.0 COMMUNICATION OF DECISION	
Application Reference Number: NBC/01/2017	Decision Number: 1/2017
In regard to Application by <i>Dr. Andrew Kiggundu</i> for: Multi-locational confined field trials of genetically modified potatoes for resistance to Late Blight disease caused by <i>Phytophthora Infestans</i>. The proposed trial sites are: Kachwekano Zonal Agricultural Research and Development Institute, Rwebitaba Zonal Agricultural Research and Development Institute, Buginyanya Zonal Agricultural Research and Development Institute The National Biosafety Committee (NBC) of the Uganda National Council for Science and Technology, (UNCST) Cap 209 of the Laws of the Republic of Uganda, hereby approves an application to conduct Multi-locational Confined field trials of Genetically modified potatoes for resistance to Late Blight disease caused by <i>Phytophthora Infestans</i> under the terms and conditions specified in sections 3.0 and 4.0 below.	
2.0 THE NATIONAL BIOSAFETY COMMITTEE(NBC) CONDUCTED THE FOLLOWING RISK ASSESSMENT	
2.1 The Application for the conduct of the confined field trial was received by the UNCST and reviewed for completeness by the NBC Secretariat at UNCST, after which the application was circulated to all members of the National Biosafety Committee. During the 1st meeting of the 5th NBC meeting that was held on 1st February 2017, the NBC reviewed the application for conduct Multi-locational field trials of genetically modified potatoes for resistance to late blight disease caused by <i>Phytophthora Infestans</i> Potato varieties were genetically transformed using <i>Agrobacterium tumefaciens</i> following standard protocol of agrobacterium-mediated transformation which has	



been routinely used at Applied Biotechnology Laboratory (ABL) in CIP headquarters at Lima in Peru since 1990. The insert (T-DNA containing the 3 *R* genes and the *nptII* gene) was introduced through transformation using a disarmed strain of *Agrobacterium tumefaciens*, EHA 105. The genes that were inserted are: *RB*, *Rpi-blb2* and *Rpi-vnt1.1* as triple *R* genes from wild species of potato namely *Solanum bulbocastanum* and *Solanum venturii*. These genetically modified potato are similar to other potatoes but can be identified by PCR using primers specific to the introduced genes (*R* genes, *nptII*).

The risk assessment concluded that risks to the health and safety of people, or the environment, from the proposed trials are negligible. No specific risk treatment measures are required to manage these negligible risks. The risk assessment process considered how the genetic modification and proposed activities conducted with the GMOs might lead to harm to people or the environment. Risks were characterized in relation to both the seriousness and likelihood of harm, taking into account current scientific/technical knowledge, information in the application (including proposed confinement measures) and relevant previous approvals. Both the short and long term impacts were considered.

Credible pathways to potential harm that were considered included exposure of people or animals to the GM plant material, potential for spread and persistence of the GMOs, and transfer of the introduced genetic material to sexually compatible plants. Potential harms associated with these pathways included toxicity or allergenicity to people, toxicity to other desirable organisms, and environmental harms due to weediness.

The principal reasons for the conclusion of negligible risks regarding this trial, are that the GM plant material will not be used for human food or animal feed. The proposed confinement measures effectively contain the GMOs and their genetic material and minimise exposure; and the GM potato has limited ability to establish populations outside cultivation or transfer the introduced genetic material to other plants.



In addition the following comments were also raised, that the Authorized party should;

- a. Provide the evidence of recruitment for all the trial personnel involved in the project.
- b. Submit a project budget reflecting aggregate contributions from funders and the scientists.
- c. Develop the 3 sites according to the site establishment procedures in the National Guidelines for Field trials of Genetically Engineered plants.
- d. Conduct biosafety trainings for all trial personnel involved in the project.

2.2. NBC DECISION

The NBC having conducted a thorough risk assessment, having considered the safety issues, risk mitigations options available, and other concerns identified, by Consensus approved the application for Multi-locational field trials of genetically modified potatoes for resistance to late blight disease caused by *Phytophthora Infestans* with the terms and conditions outlined in sections 3.0 and 4.0. The trial sites will be *Kachwekano Zonal Agricultural Research and Development Institute*, *Rwebitaba Zonal Agricultural Research and Development Institute*, *Buginyanya Zonal Agricultural Research and Development Institute*

3.0 TERMS AND CONDITIONS OF APPROVAL

The Applicant shall abide by the following conditions for conducting the trial

- a. Fenced field with chain link and rodent trap;
- b. 24 Hour Guard house located outside the fenced area;
- c. Store located inside the trial site;
- d. The trial site shall be identified with a sign that gives the Authorization Code Number(s) and the information GM plants-For Research Purposes, Not for Food or Feed. "Authorized personnel only"
- e. Keys to the Confined field trial entrance and the store must be in custody of the Trial Manager for easy monitoring of who has entered and purpose he/she serves;
- f. Any activity or work on the trial must be under supervision of the Trial Manager;
- g. Compliance document binder must be kept at the trial site. It should contain all the forms that have been filled, copies of communications and reports,



Decision document, Research clearance permit. It must be available to the Inspectors or any authorized representative(s) of the NBC;

- h. The trial has been approved for a period of One (1) Year from the time a research permit is issued by UNCST. Any replantings beyond 1 year period must be approved by the NBC and associated fees for renewal paid to the UNCST in accordance to Uganda National Council for Science and Technology standard operating procedures Section L.
- i. All commitments made in the final application document should be adhered to. Any changes must be communicated to the NBC two weeks before amendments are made and such amendments must be authorized by the NBC in writing.

4.0 ADDITIONAL CONSIDERATIONS

These additional terms and conditions shall also apply:

- a. Research must be registered with UNCST prior to implementation. Details must be obtained from the UNCST Research Registration and Clearance Office
- b. A research review and registration fee of US\$ 1800 (One thousand eight hundred dollars only) shall then be paid (as guided by the research registration and clearance office of the UNCST)
- c. Where necessary, a phytosanitary certificate must be obtained from the phytosanitary Department of MAAIF at the time of importing the seeds into the country;
- d. The consignment must be inspected at the point of entry by the phytosanitary Inspectors and the inspector must accompany your planting materials/seeds to the store at the Research Institute. The applicant (now authorized party) will facilitate the Inspector to carry out this inspection task
- e. After preparation of the trial site, the Principal Investigator (Authorized Party) will inform the NBC through the NBC Secretariat so that together with the Inspector, a few members inspect the site.
- f. At the time of planting, in the middle of the trial and at harvest, inspections by Biosafety Inspectors and NBC Members will be done. It is the responsibility of the Authorized party to inform the NBC Secretariat so that inspection can be arranged.
- g. All inspection costs will be borne by the applicant on the cost recovery basis.
- h. The NBC and the Inspectorate reserve the right to make impromptu inspections(giving you prior notice or not)



- i. The details of terms of conducting the trial, shipping and storage ,material and genetic confinement ,termination of the trial, post-harvest monitoring,incidents,data collection for regulatory purposes as well as record keeping has been provided to you in the Trial Managers' Hand book
- j. It is your responsibility as the Authorized party to ensure that all guidelines that are relevant to your crop and study are strictly followed.
- k. Standard Operating Procedures(SOPs) and Confined Field Trial Guidelines as well as other conditions of approval(Sections 3.0 and 4.0) will constitute commitment of an offence and the Authorized party will be reliable to penalties as the NBC may determine and /or a competent Court according to the laws of Uganda as well as relevant international laws, where applicable.

5.0 REJECTION OF THE APPLICATION [If Rejected]

Not Applicable

Signed

by.....*Charles F. Mugoya*.....Date.....*12/06/17*.....

Dr Charles. F. Mugoya

Chairperson, NBC



Signed

by.....*[Signature]*.....Date.....*12th June 2017*.....

Mr. Kwehangana Musa
NBC Secretariat