



Guidelines for National Performance Trials (NPTs) on Genetically Modified Crops towards commercialization in Kenya

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Conventional National Performance Trials - NPTs

- Trials designed to test new plant varieties for performance compared to varieties currently in the market.
- Otherwise termed Value for Cultivation and Use (VCU) trials.
- The trials are done across the country at specific agro-ecological zones where the full potential of the variety can be expressed.



Purpose of NPTs

- NPTs determine the agronomic potential of a new variety before it is released for commercialization.
- Candidate varieties are planted alongside existing varieties (checks) and performance gauged to ensure only superior varieties are released.



Execution of NPTs

- The tests are done for at least two growing seasons. The designs are usually done with a minimum of 3 replicates.
- Data is analysed each year of testing, with combined data analysis at 2nd year of testing.
- NPT report is prepared by KEPHIS after data analysis at the end of each season and National Performance Trials' committee (NPTC) is convened to discuss the report.



Execution of NPTs Cont.

- NPTC recommends for release varieties that meet the release criteria to the National Variety Release Committee (NVRC).
- NVRC deliberates on the recommended varieties with consideration of DUS report and makes decision on varieties to be released.
- New varieties gazetted and listed in the National Crop Variety list then the breeder can now multiply and sell the new variety





NPT POTATO





NPT Beans





NPTs on Genetically Modified Crops

- Confined Field Trials (CFT) have been conducted in the country for a number of genetically modified crops since 1991 when the first CFT was conducted on sweet potato.
- Considerable experience has been gained in this process by researchers and regulators. The path has been challenging, considering that the procedures in use during this entire period were evolving.



NPTs on Genetically Modified Crops Cont.

- Since the enactment of the Biosafety Act (2009), the National Biosafety Authority (NBA) and regulatory agencies have been working towards moving the research arena forward within the current regulatory framework.
- NPT guidelines on GM crops has since been developed.
- These guidelines are elaborate and contain well thought considerations of the experiences already gained in the research and regulatory field.





Objective

- The objective of these guidelines is to provide the general principles that shall be followed during the conduct of NPT and DUS tests of genetically modified crop varieties.



Scope

- All genetically modified varieties of crops listed in the Second Schedule of the Variety Evaluation and Release Regulations of the Seeds and Plant Varieties Act.
- To address design, general considerations and testing scenarios for NPT and DUS of genetically modified crops.



General Principles

- Biosafety clearance as prescribed in the Biosafety Act.
- The breeder or applicant should describe the variety with special attention to the modified or inserted gene and attributes or traits conferred.



General Principles Cont.

- In cases of conditional environmental release approval, NPT tests will be done in secured sites within isolation distances that will not allow gene flow and entry of the products into food and feed chain.
- NPT for conditionally released varieties sites will therefore be fenced or conducted in secured sites



General Principles Cont.

- Specific isolation distances for different crops are provided in the Seeds and Plant Varieties (Seeds) Regulations.
- The site shall be isolated from farmers' crops by a distance equivalent to the distance used to isolate basic seed of the crop from other material of the same species.



General Principles Cont.

- Duration of trials: This will be consistent with Variety Evaluation and Release Regulations:
 - Currently this is 2 seasons
- A trial site may be terminated on the advise of the National Biosafety Authority.



NPT Testing Scenarios

- (i) Where the un-modified version of the genetically modified (GM) variety has been previously released in the same crop variety for the same agro-ecological site or purpose, the GM variety will be considered an essentially derived variety (EDV).
- Use of National Performance Trial (NPT) results of the un-modified version of an EDV in scenario (i) above may be requested by the applicant.



NPT Testing Scenarios Cont.

- (ii) Subject to approval by the National Performance Trials Committee (NPTC), testing may be done for only one season to confirm the expression of the introduced trait so long as testing is conducted in more than three sites.
- (iii) Where the un-modified version of the GM variety has not been previously released, the GM variety will be considered to be a new variety even if the modified trait has been used in other varieties.



NPT Testing Scenarios

- (iv) Where the un-modified parent of the GM variety has been released previously in the same crop, but in a different variety or different agro-ecological site or different purpose, the GM variety will be considered a new variety.

The provisions in (i-iv) shall apply where an additional trait or new gene stacks or combinations of traits are being introduced in a released variety.



Site identification

- For crops requiring tests for special attributes, the site must enable testing of the introduced trait.
- For insect resistance, the site shall be controlled to introduce reasonable populations to enable comparisons.
- For herbicide tolerance traits, the specific herbicide shall be sprayed to enable trait efficacy testing.



Site identification Cont.

- Other traits: The trial sites should enable determination of the trait of interest.
- For example, where the trait is drought tolerance, the site should allow expression or should provide a rain free period where irrigation can be avoided.

The trial sites shall be clearly **labeled** as consisting of genetically modified materials.



Weed control

- Usually done manually, but pre-emergence chemical weed control is recommended to reduce cost of management.
- For genetically modified varieties conferring herbicide tolerance, the selection of herbicide will be influenced by the introduced trait.

Harvesting

- In case of conditional Environmental release, grain shall be milled and other harvested materials shall be buried at the testing site



Field Observations and Laboratory Tests

- Yield is the most important consideration.
- Other characters must also be assessed by field observations and laboratory analysis.
- For some varieties, special attributes such as insect resistance and herbicide tolerance will be the primary observations of interest.
- Biochemical test data may supplement information generated in the site.



Field Observations and Laboratory Tests Cont.

- Biochemical test data which include checking levels of specified molecules e.g. proteins, pro-vitamin or micronutrient shall be confirmed.
- The applicant shall provide protocols for detection of introduced events and data on expression of the trait.
- These tests will done at the cost of the applicant.



Distinctness, Uniformity and Stability (DUS) Tests

- DUS tests shall be conducted following procedures provided in the UPOV test guidelines (TG) for the specific crop.
- For varieties whose unmodified version has undergone DUS, testing will only involve molecular characterization to establish distinctness due to the presence of the event.
- Unless there is evidence to show that genetic modification resulted in change in morphological characteristics of the variety.



END

Thank you