Water Efficient Maize for Africa (WEMA)

Strategy for Regulatory Approval and Safe Conduct of Confined Field Trials in Uganda

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EXECUTIVE SUMMARY

This strategy is an analysis of the regulatory environment for approval and safe conduct of Confined Field Trial (CFT) in Uganda with particular emphasis on drought tolerant transgenic maize. It provides mechanisms for facilitating compliance and smooth implementation of the drought tolerant transgenic maize CFT. It was developed with direction from the Water Efficient Maize for Africa (WEMA)-Uganda regulatory team of the National Agricultural Research Organization (NARO). It is a result of a comprehensive the review of Uganda's regulatory and policy documents as well as consideration of the relevant components of the draft WEMA Regulatory Approvals Strategy for CFTs that considers the regulatory frameworks in the five WEMA countries-Kenya, Uganda, Tanzania, South Africa and Mozambique. The aim of development of this Uganda-specific strategy therefore, was to guide the WEMA-Uganda project team to comply with the country-specific regulatory requirements. The specific objectives were to: 1) analyze the existing regulatory requirements for transgenic maize approval and safe conduct; 2) analyze available capacity and competence for safe conduct of the CTF and 3) identify and suggest solutions for potential 'killer' issues for the CFT approval and implementation in Uganda.

This strategy thus, an eagles' eye peering into the regulatory path for CFT approval to identify its strengths and weaknesses or 'killer' issues as well as threats that might hamper the efforts to secure regulatory approval and subsequent smooth implementation of the trial. Furthermore, the strategy identifies key actors in the Ugandan regulatory environment for WEMA-Uganda project, analyses their interrelationship and levels of influence on the overall implementation of the CFT (Fig. 2). It also puts in place a road map and action plan for management of the weaknesses or 'killer' issues as well as overall implementation of activities that will subsequently result in regulatory approval and smooth implementation of the trial. It concludes by giving a contingency plan with a 10-points watch-out list that if implemented shall facilitate successful implementation of the CFT for drought tolerant maize as well as making input into the process for future commercialization of the technology in Uganda.

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ACRONYMS

AATF	African Agricultural Technology Foundation
ARC	Agricultural Research Council of South Africa
BMGF	Bill and Melinda Gates Foundation
CBI	Confidential Business Information
CFTs	Confined Field Trials
CIMMYT	International Maize and Wheat Improvement Center
COSTECH	Commission for Science and Technology of Tanzania
DTM	Drought Tolerant Maize
GMOs	Genetically Modified Organisms
IBC	Institutional Biosafety Committee
IIAM	National Agriculture Institute of Mozambique
IPR	Intellectual Property Rights
KARI	Kenya Agricultural Research Institute
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
MSU	Michigan State University
NARO	National Agricultural Research Organisation of Uganda
NARS	National Agricultural Research Systems
NBC	National Biosafety Committee
NCA	National Competent Authority
NFP	National Focal Point
PQS	Plant Quarantine Services
PBS	Program for Biosafety Systems
SOPs	Standard Operating Procedures
Scifode	Science Foundation for Livelihoods and Development
UNCST	Uganda National Council for Science and Technology
WEMA	Water Efficient Maize for Africa project

PART I. BACK GROUND TO THE STRATEGY

1.1 WEMA Project

The Water Efficient Maize for Africa (WEMA) is a private-public partnership between the Africa Agricultural Technology Foundation (AATF), the International Maize and Wheat Improvement Centre (CIMMYT), Monsanto, and National Agricultural Research Systems (NARS) from five eastern and southern African countries: The Kenya Agricultural Research Institute (KARI), Kenya, National Agriculture Institute of Mozambique (IIAM), Mozambique, Agricultural Research Council (ARC), South Africa, Commission of Science and Technology (COSTECH), Tanzania, and National Agricultural Research Organization (NARO), Uganda. The project is supported by the Bill and Melinda Gates Foundation (BMGF) and the Howard G. Buffet Foundation.

The project intends to exploit the potential of conventional and molecular breeding, genomics and biotechnology techniques to develop drought tolerant maize (DTM) for small-scale farmers in Africa. Furthermore, the project intends to enhance the R&D expertise of project partners both from CIMMYT and NARS. This collaboration will enable tapping of synergies between the partners to expedite development of drought-tolerance in maize. NARS and CIMMYT will provide expertise in breeding for abiotic stresses, germplasm and infrastructure, while Monsanto will provide biotechnology traits and access to molecular breeding platforms. The Project will benefit from the expertise of AATF in the management of innovative partnerships. This will enable the development and testing of DTM varieties that will be available royalty-free to small-scale farmers in SSA.

At regional and country level, the project is governed and managed by four components: Project Governance, Product Development (PD), and Regulatory (RT) and Communication teams.

1.2 WEMA Regulatory Component

The responsibility of the Regulatory team is to develop and implement strategies to secure regulatory approval for CFTs and compliance with national regulations. To support this, AATF commissioned an assessment of the regulatory environments in the five participating countries: Kenya, Mozambique, South Africa, Tanzania and Uganda, to review documents that makeup the Biosafety Frameworks, Biosafety Policies, Regulations and Guidelines for each country so as to understand the requirements that are relevant to the establishment of the CFTs. The study also assessed each country's institutional frameworks and its readiness to conduct CFTs of transgenic maize. It was observed that the countries were at different levels of biosafety legislation and capacity to conduct CFTs. The output of this study was an overall WEMA regulatory strategy '*WEMA: A Strategy for Regulatory Approvals for Confined Field Trials.*

1.3 Justification of Country Specific Strategy

Given the uniqueness of policies, guidelines, regulations as well as regulatory challenges at country level, it was imperative to develop a Uganda-specific WEMA regulatory strategy for the safe conduct of confined field trials.

The importance of this strategy is two-fold: 1) to domesticate and align the overall WEMA project strategy to suit the unique Ugandan regulatory environment and 2) to analyze in detail the specific regulatory strengths and challenges in Uganda, and design measures to address them for effective and smooth implementation of CFTs of drought tolerant transgenic maize in Uganda.

1.4 Purpose and Scope

Purpose: To guide conduct of the CFTs in compliance with country-specific regulatory requirements

Scope: The strategy analyses the national requirements and capacity for CFT approval and safe conduct. It also provides mechanisms to facilitate compliance and smooth implementation of the field testing of drought tolerant transgenic maize in Uganda.

Strategic Objectives:

- Analyze existing regulatory requirements for transgenic maize CFT approval and safe conduct
- Analyze available capacity and competence for safe conduct of the CFTs
- Identify and suggest solutions for potential "killer" issues for the CFT approval and implementation

PART II UGANDA REGULATORY ENVIRONMENT

2.1 Laws, Regulations and Guidelines

The National Biotechnology and Biosafety Policy for Uganda was approved on the 8th April 2008. The goal of the policy is to "contribute to the national goals of poverty eradication, improved healthcare, food security, industrialization and the protection of the environment through the safe application of biotechnology". The policy is consistent with the principles as laid out in the Uganda National Council for Science and Technology (UNCST) Act Cap.209, National Environment Management Act Cap.153 and the Cartagena Protocol on Biosafety, 2000, which Uganda signed in May 2000 and ratified in November 2001. The development and coordination of this policy is a mandate of UNCST. Uganda has also developed a draft National Biotechnology Safety Bill (2008), which will become an Act as soon as it has been passed by parliament, signed by the President and gazetted.

In the interim, Uganda has proactively developed a regulatory system for conducting research in modern biotechnology. This system was developed under the provisions of the UNCST Act CAP 209 and has been operational since 1996. Under this system, a National Biosafety Committee (NBC) was established, and "Confined Field Trial Guidelines" (2006) and "Guidelines for the Containment of Genetically Modified

Organisms and Microbes" (2007) were developed. This system has successfully been used to process CFT application and implement trials of a number of transgenic crops.

2.2 Institutional Framework

The interim regulatory system sets forth an institutional framework for biosafety that comprises of the following:

National Focal Point (NFP) - The Ministry Responsible for Environment – main function is to liaise with the CBD Secretarial on matters relating to the Biosafety Protocol.

National Competent Authority (NCA) – Uganda National Council for Science and Technology (UNCST) – responsible for overall Biosafety policy framework. As early as 1996, UNCST had already established a National Biosafety Committee that is still currently active in assessing applications. They also encouraged the establishment of Institutional Biosafety Committees (IBC's) in those institutions that were involved in biotechnology research.

The National Biosafety Committee (NBC) – as stated above, falls within the NCA and makes use of the secretariat within the NCA to conduct its business. NBC provides technical advice on biosafety to government and maintains links with biotechnology institutions through Institutional Biosafety Committees. The NBC reviews biotechnology research proposals involving genetically modified organisms (GMOs). The committee approves and monitors deliberate release of GMOs into the environment. It is comprised of fifteen (15) experts from various relevant sectors.

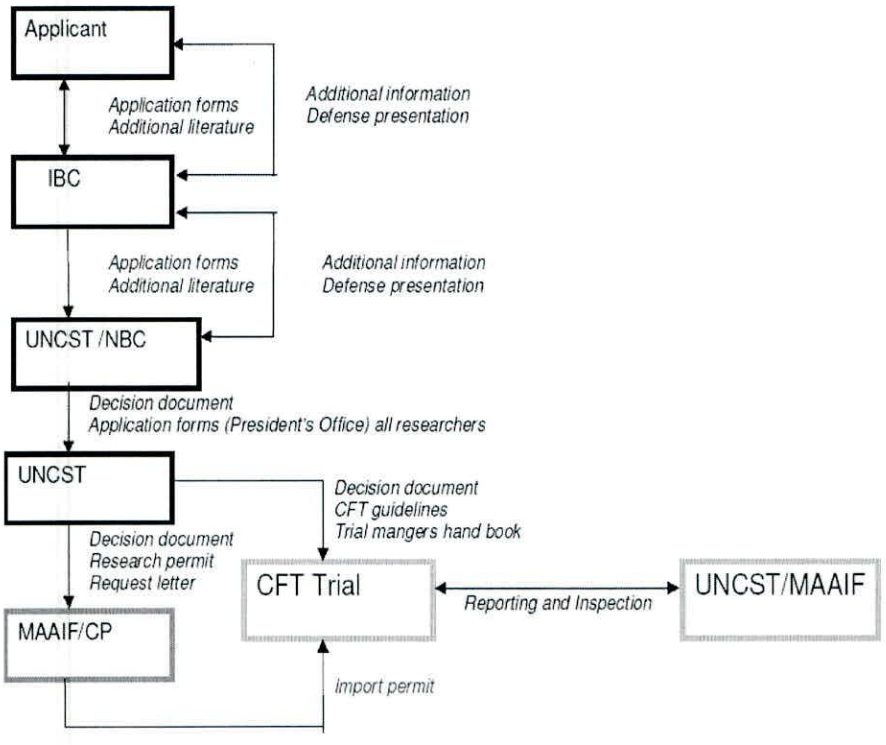
The Institutional Biosafety Committee (IBC) - Any institution where research involving GMOs is conducted is required to appoint an IBC. The committee consists of at least five persons, two of whom are not affiliated with the institution. The IBC assists the PI to ensure compliance with the National Guidelines by ensuring a complete application for CFT and evaluating facilities, procedures, record keeping and the expertise of personnel involved in the research.

Other Agencies - Relevant institutions within the National Agricultural Research System such the Plant Quarantine Service (PQS). PQS serves as the inspectorate. Inspection is part of ensuring biosafety when handling GMOs. Inspection starts right from the time of establishment of the CFT.

2.1.3 CFT Approval Process

The process for CFT approval involves initial consideration by the IBC for completeness of the application and availability of capacity to conduct CFT. After the IBC consideration, the applicant, who should be a Ugandan, prepares and submits an application to the NBC secretariat at UNCST for processing. The documentation includes all the proposed strategies and actions that will be carried out to ensure confinement as well as a review for environmental risk assessment. After obtaining a written research permit from the UNCST, the applicant submits an application for import permit from the Department of Crop Protection, MAAIF. This process is demonstrated in Figure 1 below.

Figure 1 CFT Regulatory Approval Process for Uganda



Uganda has successfully reviewed applications for transgenic field trials and therefore has the capacity and know-how in place to issue a permit for a CFT. The country currently has transgenic trials for bananas, cotton and cassava, in progress.

PART III STRATEGY FOR ESTABLISHING CFTs

3.1 Conceptual Framework

This section identifies and analyses the key issues, strengths, weaknesses/ 'killer' issues, opportunities and threats within the regulatory system with respect to the safe conduct of CFTs. It further maps out the stakeholders involved in the WEMA-Uganda project, their relationships and levels of influence.

3.1.1 Key Issues

Basing on experiences gained from the previous confined field trials that have so far been approved and conducted in Uganda, and on reviews of different Ugandan regulatory documents and other reports including the overall WEMA Strategy for Regulatory Approvals of CFTs, a number of key issues were identified and form the cornerstone for this strategy document. These comprise of the following:

i **Capacity building:** To smooth and successful conduct maize CFTs in compliance with the national regulations, it is imperative to analyze the existing human, infrastructural and institutional capacities, identify the gaps and devise mechanisms to address these gaps.

ii **Regulatory compliance:** Key steps toward attainment of regulatory compliance were identified and these include:

   a. Submission and approval of the CFT application;
   b. Site identification and development;
   c. Safe conduct of the trial;

iii **Stakeholder engagement**: Given the fact that drought tolerant maize is going to be developed using transgenic technology which still remains controversial in Uganda, there is a need for strategic stakeholder engagement especially at institutional level to ensure judicious execution of responsibilities that will facilitate timely approval of the CFT application and issuance of relevant permits.

iv **Financial implications:** In order to address the weaknesses/ 'killer' issues and facilitate timely implementations of all CFT activities, adequate financial resources need to be mobilized in time and adequately utilized.

3.1.2 SWOT Analysis

Table 1 SWOT Analysis

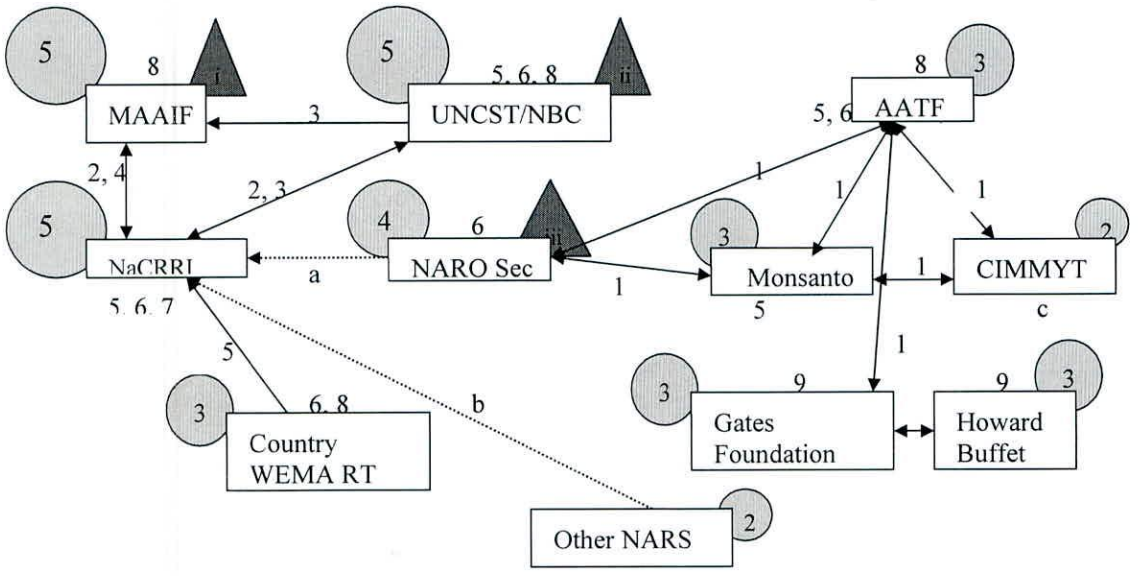
STRENGTHS	OPPORTUNITIES
• Enabling national biotechnology and biosafety policy • Exist functional capacity for CFT approval • Uganda is already conducting CFT • Guidelines and SOPs for CFTs are in place • Statutory provisions allow for confidentiality of Confidential Business Information (CBI); • NARO has a functional Institutional Biosafety Committee (IBC)	• Strong National Agricultural Research system • Potential benefits including, food security, income generation, poverty reduction, and trade; • Increasing drought challenge in the country • Competent scientific and regulatory capacity
WEAKNESSES	**THREATS**
• Unclear functional modalities between regulatory institutions • Delayed approval of CFT • Weak intellectual property rights (IPR) regime	• Potential interference from the anti-lobby groups • Low public awareness of biotechnology and WEMA project • Technology involves genetic modification which is highly controversial • Involvement of Monsanto • Reproductive biology of maize

3.1.3 Actors and Their Influence

Table 2 Actors and their Roles for approval and conduct of transgenic maize CFT

Actor	Nature	Role
Uganda National Council of Science and Technology (UNCST) and National Biosafety Committee (NBC)	Public	Field trial application review and approval CFT oversight Capacity building Stakeholder engagement
National Agricultural Research Organization (NARO)	Public	Research Policy advice
National Crop Resource Research Institute (NaCRRI)	Public	Maize research Applicant Capacity building Stakeholder engagement
Ministry of Agriculture, Animal Industry and Fisheries (MAAIF)	Public	Import permit Field inspection
AATF	International /Public	Coordinate the implementation of tripartite partnership of WEMA project Capacity building Stakeholder engagement
CIMMYT	International /Public	Provide background maize germ-plasm
Monsanto	Private	Technology owner Field trial design Capacity building
Other NARS	Public	Partners in implementation of WEMA project
Bill and Melinda Gates Foundation	International	Funds the project
Howard Buffet Foundation	International	Funds the project
In-country WEMA regulatory team (RT)	Independent	Regulatory advisory and guidance Capacity building Stakeholder engagement

Figure 2 Interrelationships between Actors and their Influence in the approval and conduct of the CFTs



Influence Rating: 0: ○ **1:** (1) **2:** (2) **3:** (3) **4:** (4) **5:** (5)

Critical regulatory steps

1. Sign contractual agreements
2. Prepare and submit applications
3. Issuance of decision document and research permit
4. Securing import permit and phytosanitary clearance
5. Capacity building
6. Stakeholder engagement
7. Conduct CFT
8. CFT oversight
9. Fund CFT

Indirect influence

a. Research policy support
b. Partners in project implementation
c. Provide germplasm

Potential 'killer' issues

i Unclear functional modalities between regulatory institutions
ii Delayed approval of CFT
iii Weak IPR regime

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Critical Regulatory Steps (Solid lines)

1. Contractual agreements shall be signed between and Monsanto, CIMMYT, AATF and with NARO from time to time
2. Applications shall be submitted by NACRRI to the UNCST/NBC and to MAAIF to obtain research approval permit and seed import permit respectively
3. Decision documents/research permit shall be issued by the UNCST/NBC to NACRRI
4. The seed import permit shall be issued by MAAIF to NaCRRI
5. Capacity building shall be conducted by NaCRRI, AATF, Monsanto and UNCST to various stakeholders and at various stages of project implementation
6. Stakeholder engagement shall be conducted by NaCRRI, UNCST and AATF
7. The Field trial shall be conducted by NaCRRI
8. The UNCST and MAAIF are responsible for CFT oversight and inspections

9. The Bill and Melinda Gates Foundation and the Howard Buffet Foundation shall fund the different capacity building, stakeholder engagement and regulatory components

Note: the yellow circles imply the level of influence at the scale of 0-5 where 0 refers to no influence at all and 5 the highest possible influence on the regulatory process.

Indirect Influences (in dotted lines)
a. NARO shall provide research policy guidance to NaCRRI
b. NARS in other WEMA partner countries—their activities and progress may influence NaCRRI WEMA activities
c. CIMMYT to provide background germplasm

Potential killer issues
i. Unclear functional modalities/mandates at MAAIF level that has in many instances delayed issuance of seed import permits
ii. Delayed approval of CFT that may result from the laxity on part of the regulators that may arise from the 270 days time-span within which decision on application is made.
iii. Weak IPR regime and capacity at NARO level that may cause some delays during the review process as the regulators may demand some IPR clarifications

It can be noted the potential killer 'issues' will remain a challenge to successful implementation of the CFT unless they are addressed. It is therefore recommended that the functional modalities or non-clarity of institutional mandates which especially delays the issuance of the import permits for transgenic seeds in Uganda needs to be handled by direct engagement and involvement in some of the WEMA activities. There will also be a need to constantly update all key players especially MAAIF and UNCST on WEMA project and regulatory compliance progress during the implementation the project. The potential killer due to the long time span of 270 days within which decision on applications has to be made, it is recommended that submission be done well in time to cushion any delays in obtaining regulatory approvals. The challenge of weak IPR regime within NARO can be addressed through capacity building of the WEMA regulatory team, involving a legal expert on WEMA-Uganda regulatory ream as well as training NARO scientists and other relevant staff in IPR.

3.2 Components of the Strategy

In order to address the key issues identified in section 3.1.1, the following components of the strategy which arise there-from were identified. They represent the critical ingredients required for successful and smooth conduct of the transgenic maize CFTs in Uganda. The different milestones that will be accomplished under each of the components are clearly mapped out in the implementation strategy implementation framework. It is important to note that the implementation of activities may not necessarily chronologically follow the listing of these components, nor does the listing represent the order of priority of importance of these components of the strategy.

3.2.1 Capacity building

Capacity building issues identified shall be addressed at three key levels:

Human resource capacity: Efforts shall be geared at recruiting and training of the Trial Manager as well as other staff that will be in charge of conducting the trial, including the security guard. The trainings conducted shall mainly be geared at ensuring compliance but will also help them gain capacity in collecting credible scientific data. In addition, to ensure sufficient capacity for conducting the trial, inspectors will also trained to enhance their skills in maize CFT inspection. As a way of providing hand-on training for the trial, a mock experiment at the proposed CFT site shall be conducted with non-transgenic DT maize.

Infrastructural Capacity: Timely implementation of activities relating to preparation of the CFT site shall be effected to ensure that the site is ready in time and is in accordance with the relevant national regulations and guidelines. In this vein, the NBC will be informed to inspect and approve the site prior to completion of construction works. The site will be developed using competent contractors and all the equipment and facilities for effective implementation of the trial installed at the site. After the site is completed, it will be commissioned in the presence of relevant regulatory agencies.

Institutional Capacity: It is noted that some efforts need to be geared toward increasing institutional capacity for compliance and for effective CFT implementation. These shall include: 1) development of a transgenic maize CFT handbook which will be the guide for implementation of the day to day activities of trial management; 2) conducting a study tour of relevant officers from key regulatory institutions to visit a developing country with experience in conducting transgenic maize CFTs and with an advanced regulatory system; 3) organizing workshops and meetings to bring NARO scientists on board regarding WEMA and matters of regulatory compliance during the conduct of the trial. Meetings shall be held to clarify the roles and responsibilities of regulatory institutions in the approval and conduct of this CFT, and 4) strengthen institutional IPR of NARO by organize trainings on IPR issues for scientists, and including a lawyer on the WEMA regulatory team.

3.2.2 Regulatory Compliance

Without regulatory compliance, it will be impossible for the small-scale farmers in Africa to benefit from the attributes of DT transgenic maize because safe conduct of the CFT is a critical step in this endeavor. It is therefore imperative that all necessary steps, as well as any potential 'killer' issues be addressed to ensure that there is maximum compliance. In order to do this, the following steps shall be taken: 1) contractual agreements shall be signed in stipulated time, 2) CFT application shall be submitted as early as possible to allow the NBC to review the application and provide approval in time, and 3) Upon receiving the decision document from UNCST, the applicant shall submit an application for import permit to MAAIF as soon as possible so that permission is granted in time to ensure the trial begins at the targeted time.

Once these are accomplished, seeds will be imported, trial planted and periodic inspections conducted as per the national regulations. During the trial proper documentation shall be kept to ensure timely reporting. At the end of the trial,

termination and post-harvest monitoring shall be effected according to guidelines. Adherence to these requirements will ultimately significantly contribute to safe conduct of the CFT.

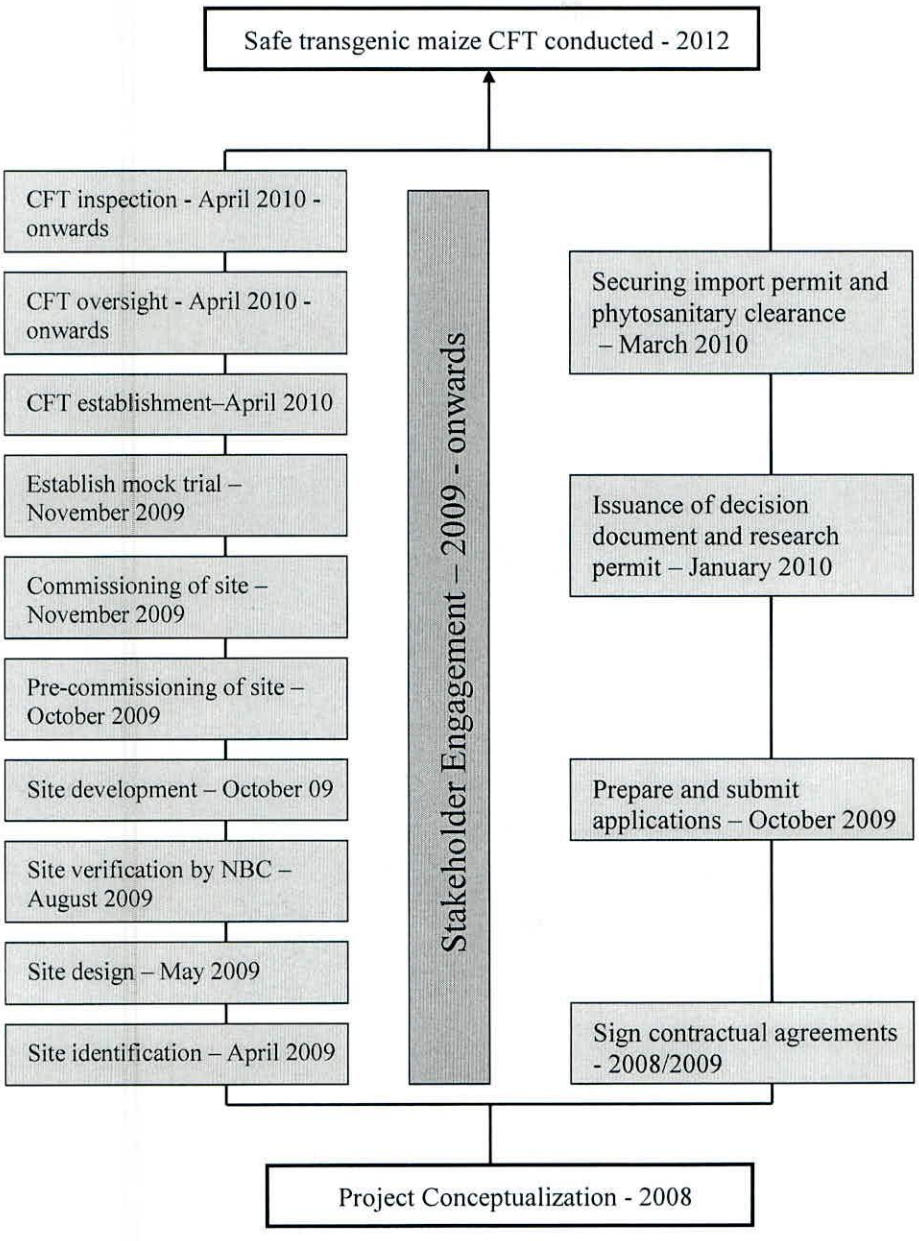
3.2.3 Stakeholder Engagement

Stakeholder engagement shall be geared at minimizing the impediments to successful implementation of the trial. The shall include putting in place mechanisms for targeted public awareness, paying particular attention to the CFT surrounding communities, involvement of MAAIF in WEMA regulatory activities, sharing reports of regulatory and other project activities with relevant regulatory institutions as well as developing capacity and pathways to ensure timely response to negative publicity in the mass media.

3.2.4 Financial implications

Well planned and executed budgeting and financing are a cornerstone to addressing regulatory and related challenges that can hamper successful conduct of CFT. In this effort, identified financial managers shall be exposed and trained in financial management and procedures of the WEMA project.

3.3 Regulatory Compliance Roadmap



PART IV PROPOSED STRATEGY IMPLEMENTATION

4.1 Action Plan

Strategic Output/Action Point	Milestone	Targeted date	Responsible
1. Capacity Built			
2.1. Infrastructural capacity	• CFT site identified	April 2009	WEMA-Ug. PD, RT teams
	• CFT site developed	October 2009	WEMA-Ug. PD, RT teams and contractor
	• CFT site commissioned	November 2009	WEMA-Ug. PD, RT teams and NBC
2.2. Human skill developed	• Trial manager and other staff recruited	June-Oct 2009	WEMA-Ug. Coordinator
	• Compliance training of trainers conducted	August 2009	AATF
	• Trial staff and inspectors trained	October 2009	Trained trainers
	• Mock trial conducted	November 2009	WEMA-Ug. PD, RT teams and Monsanto
2.3. Institutional capacity strengthened	• Maize CFT handbook developed	September 2009	AATF, WEMA-Ug. RT and consultant
	• Study tour conducted	September 2009	AATF
	• Stakeholder workshops on WEMA conducted	October 2009	WEMA-Ug. PD, RT and communication teams
	• IPR capacity strengthened	March 2010	NARO, WEMA-Ug. Coordinator, and RT team
2. CFT conducted following established regulatory procedures	• Contractual agreements signed	2008-2009	AATF and NARO
	• CFT application submitted	October 2009	WEMA-Ug. Coordinator, PD and RT teams
2.1. CFT applications approved			

2.2. CFT established and managed	• CFT application approved	January 2010	UNCST/NBC
	• Import permit secured	March 2010	Dept of Crop Protection, MAAIF
	• Seeds imported	March 2010	NaCRRI, WEMA-Ug. Coordinator and Monsanto
	• Trial Planted	April 2010	WEMA-Ug. PD team
	• Timely reporting effected	As per Guidelines	WEMA-Ug. Coordinator and Trial manager
	• Periodic inspections conducted	As per Guidelines	MAAIF, UNCST/NBC and WEMA-Ug. RT
	• Trial terminated	September 2010	WEMA-Ug. PD team
	• Post-harvest monitoring effected	As per Guidelines	WEMA-Ug. PD and RT team, MAAIF, UNCST/NBC
3. Stakeholders sentisized and involved in project implementation	• Stakeholders sensitized	Continuous	AATF, NARO, WEMA-Ug PD, RT and Comm. teams
	• MAAIF involved on the WEMA Regulatory team and project reports shared	Continuous	WEMA-Ug. Coordinator and RT team
	• Mechanism for timely response to negative publicity developed	October 2009	WEMA-Ug. Comm. team
4. Adequate funds mobilized and effectively utilized for CFT implementation	• Annual activity plans and budgets developed	2008- onwards	AATF, NARO and WEMA-Ug. Coordinator
	• Financial managers identified and exposed to project financial management and reporting procedures	2008-onwards	AATF, NARO and WEMA-Ug. Coordinator

4.3 Management and Coordination

It is important to underscore that having in place a regulatory strategy with its action plan as provided in this document does not guarantee approval and smooth implementation of the CFT. This is primarily because the regulatory component of the project cannot function on its own but has to be mainstreamed alongside the product development work, communication and public acceptance efforts as well as IP management and the overall policy for the project. Because of these inter-relationships of the project components, the regulatory aspects have got to be meticulously planned and managed for the CFT approval. There are some aspects of the project that have to be addressed through combined effort of the project teams in order to reach the desired milestones. For example developing the application is primarily a responsibility of the PD team but the RT team has to participate in this activity to make sure regulatory concerns are well addressed. On the other hand, capacity development for regulatory compliance is lead by the RT team but other members of the project team have to be involved and in this case it will be critical to lease with the PD team.

Effective management and coordination of the regulatory strategy shall be achieved through:

- Maintaining a competent regulatory team with adequate time commitment to the WEMA project.
- Participation in regular planning and review meetings with other project teams to ensure the regulatory strategy is coherent with other components and is supported.
- Exchange of planning documents and reports with other project components in order to support good coordination of project activities.
- Regular management meetings and site visits by the regulatory team members to track progress towards the milestones. These interactions of the group will be important to identify bottlenecks in the CFT approval and implementation processes and address them in a timely manner. The field visits will provide addition oversight beyond that of the crop inspectors to re-enforce compliance.

4.4 Monitoring and Evaluation Framework

Monitoring and evaluation of the strategy will be essential to establish progress towards achievements of the strategic objectives and in tracking the performance of the project milestones. The key aspects of the M&E framework include:

- Monitoring of the implementation of the activities as stipulated in the Action Plan
- Assessing the outputs and the contribution of the regulatory activities to the WEMA project targets at regular intervals.

It is important that key information and lessons learned in the process of implementing this Strategy are recorded in a systematic way so that they can be shared with stakeholders from time to time and used to improve the deliverables of the project.

PART V CONTINGENCY PLANS: A TEN-POINT WATCH-OUT LIST

Other considerations for a successful trial and general release of this drought tolerant technology are summarized in a Ten-Point Watch-Out List below:

1. Given the long time span for CFT approval, it may be opportune to make applications that cover multi-season trials. If required, supplementary information of subsequent trials shall be provided in a special letter of request to the regulatory committees.
2. To avoid unnecessary delays in CFT approval, it is important that the applications are fully completed with all the relevant information including the protocol, site maps and directions to the trial sites. If questions are asked it is essential to answer them immediately and exhaustively to avoid missing critical milestones.
3. The PD team should find information on the various fees required for approval of the application and securing the import permit. Such fees should be paid at the time of submission of the applications to avoid any unnecessary delays.
4. To enhance chances of faster approvals and smooth implantation of the CFT, it is important to expose different stakeholders and regulators to the CFT site and to the registered successes of the trial from time to time.
5. It important to provide opportunity for the involved institutions to clearly understand their roles for effective implementation of the project. It is also important devise strategies that will enhance inter-institutional collaboration and discourse as well as regular sharing of information and reports concerning the WEMA project activities.
6. With climate change, it is likely that the trial can be interpreted by unanticipated rainfall. This therefore calls for putting in place measures for managing such uncertainties.
7. In order to provide credible and sufficient scientific data to the commercial release application process, it is important standard scientific procedures are used to collect as data as comprehensively as possible during the trial.
8. In order to maximize and observe the effects of the drought trait on the performance and yield of crop under experimentation, it is important that all other management practices are uniform across treatments.
9. In anticipation of commercial release, it necessary to research on the national requirements and to use the CFT in building capacity to facilitate such approvals and implementation.
10. Another consideration is hybrid registration regulations. At this early stage it is worthwhile to try and include these requirements in future trials to ensure an early release of the transgenic hybrids!

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