



AFRICAN AGRICULTURAL TECHNOLOGY FOUNDATION
FONDATION AFRICAINE POUR LES TECHNOLOGIES AGRICOLES

WEMA Project Policy on Regulatory Approvals

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Table of contents

Acronyms and abbreviations	3
1.0 Introduction	4
2.0 Preamble.....	4
3.0. Aims, Objectives and Scope.....	5
4.0 Policy content and guidelines	6
4.1 Conduct of WEMA regulatory team members.....	6
5.0 Role and responsibilities of regulatory team	6
6.0 Effective date of the policy, monitoring and review	7

Acronyms and abbreviations

BMPs	Best Management Practices
CIMMYT	International Maize and Wheat Improvement Center
DT	Drought Tolerance
GM	Genetically Modified
NARS	National Agricultural Research Systems
NBCs	National Biosafety Committees
OPSCOM	Operations Committee of the WEMA project
R&D	Research and Development
SSA	Sub-Saharan Africa
WEMA	Water Efficient Maize for Africa project

WEMA Project Policy on Regulatory Approvals

1.0 Introduction

Sub-Saharan Africa (SSA) is the only region on the globe today where poverty and malnutrition continue to rise both as a percentage of the population and in absolute numbers. Over half of the hungry people are subsistence farmers who can not grow enough food on a consistent basis to feed their families and escape poverty. Maize is the primary grain crop grown for human consumption in SSA, comprising a significant part of the diet yet the average maize yield for a farmer in SSA is approximately 10-fold less than that of farmers in other parts of the world. The primary reason for this difference is not that the basic technology to increase maize production does not exist. Rather, the tools are not consistently used, largely because the farmer is unable to invest in them due to lack of capital, or because of unwillingness to invest the little capital available for fear of losing it due to drought stress. The high sensitivity of maize to drought stress at critical times of the growing season discourages small-scale farmers growing maize under rain-fed conditions from risking investment in best management practices (BMPs) including quality improved seed and fertilizer.

While a number of factors impact yield stability of maize, drought is certainly one of the greatest. The frequency and severity of drought varies by year and by country, but across SSA, drought stress is one of the top two factors responsible for limiting maize production. Major improvements have been made and are anticipated in maize yields through the combination of traditional breeding, marker-assisted breeding and transgenic agricultural biotechnology. Traditional breeding has provided steady improvements in yield over time. Marker-assisted breeding (MAB) has the potential to significantly accelerate that rate of improvement, while transgenes have the potential to create major paradigm shifts in a relatively short time frame.

This Water Efficient Maize for Africa (WEMA) project intends to combine the power of conventional and molecular breeding, genomics, and biotechnology techniques developed to develop drought tolerance (DT) maize for smallholder farmers in Africa. Furthermore, the project intends to enhance the R&D expertise of project partners drawn from the International Maize and Wheat Improvement Center (CIMMYT) and the National Agricultural Research Systems (NARS). This collaboration will expedite development of enhanced levels of drought-tolerance through NARS and CIMMYT's expertise in breeding for abiotic stresses, germplasm and infrastructure in sub-Saharan Africa combined with Monsanto's biotechnology traits and molecular breeding program.

2.0 Preamble

The partners in the Water Efficient Maize for Africa (WEMA) project, a Public-Private Partnership launched in February 2008 to contribute to improving food security of small producers in SSA,

Understanding that SSA is the only region on the globe today whose poverty and malnutrition continue to rise,

Understanding also that over half of Africa's small holder farmers cannot grow enough food for their family needs,

Recognizing the worsening trends in the frequency and severity of drought episodes across SSA,

Recognizing also that maize is the primary grain cereal in SSA,

Noting that the high sensitivity of maize to drought stress often discourages small holder farmers from investing in BMPs in growing it,

Appreciating the vast potential that a combination of conventional breeding, MAB and GM technology can have on raising maize yields and ameliorating food insecurity in SSA,

Acknowledging that application of GM technology for crop improvements require considerations for regulations that allow optimization of benefits while safeguarding potential risks to the environment and also to human health,

Hereby formulate a policy that shall guide all project activities in areas that require regulatory oversight and compliance.

The WEMA regulatory policy is founded on the vision of combining molecular breeding and biotechnology for the development of drought tolerant (DT) hybrid white maize seed that provides the yield stability and catalyses adoption of best management practices. It is also founded on the charitable purpose of improving food security and rural livelihoods for African small-scale maize producers to whom the developed drought tolerant lines will be delivered royalty-free.

3.0. Aims, Objectives and Scope

The purpose of this policy is to guide the WEMA Project in the development, management and implementation of strategies to secure regulatory approvals by the Regulatory Team for safe confined field trials on the basis of legal, scientific and professional applications by ensuring that:

- WEMA project activities are carried out in compliance with standing partner country regulations and operative international standards of Biosafety
- WEMA project seeks and secures approval permits for all activities requiring such
- WEMA project activities comply with respective stipulations of regulatory permits from each of the five partner countries

The policy will guide the work of the regulatory affairs component of WEMA project that is responsible for among other things, for developing capacity within national and international product development teams to conduct risk assessment and preparation of safety data dossiers, essential for regulatory approvals. This will go a long way in ensuring that submission of permit requests to regulatory authorities in partner countries is carried out on time and once secured, that trials are installed in conformity with partner country's regulations and authorization conditions for confined field testing.

This policy is subject to agreements with, as well as the laws and customs of, countries where WEMA project has activities and shall be implemented in consistency with relevant provisions the Grant Agreement with donors. The WEMA Project Management reserves the right to modify, suspend or terminate this policy as may be required.

4.0 Policy content and guidelines

To secure regulatory approvals and ensure compliance, WEMA project proposes to:

- draw on best expertise and practices from project partners, Sub Saharan Africa and elsewhere around the world; promote efficiency and ensure consistency in the performance of project regulatory activities.
- constitute a compliance management team, drawn from WEMA Project partner institutions with a mandate and *modus operandi*

4.1 Conduct of WEMA regulatory team members

The Policy requires regulatory team members to conduct themselves in a manner that does not involve covert or overt conflict of interest in the discharge of their responsibilities. To this end, regulatory team members, when serving on the National Biosafety Committees (NBCs) of their respective countries, should recuse themselves from any processes prior to NBC decisions (not limited to voting) regarding applications submitted by the WEMA project for regulatory approvals. Specifically, the regulatory team members shall be expected to:

- follow up and make necessary adjustments in response to the regulatory environment developments in the partner countries.
- generate yearly plans of action in accordance with the WEMA project document

5.0 Role and responsibilities of regulatory team

The team has responsibility for ensuring regulatory compliance by the WEMA project, consistent with section 4.0 and for ensuring that the in-country teams have the capacity to meet regulatory requirements. Specifically, the team shall:

- guide WEMA project in assessing the regulatory policy and legal environment of WEMA partner countries regarding oversight of R&D activities involving modern biotech applications.

- provide advice on approaches for identifying biosafety and regulatory needs in WEMA partner countries.
- arising from (1) and (2), develop an appropriate regulatory approval strategy for testing Drought Tolerant maize in collaborating countries.
- arising from (1) and (2), develop an appropriate capacity building plan of action to ensure regulatory compliance for all project partners during field testing and deployment of Drought Tolerant maize varieties in collaborating countries
- guide WEMA Project regarding appropriate steps for generating information and data essential for biosafety assessment and regulatory approval during the field testing and deployment of Drought tolerant maize varieties in collaborating countries
- provide advice on effective mechanisms for compiling safety and allied information into files for submission in pursuit of regulatory permits essential for testing and deployment of Drought Tolerant maize varieties in collaborating countries
- provide advice on approaches for managing enabling activities essential for permit approval and regulatory compliance during testing and deployment of Drought Tolerant maize varieties in collaborating countries
- interface as appropriate with other substantive committees of WEMA project to ensure effective project implementation by among other ways continuously providing information and guidance on country procedures to the product development team to ensure that the regulatory milestones of the WEMA project are met..

6.0 Effective date of the policy, monitoring and review

- The policy will come into effect in August 2009 once approved by the Operations Committee (OPSCOM).
- All regulatory team and other WEMA substantive committees' members will be required to adhere to this policy as long as they hold public offices that may influence or be construed to have an influence on the approval of Wema project applications.
- Adherence to the policy and ascertainment of its applicability will be monitored by the regulatory team. Any revisions to this policy will require the approval of the OPSCOM.