

# DROUGHT TOLERANT GMO MAIZE IN AFRICA

## Anticipating Regulatory Hurdles

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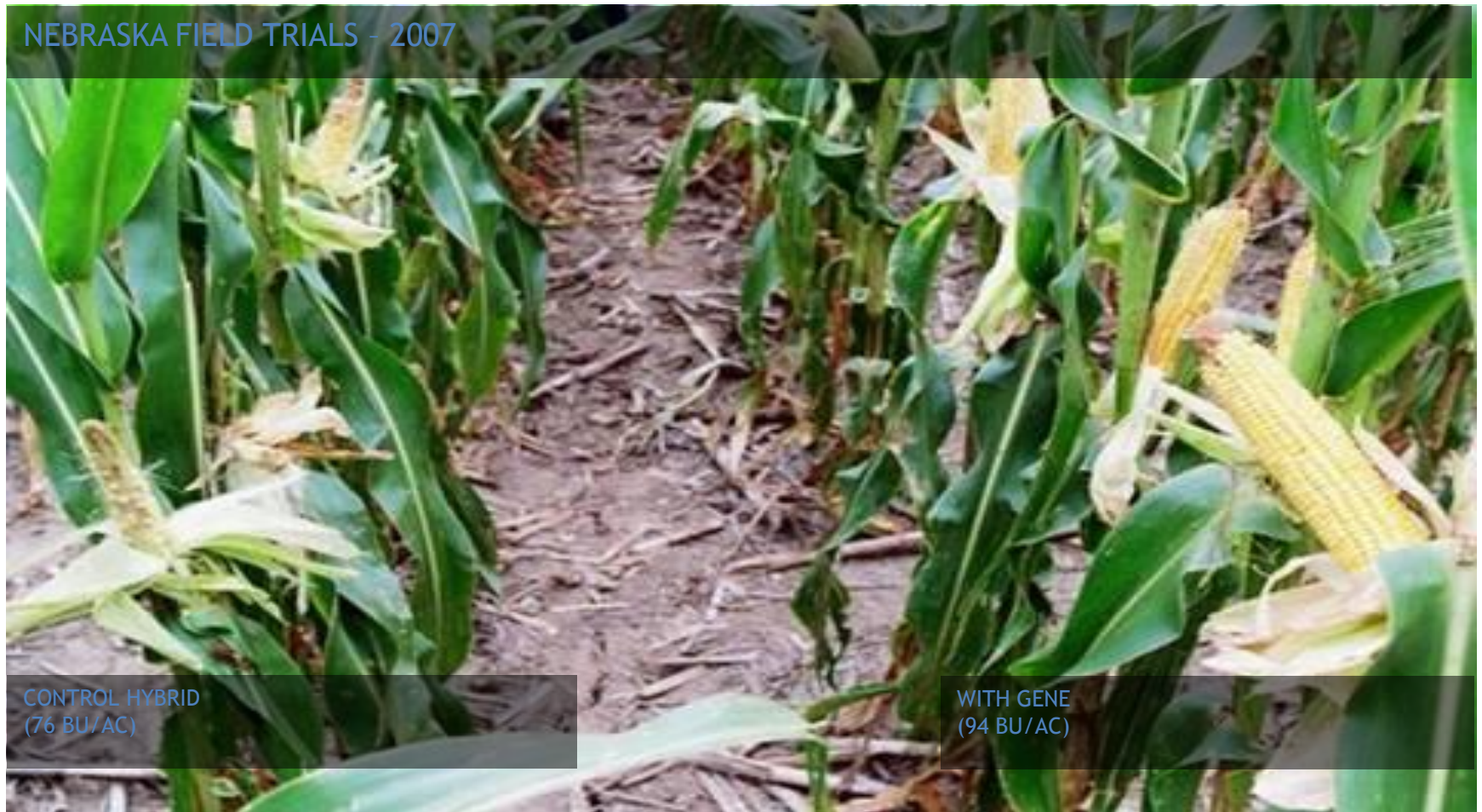
Wellesley College/Harvard University

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# Drought Tolerant Hybrid Yellow Maize: Expected on U.S. Market in 2012

NEBRASKA FIELD TRIALS - 2007



CONTROL HYBRID  
(76 BU/AC)

WITH GENE  
(94 BU/AC)

# Drought Tolerant Tropical White Maize Hybrids: Under Development by WEMA Project

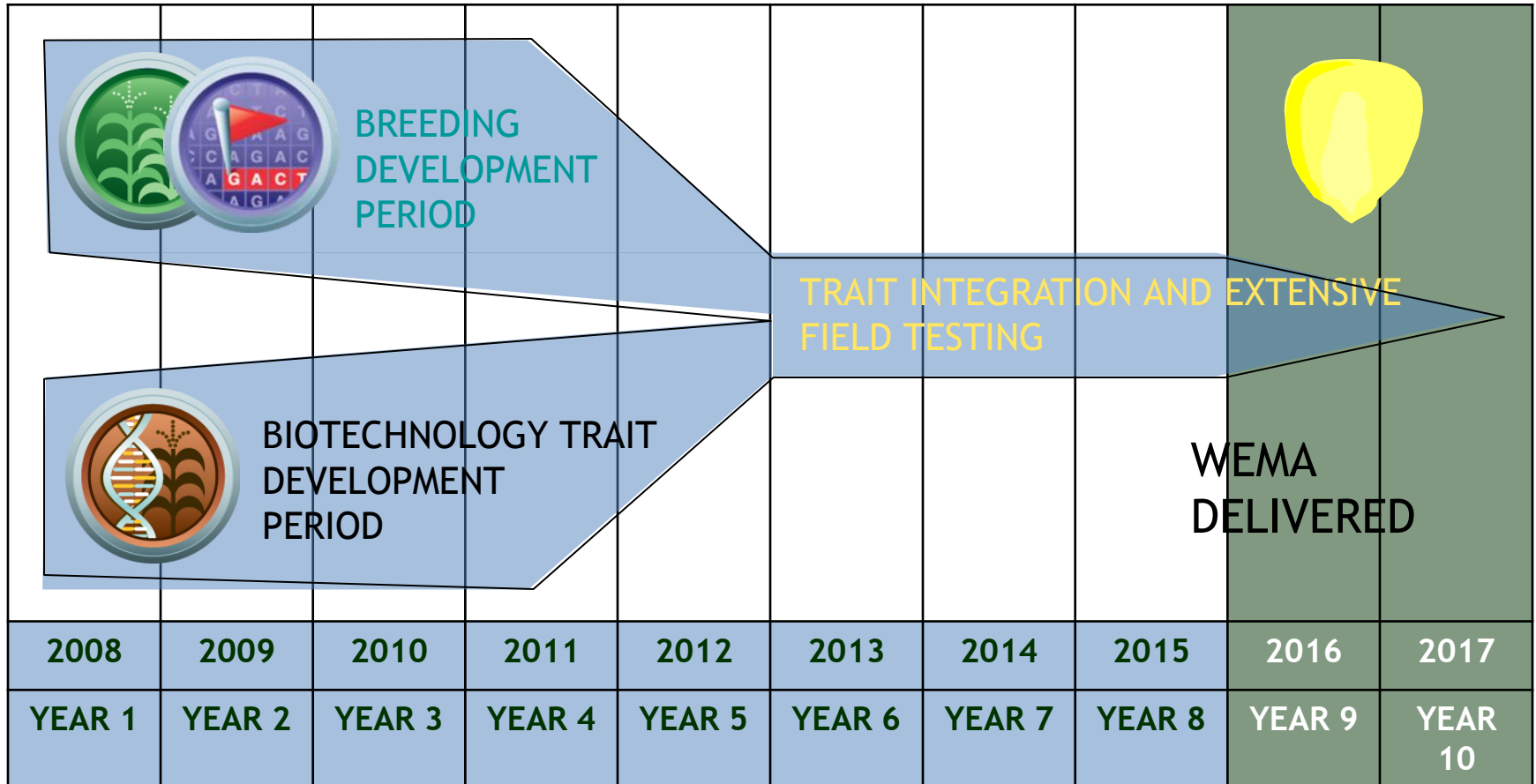
- WEMA funded in 2008 by Bill & Melinda Gates Foundation
- \$45 million grant made to AATF in Nairobi, which will partner with CIMMYT and NARS in 5 countries
- Technical approach is to combine traditional drought stress breeding with MAS and GE
- Genes for drought tolerance provided on royalty free basis by the Monsanto Company

# TECHNICAL GOALS OF WEMA:

- Best African hybrids today yield 3 t/ha under moderate drought conditions
- Marker Assisted Breeding can improve that by 1.5% per year
- Use of Monsanto gene will add another 8-10% yield improvement under moderate drought
- Final Goal: In 10 years, increase yield under moderate drought by 25%

# Technical Timeline for WEMA

FIRST 5 YEARS ARE RESEARCH, THE NEXT 5 ARE PRODUCT DEVELOPMENT



EXPECTED TO BE AN EIGHT- TO TEN-YEAR DEVELOPMENT TIMEFRAME

# HIGHER REGULATORY HURDLES IN AFRICA FOR GMOs

- Parliaments must pass separate “biosafety laws”
- Ministries must promulgate separate regulations
- A functional NBC must be formed and trained
- NBCs must approve each separate research experiment (such as a confined field trials)
- NBCs must approve unconfined use (“environmental release”)

# WHY AFRICAN REGULATIONS FOLLOW EUROPEAN MODEL

- Bilateral foreign assistance from Europe
- Multilateral technical assistance from Europe
- NGO advocacy campaigns from Europe
- Imports of African farm commodities by Europe
- Cultural influence from Europe

***“We have found no new risks to human health or the environment from GMOs approved by regulators so far.”***

Research Directorate General of European Union (2001)

French Academy of Sciences (2002)

French Academy of Medicine (2002)

Royal Society (UK) (2003)

British Medical Association (2004)

Union of German Academies of Science and Humanities (2004)

Organization for Economic Cooperation and Development (OECD)  
(2000)

Director-General of World Health Organization (2002)

International Council for Science (ICSU) (2003)

Food and Agriculture Organization of the UN (2004)



## 2010 REPORT FROM EU COMMISSION DIRECTORATE-GENERAL FOR RESEARCH:

*"The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than, for example, conventional plant breeding technologies."*

# REGULATORY TIMELINE FOR WEMA: “Best Case” Scenario

- 2010-11: Confined Field Trials begin in Kenya, Uganda, Tanzania
- 2015: Technology developers begin to apply to NBCs for “environmental release”
- 2016: NBCs begin to approve environmental release
- 2017: Performance trials and seed registration
- 2018: First seeds available to farmers

# WEMA PROGRESS SO FAR IN KENYA

- Biosafety Bill passed in 2009 (after 5 year debate)
- New Regulations drafted in 2009-10 (but not yet gazetted)
- In May 2010, KARI submits application to begin confined field trials
- In August 2010, NBA approved this request, authorizing three sequential seasons of CFTs.
- KEPHIS grants import permit to bring transgenic materials into Kenya
- First trial planted December 1, 2010. Harvest expected March 2011.

# WHAT COULD SLOW FUTURE PROGRESS IN KENYA?

- New regulations for mandatory labeling, tracing, and co-existence?
- Will NEMA demand full EIA versus just ERA?
- Will KEPHIS permit full scale multi-location performance trials?
- Will WEMA seeds perform significantly better than DTMA seeds?
- Opposition in Parliament?

# WEMA PROGRESS SO FAR IN UGANDA

- In 2006 Uganda's NCST promulgates R&G for confined field trials of GMOs, and approves trials for banana, cotton, and cassava.
- In 2006 Cabinet Secretariat approves summary of biosafety bill
- In July 2010, NBC approves WEMA request to conduct 3 sequential seasons of CFTs at Kasese, in Western Uganda
- In November 2010, first round CFT planted, harvest expected in March 2011

## WHAT COULD SLOW REGULATORY APPROVALS: UGANDA?

- Absence of a national Biosafety Act?
- Will WEMA seeds perform significantly better than DTMA seeds?
- Will hybrid maize sector make loud enough demands?
- Will President's Office see maize as a priority?

## WEMA PROGRESS SO FAR IN TANZANIA

- In 2009, MARI conducts “mock” field trials at dryland site in Dodoma
- In 2010, request to approve CFT was screened by NBFP inside office of VP, by MCA in Min of Ag., and by ABSAC, then returned to NBFP.
- In August 2010, NBC declined request for CFT, requesting additional information on horizontal gene transfer and on Environmental Risk Assessment.

# WHAT COULD SLOW REGULATORY APPROVALS IN TANZANIA?

- Fragmentation of GMO regulatory system
- Divided opinions on GMOs within government
- Full EIA will be required at environmental release stage
- Differences with technology providers over “strict liability”
- Will WEMA seeds perform significantly better than DTMA seeds?
- Will hybrid maize sector make loud enough demands?



## CONCLUSION

- The WEMA project has made significant progress in overcoming the regulatory barrier to CFTs
- Securing approval for an environmental release will be more challenging
- The key: Will the WEMA (GMO) varieties perform significantly better than the DTMA (non-GMO) varieties?