

# Maximizing the Value of Confined Field Trial Results through Data Transportability



**Confined field trials (CFTs) are conducted** to inform the environmental risk assessment (ERA) required by regulatory authorities prior to approval of genetically engineered crops.



**Many countries require in-country field trials that duplicate the data** generated elsewhere. The scientific basis for requiring these trials is questionable, but policy and perception issues make accepting data from other countries difficult for many regulators.



**The primary variable that differentiates CFT locations is agro-climate.** Because of this, if data generated outside of a country can be shown to have been generated in the same agro-climatic conditions as those within a country, those data should satisfy any requirements for collecting in-country data.

Can agro-climate zones be used to identify surrogate environments outside of a country that can satisfy the need for collecting in-country field trial data?

The ILSI Research Foundation is addressing this question

2011-2013

## Conceptual Framework

The ILSI Research Foundation convened an expert working group of agronomists, plant breeders, entomologists, risk assessors and product developers. After two years of deliberation, the group published on a Conceptual Framework for Data Transportability in *Transgenic Research Journal*. The major conclusions of the paper indicated that the physical environment accounts for nearly all of the variability between CFT locations, because the biological and agronomic variables are tightly controlled.

2015-2016

## Tool Development

A second expert working group was formed by the ILSI Research Foundation in 2015, with expertise in crop modeling and global information systems, to develop criteria for an appropriate agro-climate stratification system to identify surrogate environments. They concluded that a global stratification system would be the appropriate tool and identified criteria for the preferred system.

2017

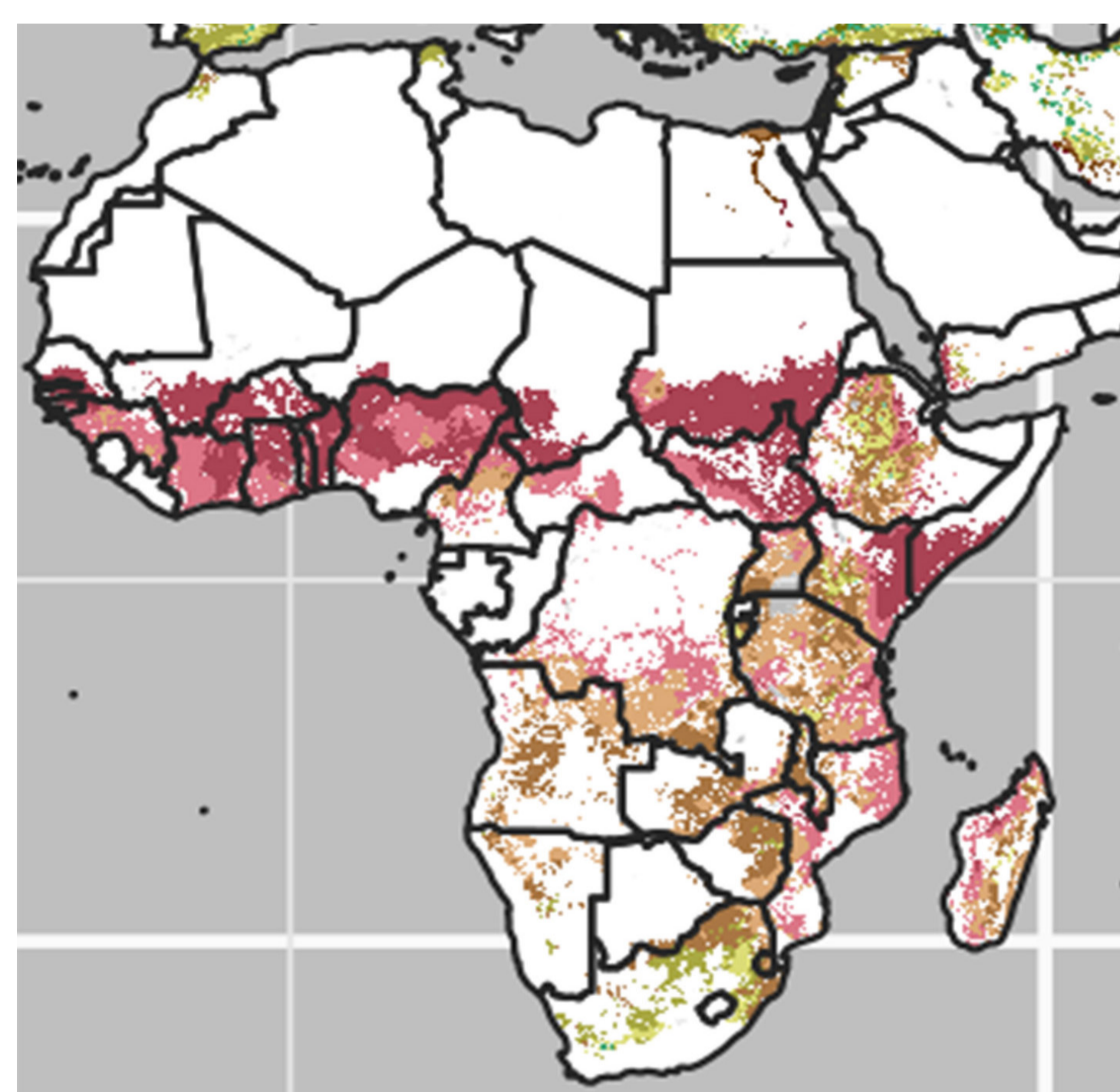
## Application

The ILSI Research Foundation is currently working with the Common Market for Eastern and Southern Africa (COMESA) to turn this concept into a practical tool for application in regional risk assessments in Eastern and Southern Africa. This tool will also be useful for planning field trials in other parts of the world. The Research Foundation is committed to making this resource available to benefit data collection and regulatory review for future crop development.

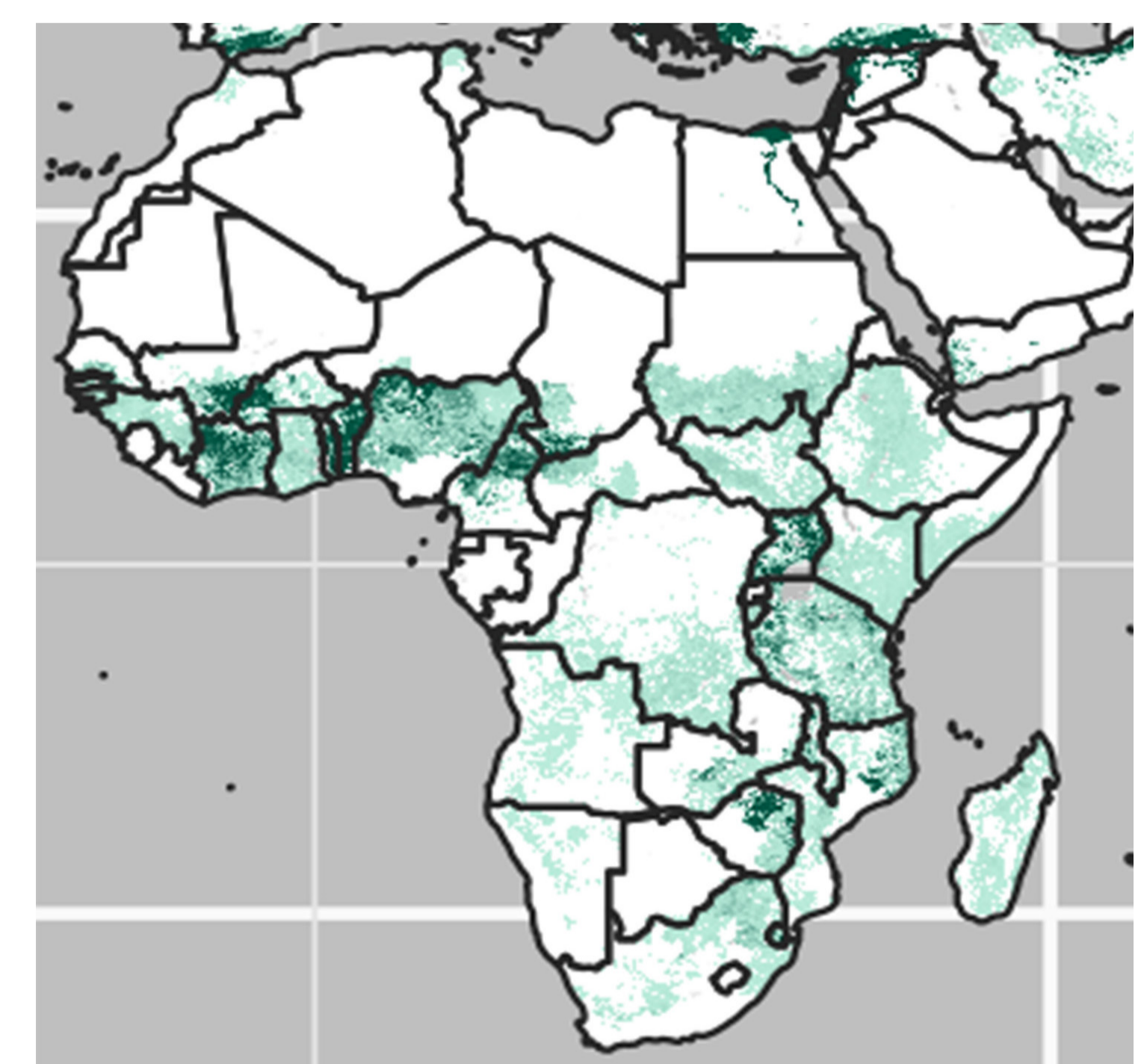
How could the concept of data transportability be applied toward informing regulatory decisions for GE cotton in Africa?

COMESA countries have adopted a regional policy in which GE crop applications are submitted to individual member states, however, risk assessment is performed by a COMESA committee at the regional level. By using a surrogate environment approach, these risk assessments can provide solid scientific support to decision makers in multiple countries throughout the region while minimizing the duplication of CFTs between countries.

1. The different colors in Map I represent different agro-climatic zones. In Map II, the green color represents all areas where cotton is grown in Africa. Note that cotton grows in areas corresponding to multiple agro-climate zones in Kenya.
2. The different colors representing agro-climate zones that occur in Kenya are also present in most other COMESA countries. Field trial data conducted in these climate zones within Kenya could facilitate GE cotton approval in other COMESA countries with similar climates.
3. CFT data obtained in Kenya could assist regulators in decisions regarding Bt cotton for ERA in Uganda, Rwanda, Burundi, Sudan, Ethiopia, D.R. Congo, Zambia, Zimbabwe, Malawi, Madagascar and Swaziland.



Map I: Distribution of Climate Zones



Map II: Distribution of Cotton Production



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