Data Transportability for Environmental Risk Assessment of GE Plants:
“Rationalizing Field Trials in an Irrational World”

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Contents of the Presentation

• Introduction to the ILSI Research Foundation and CERA
• Confined Field Trials for GE Crops
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  ▪ How did we get where we are?
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• CERA’s work on Data Transportability
  ▪ How did we start, and what have we learned?
  ▪ Where do we hope to go next?
International Life Sciences Institute (ILSI)

• ILSI is a nonprofit organization with a mission to provide science that improves human health and well-being and safeguards the environment

• Multisectoral and collaborative
  ▪ Outcomes are more impactful when informed by the international expertise and experience of scientists from government, private sector, academia and NGOs

• ILSI is a proven leader in fostering effective public-private partnerships worldwide
ILSI’s Thematic Areas

- Food & Water Safety
- Toxicology & Risk Science
- Nutrition, Health & Wellness
- Sustainable Agriculture & Nutrition Security
The ILSI Research Foundation improves environmental sustainability and human health by advancing science to address real world problems.
ILSI Research Foundation

• A distinct, complementary, non-membership component of the ILSI network
• Funded through grants and donations from public and private sector sources
• We use the same global, multi-sectoral approach as ILSI’s other entities to advance our mission
2015 Sources of Funding

- Public Sector: 76%
- Intergovernmental Organizations: 9%
- Private Sector: 15%
How we work

The ILSI Research Foundation is:

• A **leader** of collaborative research in a carefully curated portfolio of scientific areas.

• A **convener** to address immediate or longer term scientific issues of importance.

• A **facilitator** that helps build bridges between organizations to work collectively on scientific topics that warrant action.
How we are organized

Other Programs

Global Nutrition Strategy

Open Data
The Center for Environmental Risk Assessment (CERA) works to develop and apply sound science to the environmental risk assessment of agricultural biotechnologies so their contributions to sustainable production of food, fuel and fiber may be safely realized*. 

*The original text had an asterisk next to the word "realized."
Confined field trials for GE crops

• What is the role of a confined field trial?
  ▪ For biosafety testing?
  ▪ For product development?

• What sort of data is routinely collected during confined field trials
  ▪ How does this relate to biosafety?
What is the role of the Confined Field Trial?

Developers conduct field trials for a variety of purposes
• Basic Research
• Collecting experimental biosafety information
• Generating material for laboratory testing
• Agronomic testing - which is different than biosafety testing
The OECD “Scale up” Document

- Describes how the considerations for environmental safety change at each level of product development
  - “Stepwise development”
  - From laboratory to greenhouse to confined field release to full environmental release
  - Each step is useful for informing the eventual environmental risk assessment
“Stepwise Development” has been widely misconstrued

- Frequently interpreted to mean every country should require a GE plant to enter the laboratory, greenhouse and CFT for studies within their jurisdiction.
  - Almost all countries have a de facto requirement for “local” CFTs
  - To understand why this may not be useful or necessary, it is helpful to consider what sort of data from CFTs actually supports ERA
Measuring intended characteristics

• Confirm that the trait is functional in realistic environmental conditions
  ▪ Often more of a performance issue than a safety one
Addressing unintended effects of genetic engineering

• Most of the data collected (by volume) in a CFT is to address “unintended effects.”
  ▪ Generally not hypothesis driven
• Measurements are taken to compare with the non-transformed plant
  ▪ Just to see if there is anything abnormal that might indicate a potential risk
  ▪ Match up with agronomic performance data that would be collected anyway
  ▪ Typically measure growth and reproductive characteristics that have some relevance to the ability of the plant to survive, persist, or spread in the environment
• These data are all comparative
  ▪ Measured against the untransformed counterpart and typically reference varieties as well.
What is not typically measured in CFTs?

• Data are generally not collected detailing how the plant interacts with the biotic environment
  ▪ Biotic interactions are typically tightly controlled and minimized under conditions of confinement
  ▪ Sometimes arthropod surveys are conducted
    • These are not very informative for a variety of reasons
  ▪ Occasionally soil measurements are taken
    • These usually are swamped by natural variability in soil measurements

• Most of the useful data on biological interactions comes from the laboratory
  ▪ Laboratory tests are more definitive
How does this look in practice?

• In the country where the crop originates
  ▪ Laboratory and field research is carried out
  ▪ These tests are necessary for development, and provide valuable data for ERA and safety assessment

• When a product developer tries to move that crop to a new country
  ▪ Most of the laboratory data is considered “transportable”
  ▪ However field trials are typically required
    ▪ Usually under the guise of making observations about biodiversity interactions - data for which generally don’t come from field trials
How has CERA been addressing this question

• We approach the issue from a “ground up” scientific perspective
  ▪ “What do you need to know about two environments in order to know if they are similar enough to make field trial data from one applicable to another”

• Expert working group formed in 2011
  ▪ Agronomists, plant breeders, entomologists, risk assessors and product developers
  ▪ Met four times over two years and eventually produced a publication
  ▪ Supported by a grant from USDA
Transportability of confined field trial data for environmental risk assessment of genetically engineered plants: a conceptual framework

Monica Garcia-Alonso · Paul Hendley · Franz Bigler · Edgar Mayeregger · Ronald Parker · Clara Rubinstein · Emilio Satorre · Fernando Solari · Morven A. McLean

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Major conclusions of the paper

• The physical environment dominates the results of the CFT
  - Climate
  - Cultivation practices

• The biotic environment is tightly controlled
  - This is by design to achieve consistent results in comparisons between the GE plant and controls
  - Doesn’t have a significant influence on the comparative assessments resulting from CFTs
Some Key Recommendations

• Consider preparation of a tool to identify agroclimatic zones where CFTs would be expected to produce similar results
• Produced a “Conceptual Framework” for doing that
• Identified some outstanding scientific issues
  ▪ Would a map need to be crop specific?
  ▪ Can a generic global zonation scheme be applied for this purpose?
  ▪ Would local or regional maps add value?
Expert working group #2

• Convened in 2015 (supported by a different USDA grant)
• Including different expertise
  ▪ Crop Modelers and Global Information System experts
Conclusions from EWG # 2

• A global stratification system is appropriate to identify climatic zones expected to produce similar field trial results

• Identified Criteria for a preferred system
  ▪ Global stratification is preferred, as regional strata may mis-identify zones
  ▪ Sufficiently high number of zones to indicate homogeneity within a zone
  ▪ Data sources should be transparent and preferably accessible to users
  ▪ Scheme should be flexible to allow modification over time
    ▪ Including to incorporate changes in climate and cropping over time.
Global Environment Stratification (GEnS) selected for pilot

- Peer reviewed
  - Published and demonstrated applications for multiple purposes and regions
- Sufficient number of strata
- Fully transparent
- Freely accessible
- Largely data driven rather than subjectively chosen zones
  - Exclusively climatic data
- Well justified selection of variables
- Statistically Hierarchical
- Flexible
- The statistical method aims for maximizing within-strata homogeneity
- Uses real data rather than modeling data
- Base spatial resolution is fit for purpose
- Uses well accepted global data
- Validates successfully against zonations developed by other means
Based on the conclusions we have proceeded with some additional work

• Using GEnS to map crop production areas (as identified in Monfreda et al. 2008)
• Overlaying the GEnS agroclimatic zones over those crop production areas
• I will present two examples:
  ▪ Maize
  ▪ Cassava
Step one: Where is the crop grown? (Maize)
What do those environments look like? (Maize)
How does global maize production look, across environments?
Maize Production in Africa
Environment for Maize production
Global cassava production

Harvested area

Fraction of gridcell

- >0.0083
- 0.0062
- 0.0042
- 0.0021
Production environments for cassava
Cassava production by volume across environments

% total harvested area

<table>
<thead>
<tr>
<th>Environment</th>
<th>% Harvested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arctic</td>
<td>Low</td>
</tr>
<tr>
<td>Extremely cold and mesic</td>
<td>Low</td>
</tr>
<tr>
<td>Extremely cold and wet</td>
<td>Very Low</td>
</tr>
<tr>
<td>Cold and mesic</td>
<td>Very Low</td>
</tr>
<tr>
<td>Cool temperate and xeric</td>
<td>Very Low</td>
</tr>
<tr>
<td>Cool temperate and moist</td>
<td>Very Low</td>
</tr>
<tr>
<td>Warm temperate and xeric</td>
<td>Very Low</td>
</tr>
<tr>
<td>Warm temperate and mesic</td>
<td>Low</td>
</tr>
<tr>
<td>Hot and arid</td>
<td>Very Low</td>
</tr>
<tr>
<td>Hot and dry</td>
<td>Low</td>
</tr>
<tr>
<td>Extremely hot and arid</td>
<td>Very Low</td>
</tr>
<tr>
<td>Extremely hot and xeric</td>
<td>Very Low</td>
</tr>
<tr>
<td>Extremely hot and moist</td>
<td>Low</td>
</tr>
</tbody>
</table>

The bar chart shows the percentage of total harvested area for different environments. The y-axis represents the percentage of harvested area, while the x-axis lists various environmental conditions. The chart indicates that the highest percentage of harvested area is in the extremely hot and moist environment, followed by hot and dry, and extremely hot and xeric environments.
Cassava production in Africa
Cassava production environments
What’s Next

• Continue producing crop production area and climate maps
  ▪ Ultimately working towards an online tool that allows people to use these maps to identify representative trial sites

• Proposed work with COMESA
  ▪ Subject of a USDA grant
  ▪ Approved, barring some additional administrative work
Why does this work benefit COMESA?

• The regional risk assessment model proposed under RABESA lends itself to a data transportability model
  ▪ To better understand how data collected in one country relates to the different countries in COMESA
  ▪ To rationalize CFT requirements for crops developed outside of COMESA
  ▪ To facilitate rational planning for “locally” developed crops
Thank You!

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Find out what’s new with the ILSI Crop Composition Database

Advancing Science to Address Real World Problems

The International Life Sciences Institute Research Foundation (ILSI Research Foundation) is a non-profit, public charitable organization with a mission to improve environmental sustainability and human health by advancing science to address real world problems.

Working for Public Benefit

As an international science leader, the ILSI Research Foundation collaborates with experts to respond to relevant issues that have a global impact. The Research Foundation’s work is organized into four areas:

- Food & Water Safety
- Nutrition & Health
- Risk Science & Toxicology
- Sustainable Agriculture & Nutrition Security
Environments are organized around heat and moisture