The ILSI Research Foundation: Scientific Support for the Safety Assessment of Food and Feed Derived from Agricultural Biotechnologies

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Contents of the Presentation

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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

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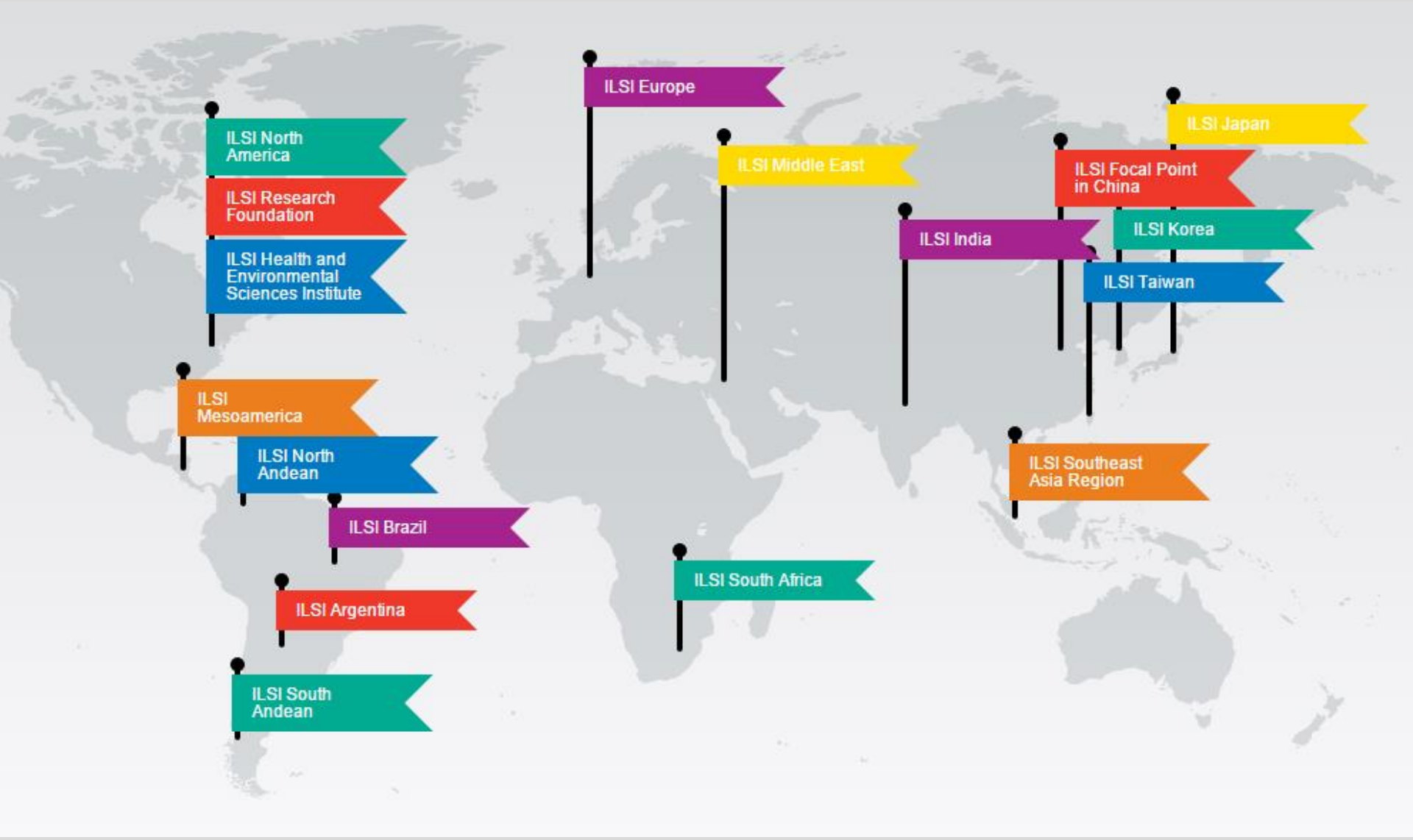
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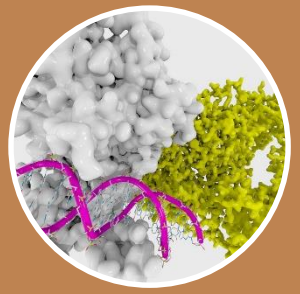
ILSI's Thematic Areas

Food & Water Safety



Toxicology & Risk Science

Nutrition, Health & Wellness

Sustainable Agriculture & Nutrition Security

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The ILSI Research Foundation improves environmental sustainability and human health by advancing science to address real world problems.

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- 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

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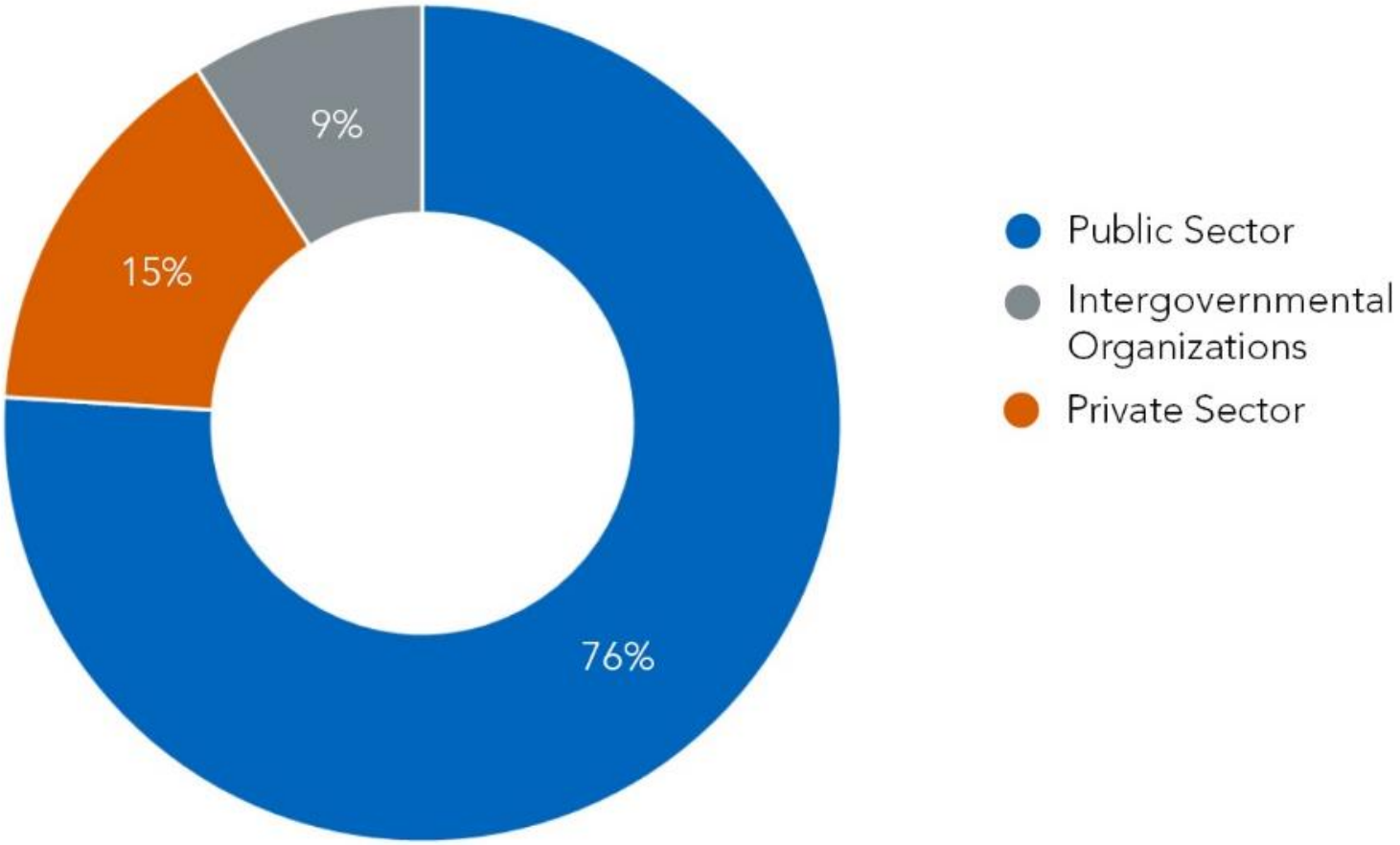
2015 Sources of Funding



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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.

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How we are organized

cimsans

Center for Environmental Risk Assessment

Center for Safety Assessment of Food & Feed

Other Programs

Global Nutrition Strategy

TAKE 10

Open Data

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The Center for Safety Assessment of Food and Feed (CSAFF) promotes science-based approaches to the safety assessment of food and feed, with a strong emphasis on improved knowledge dissemination and capacity building.

Center for Safety Assessment of Food & Feed (CSAFF)

- Protein monographs
- Retrospective of the safety assessment of foods derived from genetically engineered plants
- Toxicology training program
  - Phase I: Concepts & principles, bioinformatics
  - Phase II: Experiential training at DuPont's Stine Haskell Research Center

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Capacity Building

- South Asia Biosafety Program
  - India, Bangladesh, Pakistan
- Partnership for Biosafety Risk Assessment and Regulation
  - OECD, World Bank, Bangladesh, Colombia, Kenya, Paraguay, Tanzania, Uganda, Uruguay, Vietnam

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Why does the ILSI Research Foundation work on Biotechnology?

- We aren't a product developer
- We aren't a lobbying organization
  - We don't advocate for the adoption of technologies or particular policies
- But we do have a mission to advance science for public benefit
- Science is needed to inform public policy

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What is the impact of Biotechnology on sustainable food security?

- Biotechnology is a tool
  - Not a single product or idea
  - Like ALL tools it has the potential to be beneficial or harmful depending on how it is used
  - Biotechnology is not “good” or “bad”
    - But it is powerful!
- There is accumulated evidence that biotechnology applications are making substantial contributions to sustainable food security
  - And future products show even more promise

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Biotechnology contributes to sustainable food security (1 of 3)

- Herbicide tolerant crops have contributed to increased use of low and no tillage agriculture
  - These practices prevent erosion and conserve soil nutrients
- Insect resistant maize improves quality
  - Reducing insect damage
  - Preventing the growth of fungi that produce mycotoxins

Biotechnology contributes to sustainable food security (2 of 3)

- Virus resistant papaya
  - Has been essential for continued production of this crop
- Agronomically improved varieties provide flexibility to producers
  - Leading to reduced use of undesirable chemicals
  - Reduced greenhouse gas emissions

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Biotechnology contributes to sustainable food security (3 of 3)

- Products under development will contribute to improved nutrition and sustainable food production
  - Golden Rice
  - Iron Fortified Rice and Sorghum
  - Water Efficient Maize for Africa (WEMA)
  - Late Blight Resistant Potato

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Regulation is intended to facilitate the use of beneficial technologies

- Access to biotechnology products, and corresponding benefits to sustainable food security, is limited in the absence of effective science based regulation
- Our programs are intended to provide technical support to enable regulators to accomplish their goals
  - Environmental Risk Assessment
  - Food Safety Assessment
- Allowing countries to further the policies they choose with respect to biotechnology

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Why do we conduct food safety reviews?

- Food safety is a fundamental public health concern
- Ensuring a safe food supply is goal of national food safety program.
- There are many challenges to accomplishing this
  - Changing global patterns of food production
  - International trade
  - Technology
  - Changing public expectations for health protection

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Putting gene edited plants in context

- Humans first began practicing agriculture over 12,000 years ago, and since that time, there has been a continuous development of new plant varieties.
- For example, US Department of Agriculture's Plant Introduction Station in Ames, Iowa holds 19,780 different samples or "accessions" of maize.

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How do we know any foods are safe?(1 of 2)

- Historically, based almost entirely on tradition and cultural experience
- In practice: very few of the foods eaten today have been subjected to any toxicological studies
  - Yet, these are generally accepted as safe

How do we know any foods are safe?(2 of 2)

- Even foods with toxins, anti-nutrients, or allergens are considered safe because of long history of use
  - peanuts, eggs, fish, shellfish, potato, tomato, cassava, etc.
- Food safety regulations are mostly concerned with microbial and chemical contaminants
  - Not the safety of the foods themselves

Excerpted from the Codex Guideline CAC/GL 45-2003

Section 1 paragraph 3

"The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities, such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods have been assessed scientifically in a manner that would fully characterize all risks associated with the food. Further, many foods contain substances that would probably be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered."

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The introduction of Biotech foods has led to a new safety assessment paradigm (1 of 3)

- At least partly a response to public perception
  - Rather than evidence of safety issues in Biotech plants
  - The perception that these foods are “new and different” and “someone should look at whether they are safe”

This is not always a well informed perception…

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The introduction of Biotech foods has led to a new safety assessment paradigm (2 of 3)

- The paradigm for conducting these assessments was developed in the 1980's and 1990's
  - Beginning with the Organization for Economic Cooperation and Development (OECD)
  - Internationally agreed in the form of the Codex guidelines for foods derived from modern biotechnology
    - CAC/GL 45-2003

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The introduction of Biotech foods has led to a new safety assessment paradigm (3 of 3)

- This paradigm is for the assessment of the safety of a whole food
  - It is comparative, by necessity
  - The biotech food is compared to the conventional counterpart with regard to specific characteristics
    - Any identified differences are assessed to determine if they are a safety concern

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Codex Safety Assessment (in brief)

- expressed substances (non-nucleic acid substances)
  - Often referred to as “novel” or “introduced” substances
  - Assessed for toxicity and allergenicity

- intended changes

- compositional analyses of key components,
- evaluation of metabolites
- food processing
- nutritional modification

- unintended changes

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Conclusions

- Foods derived from agricultural biotechnology are the only foods to undergo routine whole food safety evaluations
  - The assessment paradigm could be used for foods derived from other technologies, or for conventionally derived foods
- This evaluation is comparative
- Consideration is given to any newly introduced substances
  - Toxicity or allergenicity
- As well as the composition of the food

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Thank You!

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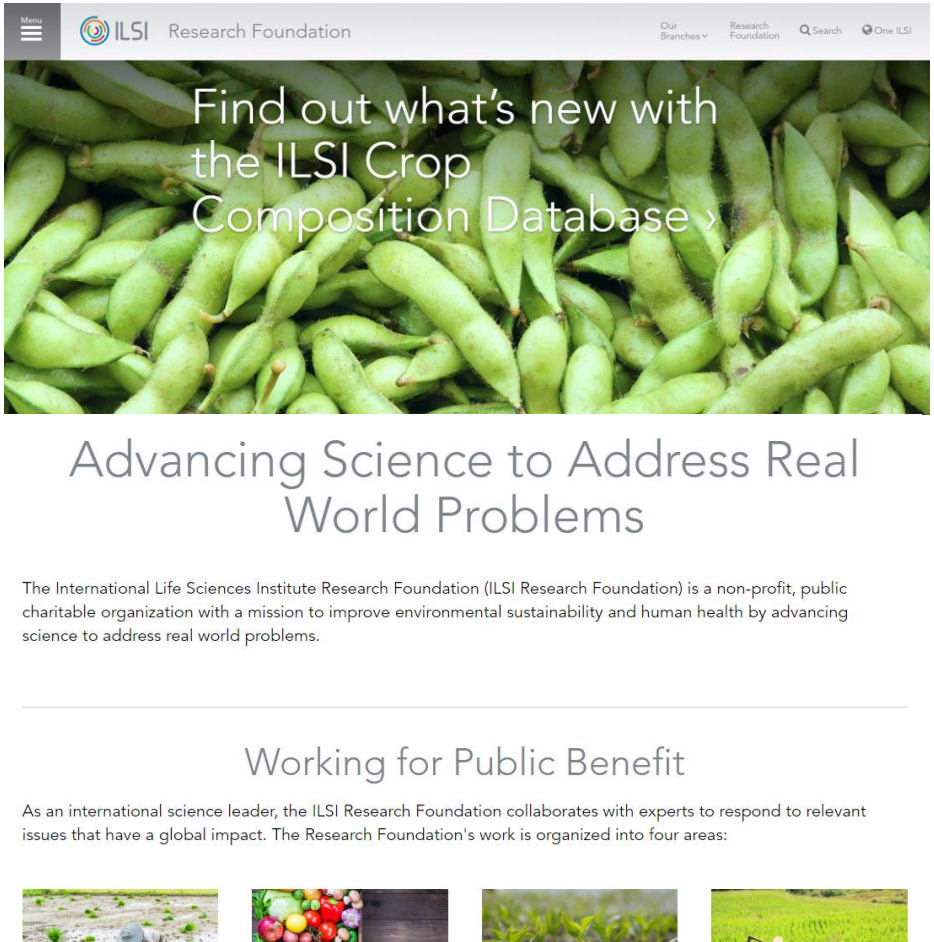

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