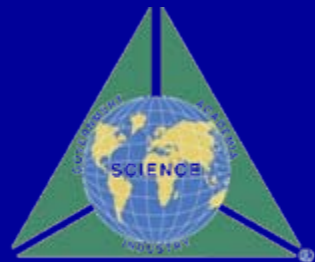


ILSI Health and Environmental Sciences Institute (HESI)

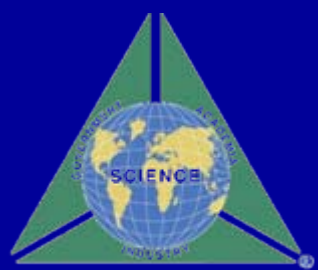
Protein Allergenicity Technical Committee

New Methods Workshop

October 23-25, 2007



H E S I.



What is HESI?

H E S I.

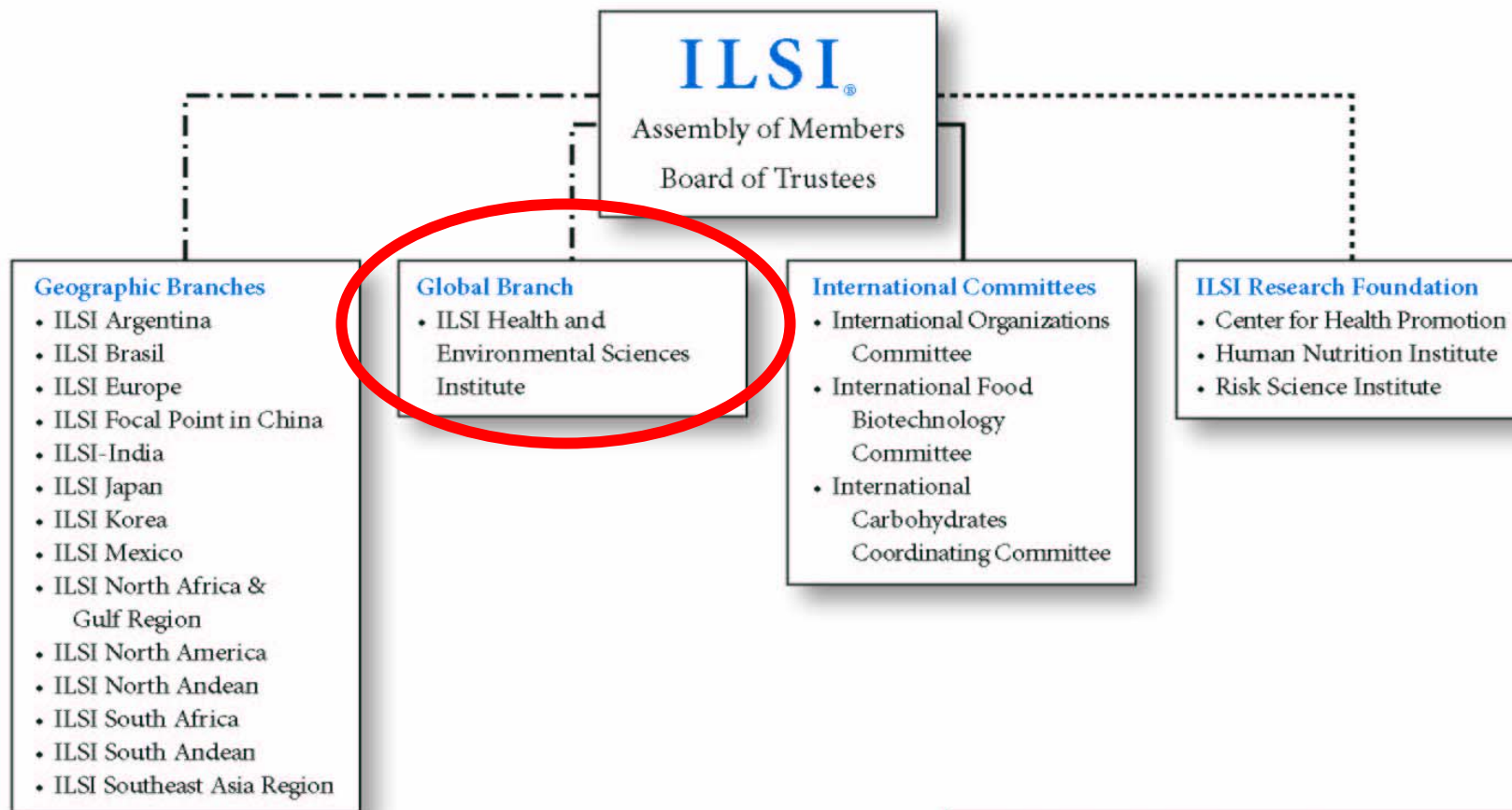
HESI = Health and Environmental Sciences Institute

MISSION STATEMENT: To stimulate and support scientific research and educational programs that contribute to the identification and resolution of health and environmental issues of concern to the public, scientific community, government agencies, and industry.



INTERNATIONAL LIFE SCIENCES INSTITUTE®

ORGANIZATION CHART



Solid line (—) denotes legal/fiduciary responsibility.
Dotted line (· · ·) denotes oversight and control of a supporting organization.
Dots and Dashes (· · - -) denotes affiliation by charter agreement.



What is HESI?

HESI Membership

- ❖ Agricultural Chemicals
- ❖ Biotechnology Products
- ❖ Chemical Industry
- ❖ Consumer Products
- ❖ Petrochemicals
- ❖ Pharmaceutical Industry

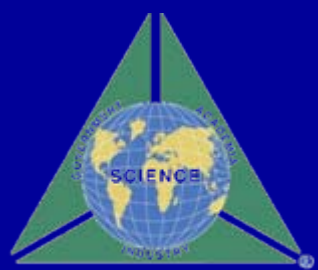
*53 corporate members as of July 2007
(representing 10 countries on 3 continents)*



HESI Board of Trustees

❖ 31 members: 16 public (academic and gov't) + 15 industry.

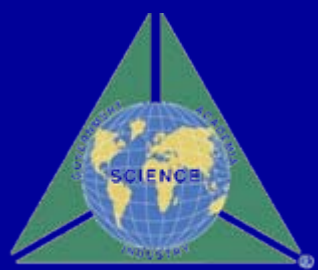
- Global board – Denmark, France, Germany, Japan, Netherlands, Sweden, U.K. and U.S.
- Exemplary leadership in toxicology, risk assessment, drug discovery and drug development – >5,500 scientific publications.



What does HESI do?

H E S I.

- ❖ HESI provides a collaborative forum for government, academic, and industrial scientists to work in concert to develop innovative and high quality approaches to resolving complex scientific issues that cross all sectors.
- ❖ HESI operates as a membership-based non-profit: companies pay annual fees to be members.
(Some project funding also comes from government and other sources)



What HESI is not...

- ❖ Not an industry trade association – no lobbying or advocacy purposes.
- ❖ Not designed to directly change regulatory policy – HESI works on scientific issues.
- ❖ Not designed to address business- or product-related issues – HESI works on scientific issues.
- ❖ Not a professional society – individual scientists cannot “join”; but are engaged in activities.
- ❖ Not (necessarily) a short-term fix – HESI project objectives tend to address mid- to long-term scientific issues.



What are HESI's Strengths?

❖ Long Track-Record of Successful Collaborations:

- Initiated in 1989
- Extensive experience, dozens of programs and committees
- Respected internationally for open, balanced approach; and for ability to reach consensus
- Demonstrated ability to create partnerships that promote synergy among industry, government, and academic colleagues



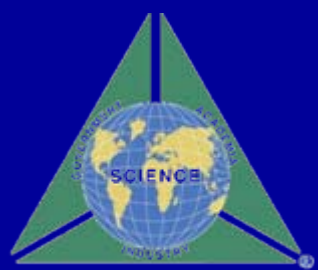
What are HESI's Strengths?

❖ Global scientific organization:

- Public and private sector participants in North America, Europe, Asia, and South America.

❖ Transparent

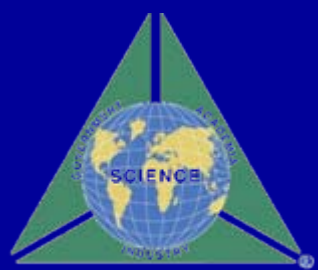
- All work is published and publicly available.
- Most work products destined for peer reviewed literature. HESI has own peer-review process BEFORE submitting to journals.



What are HESI's Strengths?

❖ Diverse:

- Tripartite approach is key: industry + academic + government scientists.
- Academic advisors and government scientists are critical participants in aspects of all projects: identification, design, execution and interpretation.
- Board leadership is 50% public/ 50% private.
- Multi-sector committees.



H E S I.

2007 HESI Scientific Portfolio

Technical Committees

- Application of Genomics to Mechanism-based Risk Assessment
- Development and Application of Biomarkers of Toxicity
- Developmental and Reproductive Toxicology
- Immunotoxicology
- Integration of Biomonitoring Exposure Data into the Risk Assessment Process
- Nonclinical / Clinical Safety
- Correlations
- Protein Allergenicity
- Risk Assessment Methodology

Project Committees

- Biological Significance of DNA Adducts
- Cancer Hazard Identification Strategies
- CV Safety – Proarrhythmia Models
- Development of Methods for a Tiered Approach to Assess Bioaccumulation
- Nanomaterials Environmental Health and Safety
- PPAR Agonist Tumorigenicity

Emerging Issues Subcommittees

- Impact of Positive Results from in vitro Genotoxicity Assays
- Pharmacokinetics / Route-to-Route Extrapolation
- Risk Assessment in Sensitive Populations
- Emergence of Animal Alternative Needs in Environmental Risk Assessment



HESI Portfolio Development & Maintenance

H E S I.

- ❖ Project proposals solicited annually from multi-sector base; Open call for proposals
- ❖ Project selection based on multi-sector voting process
- ❖ New programs must address high priority scientific issues with potential for resolution; where HESI can make a unique impact
- ❖ Board level Committee reviews portion of portfolio every 2 years to ensure continued quality
- ❖ Many Committees undertake multiple projects

Project Outcomes

- ❖ Fund Basic Research to Improve Scientific Understanding for Benefit of Public Health
- ❖ Development of Predictive Assays for Human Outcomes
- ❖ Hosting International Workshops, Symposia, and Conference
- ❖ Development of Peer-Reviewed Publications
- ❖ Project Outcomes are Publicly Available