HESI SCIENTIFIC MAPPING

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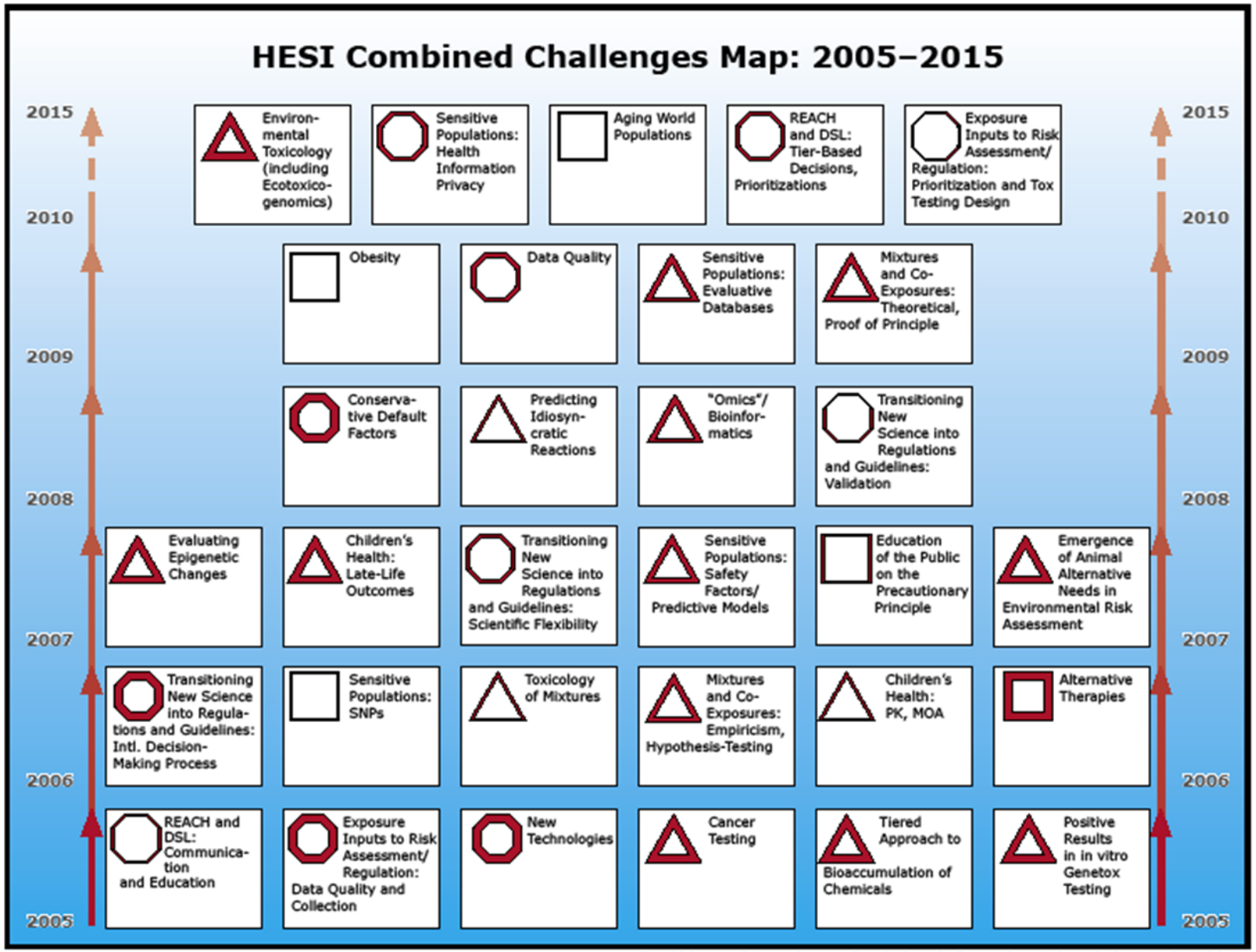
HESI Associate Director
Scientific Program Stewardship

12 May 2010
AOM Business Meeting
HESI Annual Meeting
Reston, VA

Updated Spring 2008



2010-2020 HESI COMBINED CHALLENGES MAP

New!

H E S I

Relative impact

- Animal use and welfare
- Vaccine development, use, and safety
- Genomics
- Human health: scientific evaluation of sensitive populations
- Sustainability
- Stem cell technology
- Food safety
- Communication and perception of risk versus benefit

- Improved risk assessment through biomonitoring and epidemiology
- Risk / benefit: regulation of chemicals in commerce
- Translational biomarkers
- Risk assessment of sensitive / vulnerable populations
- Environmental quality
- Emerging contaminants
- Safety of genetically modified organisms and foods

- Regulatory framework for new methods
- Computational tools / toxicology
- Use of science in setting public policy
- "Omics" in risk assessment
- Risk assessment of co-exposures
- Nanomaterials / nanotechnology
- Paradigm shifts in risk assessment / life cycle assessment
- Stem cell therapy
- Individual susceptibility

- Improved testing and assessment strategies
- Regulatory framework for carcinogenicity testing
- Alternatives to animal models
- Epigenetics in risk assessment
- Exposure-based risk assessment
- Improved biomonitoring through biomarkers

Time: immediate (2010) to long-term (2020)

Each axis appearing on the 2010-2020 HESI Combined Challenges Map is a continuum. All issues on the map are of high importance/impact based on prioritization by the participants in the 2009 HESI mapping exercise. "Relative impact" is a qualitative measure of importance among high priority topics. The location of issues along the "time" continuum is an approximation of when the topic is likely to become a major issue in the timeframe from 2010 to 2020.

2009 Scientific Mapping Initiative

Purpose:

- **To identify health and environmental issues of scientific, regulatory, and societal importance during the next decade.**
- **To focus on and predict issues likely to be central to the strategic agendas of individual companies and regulatory authorities in the developed world.**
- **To directly contribute to HESI's strategic planning, but also to develop objectives that could be relevant for other institutions and organizations.**

2009 Scientific Mapping Initiative

Not in the scope of this initiative:

Efforts to address, advocate, or manage the prioritized issues.

2009 Scientific Mapping Initiative

Staged initiative:

1) **January 28-29, 2009, mapping meeting in Hamamatsu, Japan**

2) **July 28-29, 2009, mapping meeting outside of Washington, DC**

January 28-29, 2009, HESI Scientific Mapping Meeting

ACT CITY Hamamatsu Congress Center, Shizuoka, Japan

Japan Mapping Meeting Steering Team

- Dr. Marc Bonnefoi (sanofi-aventis)
- Dr. Samuel M. Cohen (University of Nebraska Medical Center)
- Ms. Nancy Doerrer (HESI)
- Dr. Shoji Fukushima (Japan Bioassay Research Center)
- Dr. Ronald Hines (Medical College of Wisconsin)
- Dr. Michael Holsapple (HESI)
- Dr. Toshihisa Ishikawa (Tokyo Institute of Technology / RIKEN)
- Dr. Sunao Manabe (Daiichi-Sankyo)
- Ms. Ayako Takei (ICaRuS Japan)
- Dr. Hiroyuki Tsuda (Nagoya City University Graduate School)

Japan Mapping Meeting: Main Objectives

- Develop and secure agreement on a list of key issues (scientific, regulatory, and societal challenges) to be included in the July 2009 HESI Scientific Mapping Meeting in the US

- Introduce the HESI Scientific Mapping process to the scientific community in Japan

Japan Mapping Meeting: Pre-Meeting Survey

- Survey (in Japanese) distributed in fall of 2008 to > 140 HESI key contacts and stakeholders in Japan
- 40 respondents
- 103 topics identified

Japan Mapping Meeting: January 28-29, 2009

- 27 Participants (64% public, 36% industry)
- Plenary sessions and concurrent breakout groups
  (*objective*: to foster clustering and prioritization of topics)

CONCLUSIONS:

High priority:

- Stem cell research and testing
- Nanomaterial safety
- Reevaluation of carcinogenicity testing/assessment

Medium priority:

- GMOs
- Training of regulatory staff in toxicity evaluation
- Exposures to multiple chemicals

July 28-29, 2009, HESI Scientific Mapping Meeting

Hyatt Regency Reston Hotel
Reston, VA, USA

PLANNING COMMITTEE

CO-CHAIRS:

Dr. Marc Bonnefoi (sanofi-aventis)
Prof. Alan Boobis (Imperial College London)

Dr. Scott Belanger (Procter & Gamble Company)
Dr. Henry Chin (Coca-Cola Company)
Dr. Samuel Cohen (University of Nebraska Medical Center)
Dr. Dennis Devlin (ExxonMobil Biomedical Sciences)
Ms. Nancy Doerrer (HESI)
Dr. Jay Goodman (Michigan State University)
Dr. Ernie Harpur (sanofi-aventis)
Dr. Ronald Hines (Medical College of Wisconsin)
Dr. Michael Holsapple (HESI)
Dr. Lewis Smith (Syngenta Ltd)
Dr. James Stevens (Eli Lilly and Company)
Ms. Ayako Takei (ICaRuS)
Dr. Sally Tinkle (NIEHS)
Dr. Jan Willem van der Laan (RIVM)
Dr. Kendall Wallace (University of Minnesota Medical School)
Dr. Hal Zenick (US EPA NHEERL)

July Mapping Meeting: Pre-Meeting Survey

- Online survey distributed in Spring 2009 to HESI contact list (hundreds of industry, government, and academic representatives)
- 84 respondents
- 115 topics identified

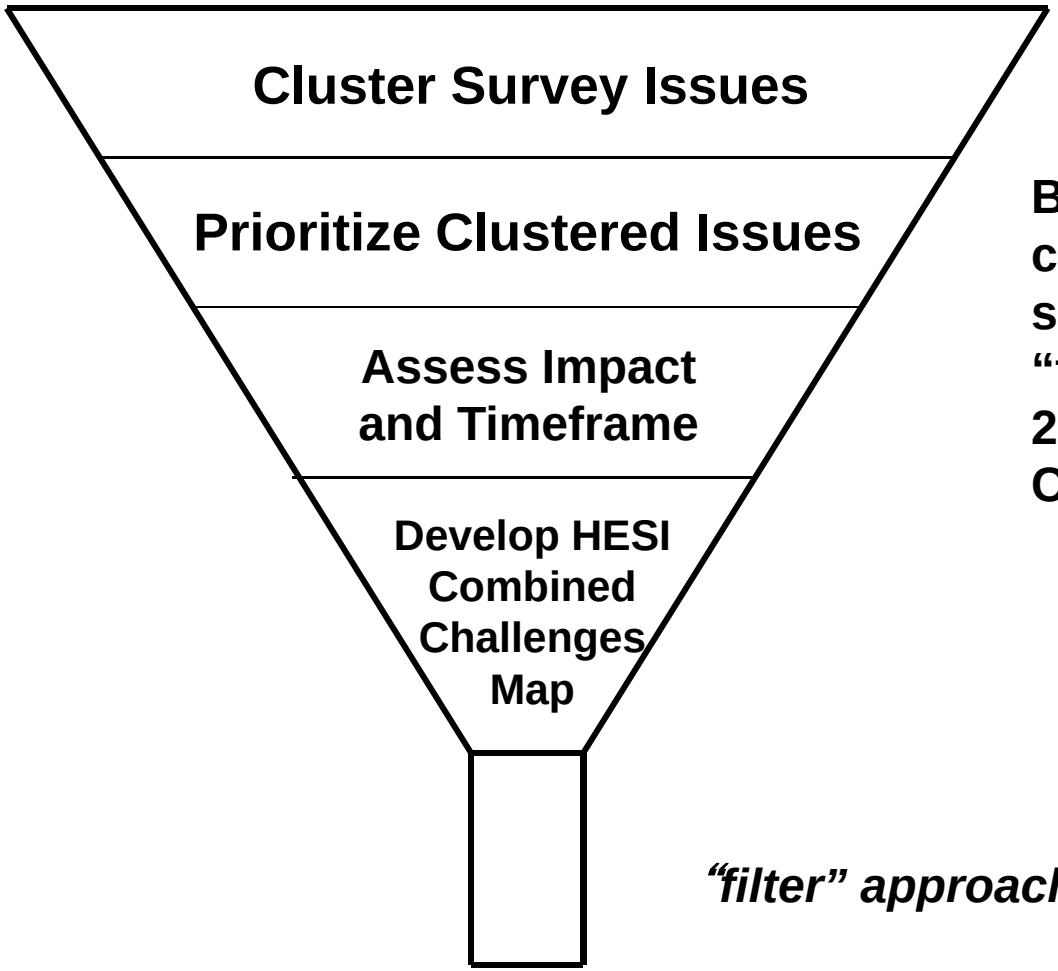
Pre-Meeting Streamlining

- Many topics were redundant or overlapped in some significant way
- Before the July meeting: The Planning Committee streamlined the number of topics by clustering into “like” categories

SCIENTIFIC MAPPING MEETING
July 28-29, 2009

- 48 Participants (69% public, 31% industry)
- Plenary sessions and concurrent breakout groups
- All high and medium priority issues identified at the Japan meeting were included

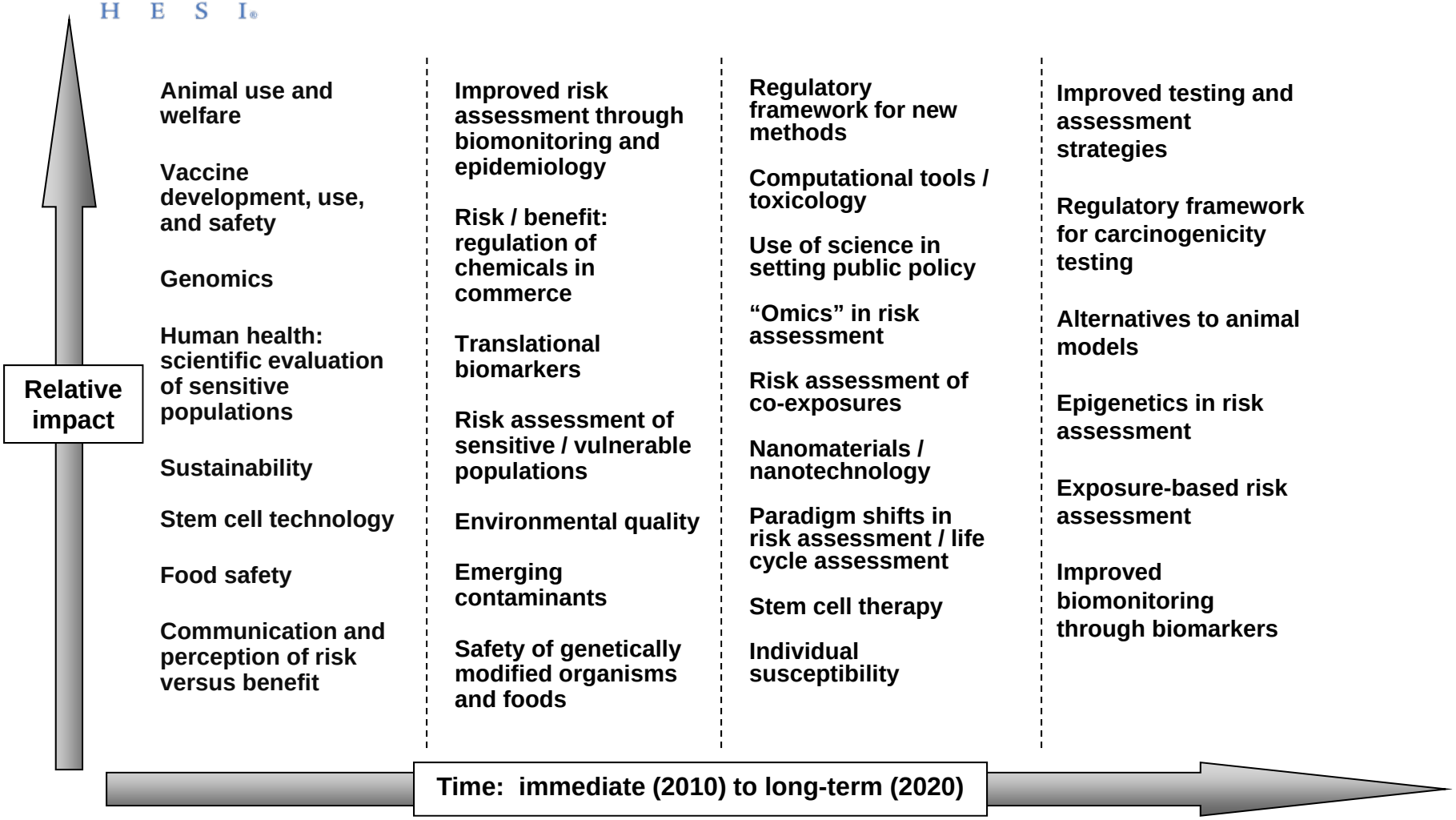
Mapping Process



"filter" approach

Breakout groups began by clustering, and then moved successively through the "filter" to arrive at the 2010-2020 HESI Combined Challenges Map.

2010-2020 HESI COMBINED CHALLENGES MAP



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HOW DOES THE 2010-2020 HESI COMBINED CHALLENGES MAP COMPARE TO HESI'S FIRST MAP (DEVELOPED IN 2004)?

Differences between 2004 and 2009 HESI Maps: Topic Classification

FIRST MAP:

Topics were identified by geometric shape:

SECOND (2009) MAP:

Because most topics could be characterized by more than one of the above classifications, a decision was made by to remove the designations.

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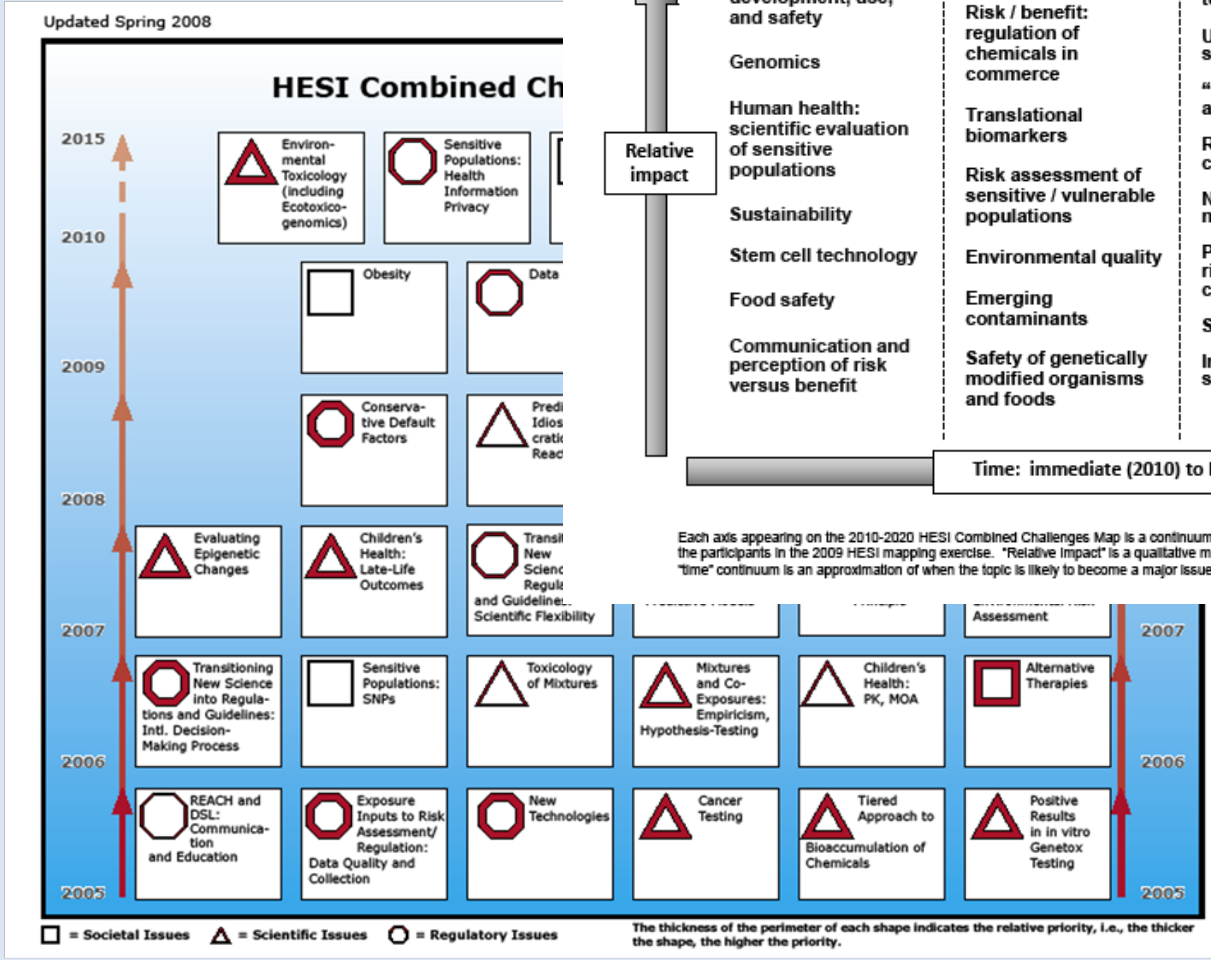
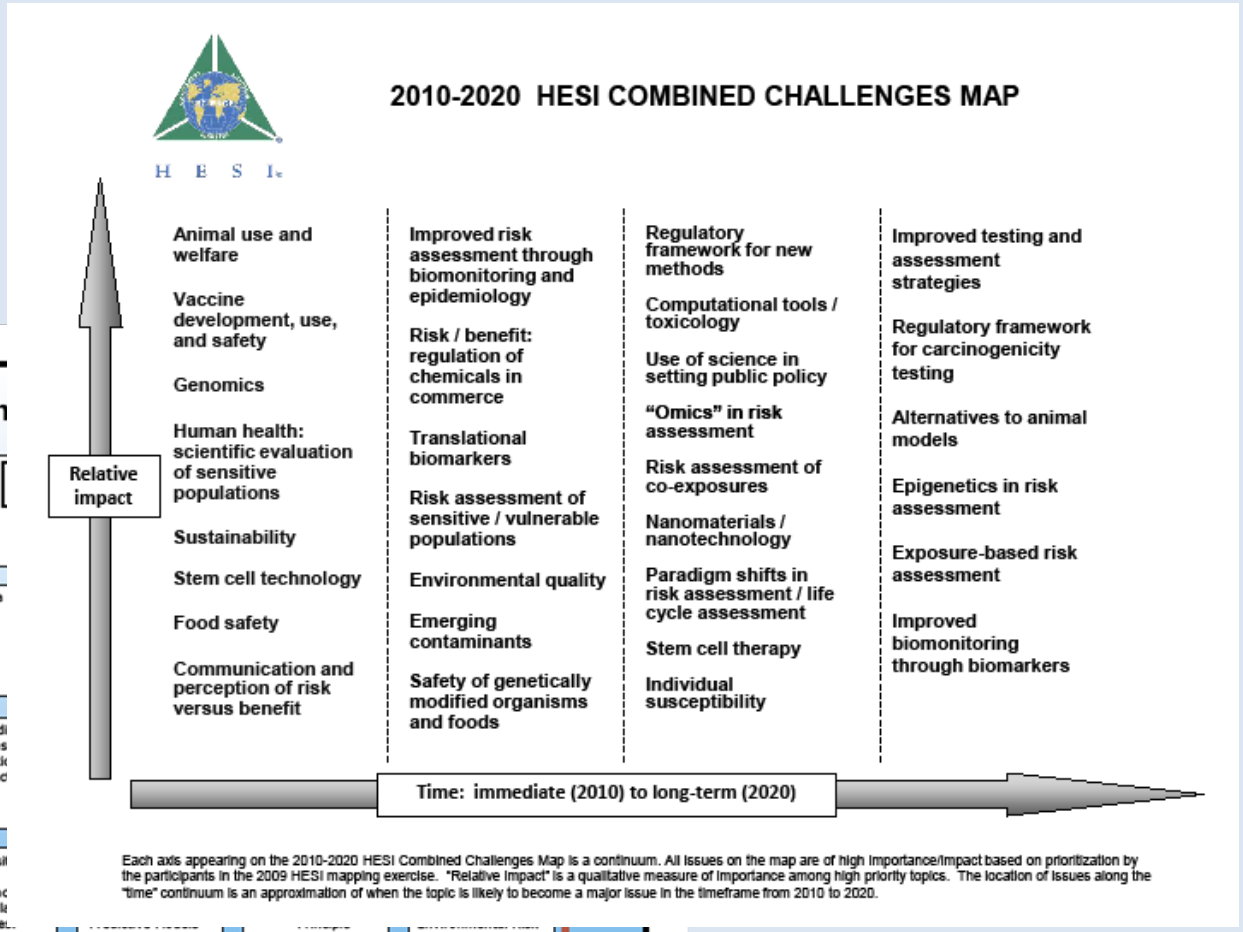

Updated Spring 2008
HESI Combined Ch
2015
2010
2009
2008
2007
2006
2005
Environ-mental Toxicology (including Ecotoxico-genomics)
Sensitive Populations: Health Information Privacy
Obesity
Data
Conserva-tive Default Factors
Evaluating Epigenetic Changes
Children's Health: Late-Life Outcomes
Scientific Flexibility
Transitioning New Science into Regula-tions and Guidelines: Intl. Decision-Making Process
Sensitive Populations: SNPs
Toxicology of Mixtures
Mixtures and Co-Exposures: Empiricism, Hypothesis-Testing
Children's Health: PK, MOA
Alternative Therapies
REACH and DSL: Communica-tion and Education
Exposure Inputs to Risk Assessment/ Regulation: Data Quality and Collection
New Technologies
Cancer Testing
Tiered Approach to Bioaccumulation of Chemicals
Positive Results in in vitro Genetox Testing
= Societal Issues
= Scientific Issues
= Regulatory Issues
The thickness of the perimeter of each shape indicates the relative priority, i.e., the thicker the shape, the higher the priority.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Differences between 2004 and 2009 HESI Maps: Timeline

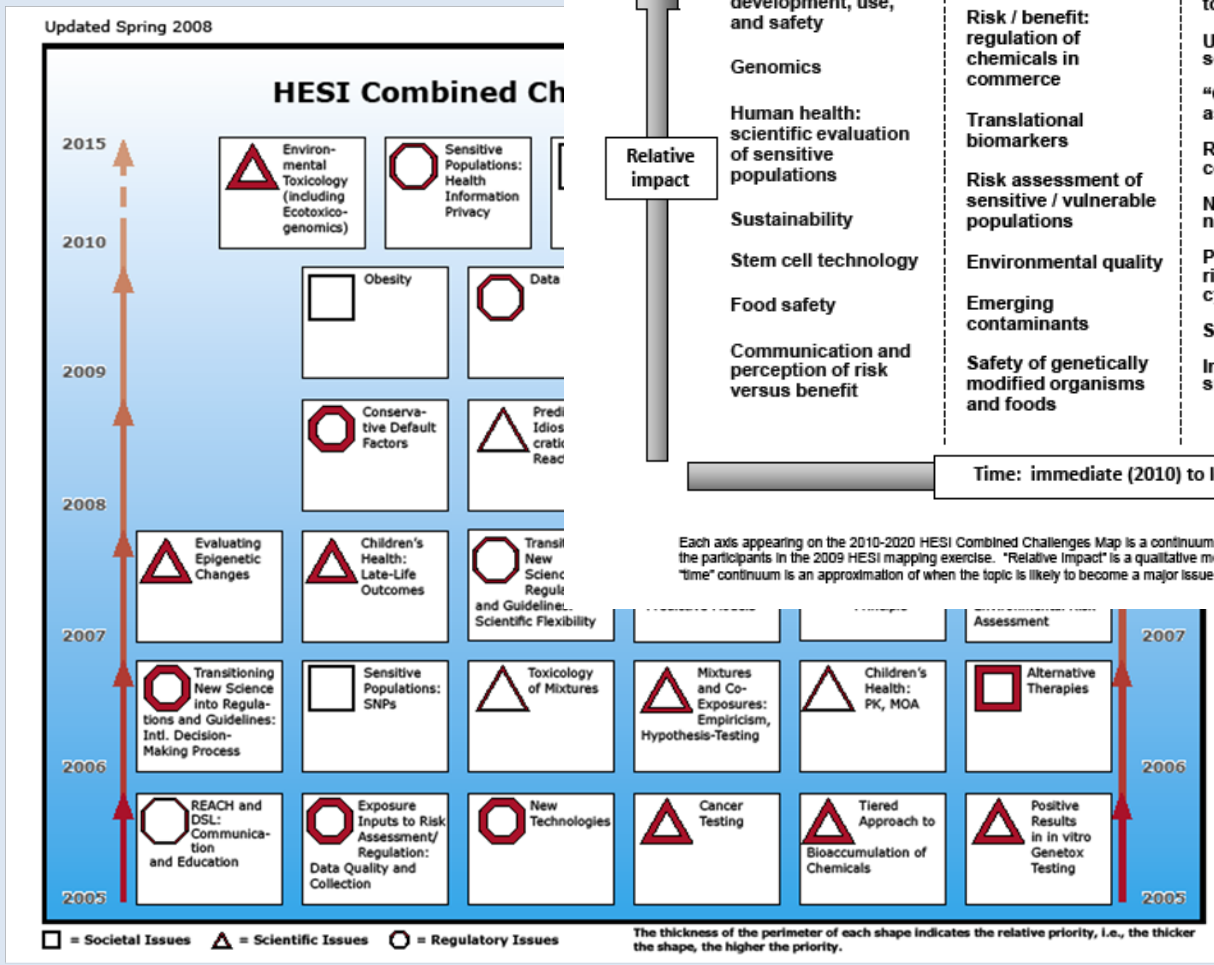
FIRST MAP:

Topics were arranged on a vertical timeline from 2005-2015.

SECOND (2009) MAP:

Topics are arranged along a continuum (the "x" axis) according to when HESI might reasonably contribute to the resolution of each issue [*i.e.*, immediate, short-term (1-2 years), medium-term (2-5 years), and long-term (5-10 years)].

Timeframe = 2010 to 2020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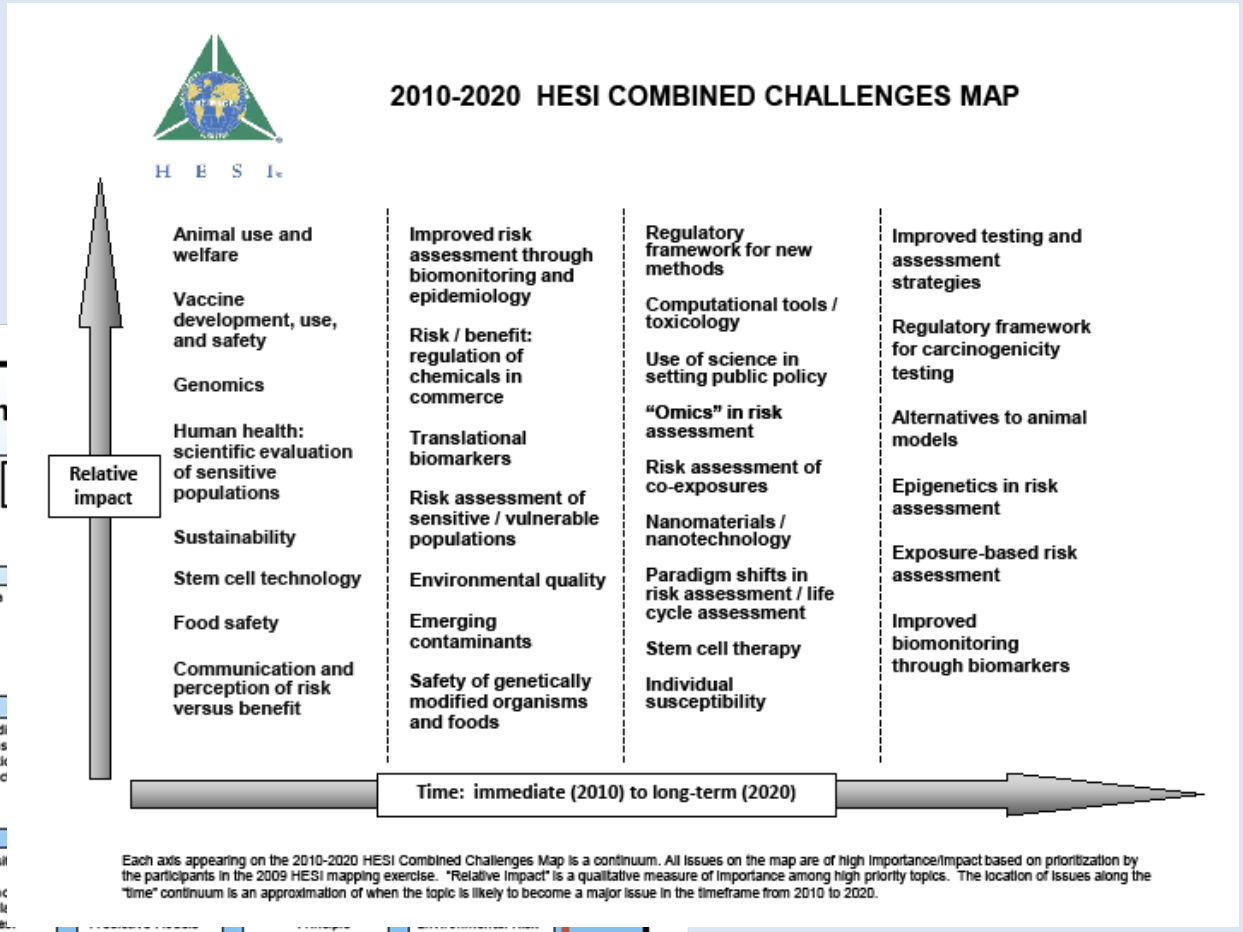
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Differences between 2004 and 2009 HESI Maps: Priority / Impact

FIRST MAP:

Priority was characterized by the thickness of the shapes (i.e., the thicker the shape, the higher the priority).

SECOND (2009) MAP:

Topics are placed strategically on the map to indicate "relative impact" (the "y" axis), which is a qualitative measure of importance among the high priority topics.

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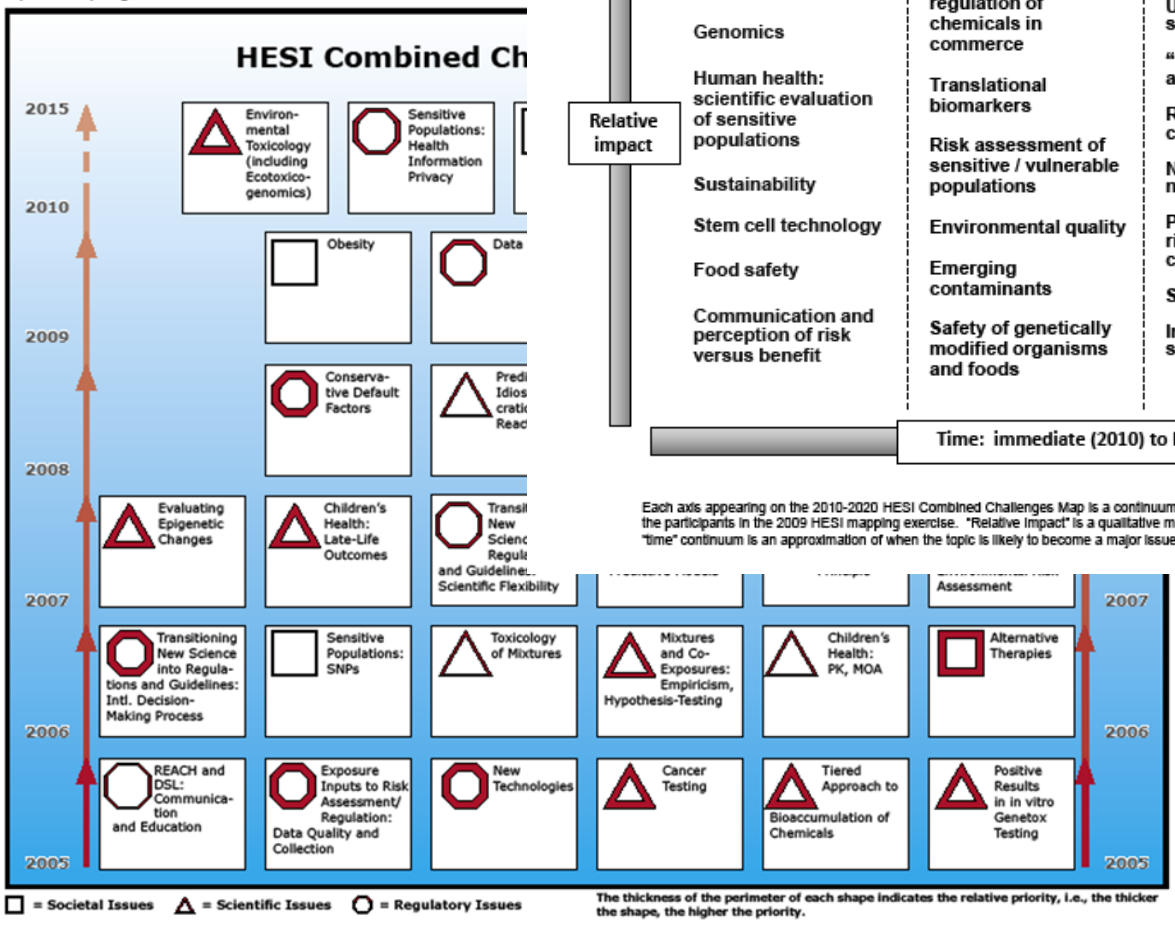

The thickness of the perimeter of each shape indicates the relative priority, i.e., the thicker the shape, the higher the priority.

Differences between 2004 and 2009 HESI Maps: Topics

- Very few of the 2004 challenges were dropped from the 2009 map; some topics have been re-framed (e.g., children's health → sensitive/vulnerable populations).
- Some topics appearing on the 2004 map but not on the 2009 map already are under investigation, and progress toward resolution is underway (e.g., a tiered approach to assessing bioaccumulation of chemicals).
- Some issues are new to the 2009 map (e.g., animal use and welfare).

Publication

A manuscript describing the process, value, and outcome of the 2009 HESI Scientific Mapping initiative has been submitted for publication in *Critical Reviews in Toxicology*.

[Also see: Smith et al. (2008). Predicting future human and environmental health challenges: the Health and Environmental Sciences Institute's Scientific Mapping Exercise. *Crit Rev Toxicol* 38, 817-845.]

How Can HESI Use the New Combined Challenges Map?

- To encourage submission of proposals to HESI on areas of high priority on the map.
- To provide guidance on next steps for existing projects in the HESI scientific portfolio.
- As a tool for identifying common goals and objectives with partner organizations.