EPA
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Agency

Chemical Safety for Sustainability: EPA Research to Meet 21st-Century Needs

Presentation to the Computational Toxicology Community of Practice

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24 February 2011

United States Environmental Protection Agency

Purpose of Presentation. To describe how EPA is realigning its research programs and to solicit your input into the development of our realigned chemicals research program.

Presentation Overview

- Realignment of EPA's research portfolio
- Chemicals issues facing EPA
- Description of the Chemical Safety for Sustainability Research Program
- Time Line and Next Steps
- Solicit Your Input

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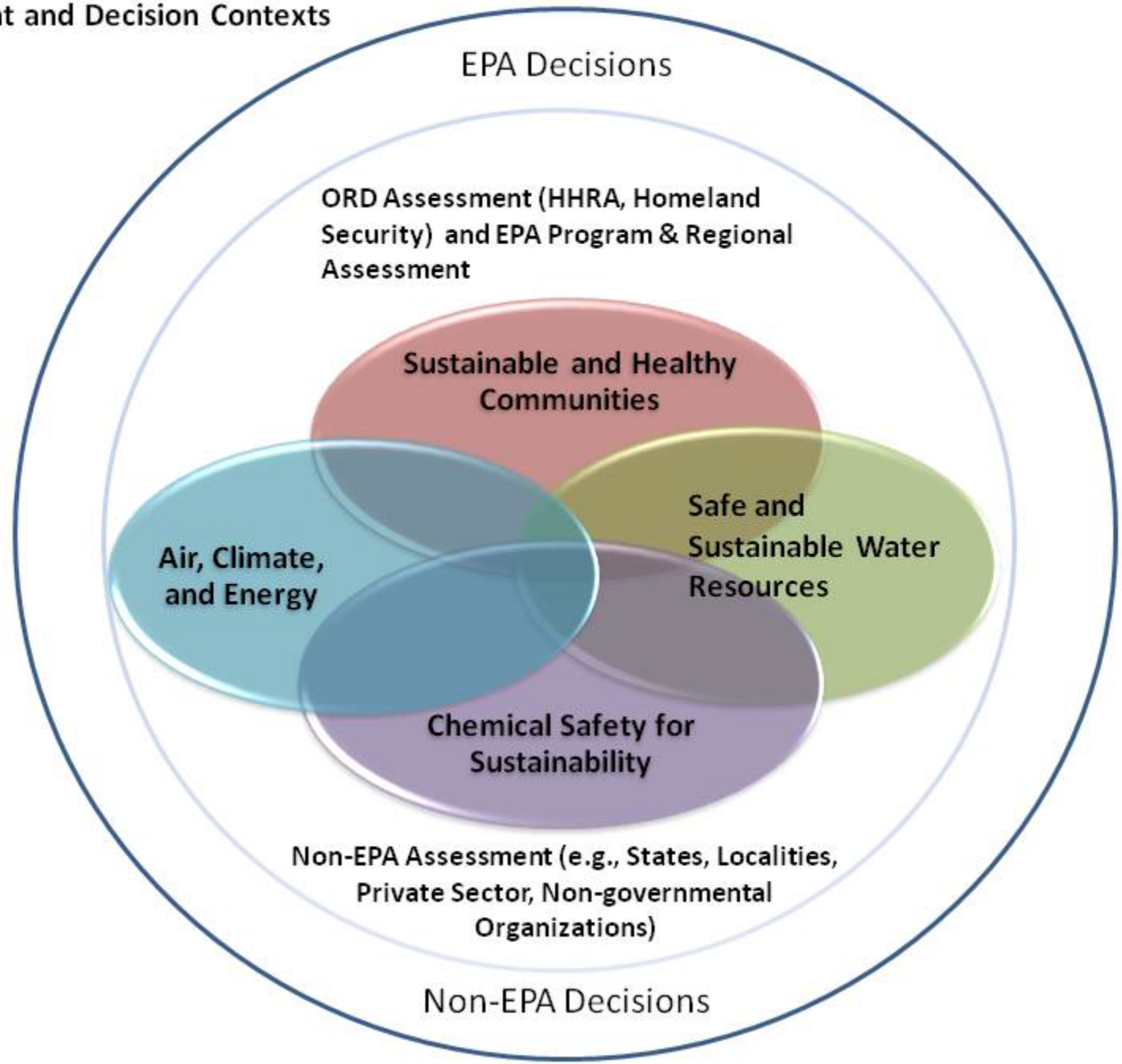
"… Environmental challenges do not obey bright lines or numerical limits. They are not constrained by disciplinary boundaries or the boxed walls of an organizational chart."

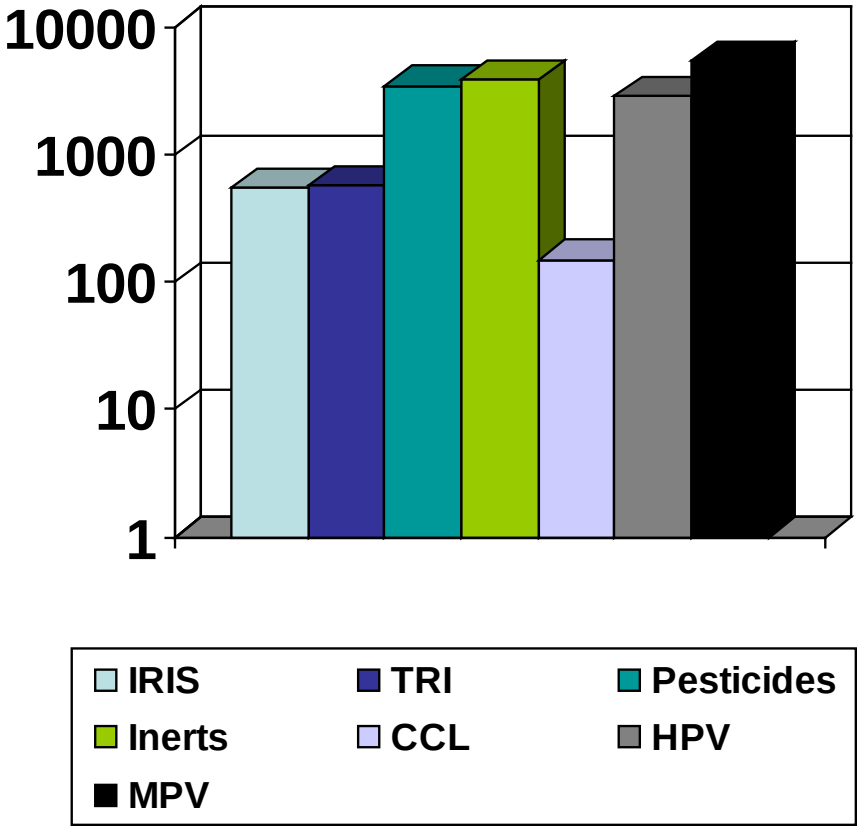
-- EPA Administrator Lisa P. Jackson

ORD Integrated Research Informs, and is Informed By, EPA and Non-EPA Partner and Stakeholder Assessment and Decision Contexts

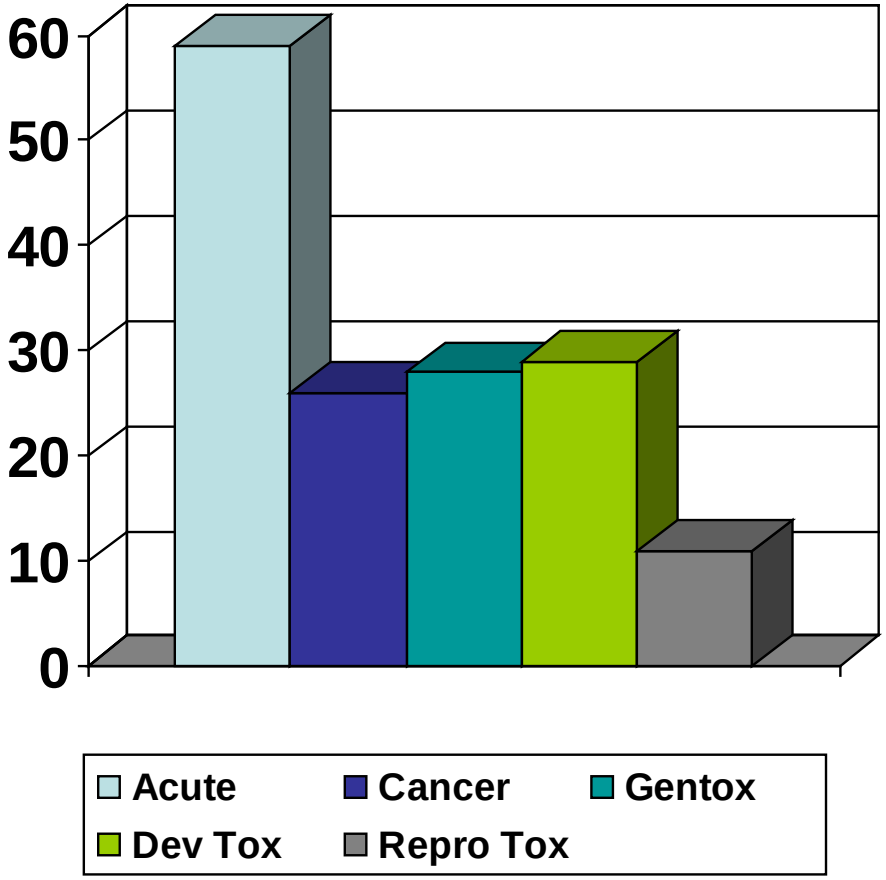


The Chemicals Situation

Many Chemicals



Little Data (%)



Judson, et al *EHP* (2009)

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Problem Statement

Although chemicals are essential to modern life, we lack innovative, systematic, effective, and efficient approaches and tools to inform decisions that reduce negative environmental and societal impacts of chemicals.

Vision

EPA science will lead the sustainable development, use, and assessment of chemicals by developing and applying integrated chemical evaluation strategies and decision support tools.

EPA Context

Challenges:

1. Making more, faster, and smarter decisions, guided by science, on the problems facing us today.
2. Anticipating tomorrow's problems by identifying and applying approaches that better inform and guide environmentally sustainable behavior.

EPA Administrator Jackson's principles for chemicals reform:

EPA must review all chemicals against risk-based safety standards.

Responsibility for providing information should rest with industry.

Give special consideration to vulnerable groups.

When chemicals fall short of the safety standard, EPA must have clear authority to take action.

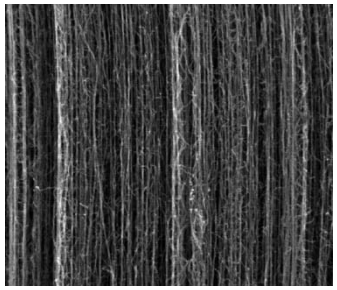
Encourage innovation in green chemistry and sustainable processes.

EPA's safety assessments must be resourced properly, with industry contributing its fair share.

Why Is It Time to Change How EPA Conducts Chemicals Research?

Because new technology and greater knowledge give us the opportunity to

. . .introduce new substances, such as carbon nanotubes . . .



Source: NASA

. . . in a more environmentally sustainable way than we were able to do with substances such as asbestos in the 20th century . . .

Source: ATSDR

. . . and provide more efficient tools for assessments.

HTS Robotic Platform

What is Chemical Safety for Sustainability?

CSS focuses on approaches that enable transformative (rather than incremental) improvements to environmental decision making, by:

- Giving decision makers tools that inform **sustainable chemical/material design** and use (e.g., green product "dashboards.")
- Providing methods for much **faster screening and prioritizing** of many more chemicals than is currently possible.
- Providing the scientific knowledge and tools to effectively **understand real-world risks** (cumulative risk, population vulnerability, etc.)
- Developing assessment approaches that are **tailored to specific decision contexts**; i.e., using enough information (but no more than necessary) to make timely decisions, and more of them, that are scientifically defensible.
- Considering where impacts may occur throughout a chemical's **life cycle**.

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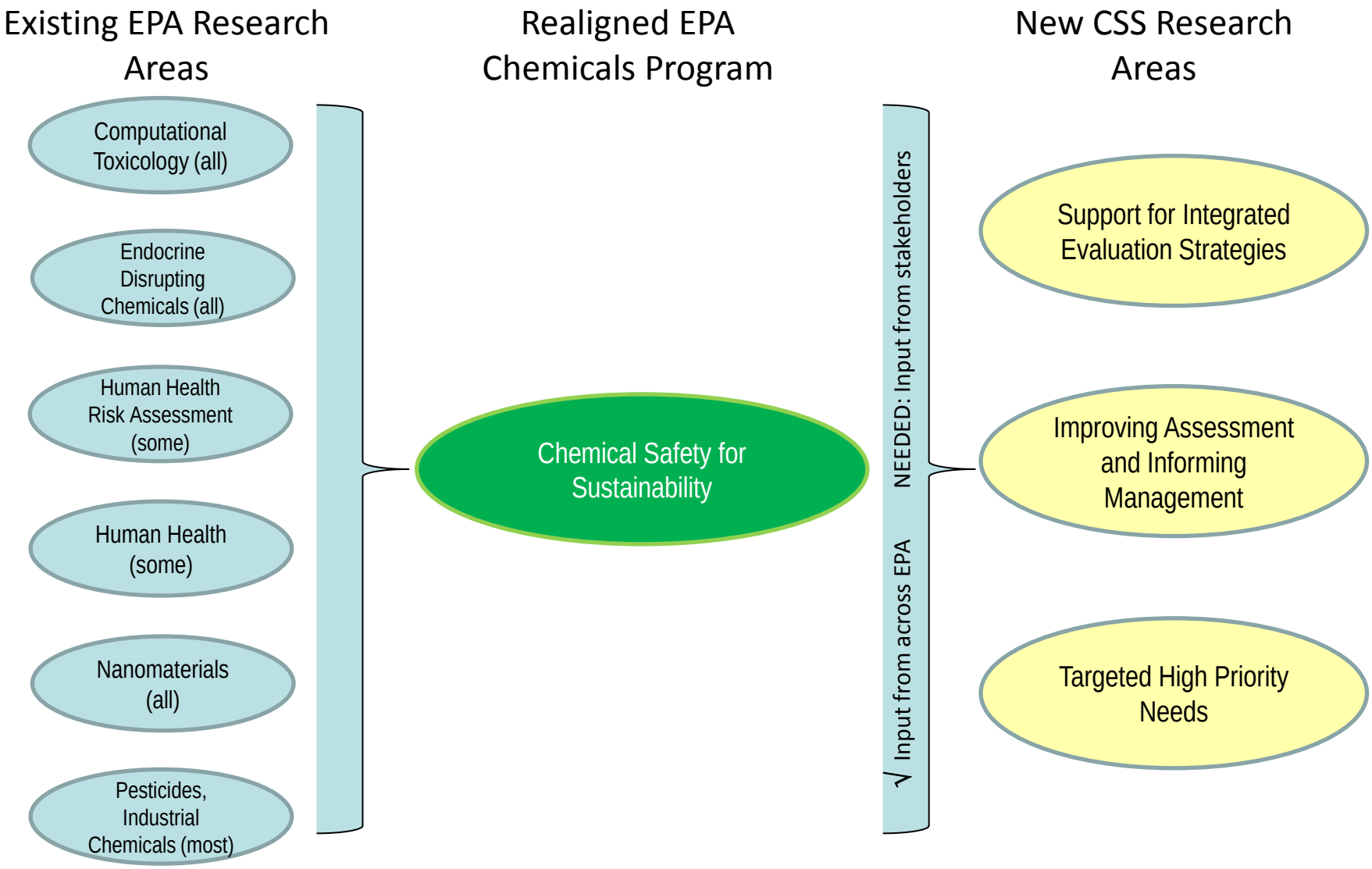
In the CSS research program, ***chemicals*** refer to intentionally produced or manufactured chemicals, particles, and materials, and in some cases the products into which they are incorporated. It may refer to single chemicals, particles, or materials, or mixtures of chemicals, particles, and/or materials, products, as well as forms of chemicals that are transformed as they move through the environment.

Aligning EPA's Chemicals Research Activities



Example of a **CSS Problem**: Life Stage Impacts from Chemicals

Agarwal, et al. *"The average country-level decreases in various categories of TRI concentrations saved an excess of 13,800 infant lives from 1989 to 2002."**

Yet every year, hundreds of millions of pounds of toxicants continue to be emitted into the nation's air, water, and land.**

A CSS Challenge:

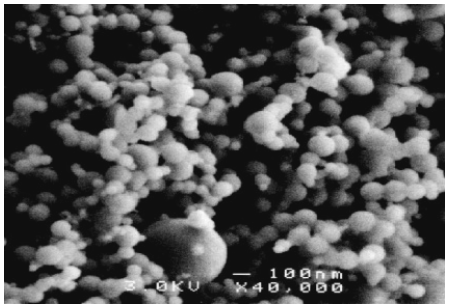
- Recognizing that infants are more vulnerable to toxicants,
- and realizing that reducing exposure can save lives,
- how to develop and apply new scientific tools that identify: (1) what chemicals/chemical properties are causing the most impact, (2) how those impacts can best be addressed to reduce environmentally induced infant mortality and morbidity, and (3) what factors should be considered in designing safer alternative chemicals.

*Nikhil Agarwal, Chanont Banternghansa, and Linda T.M. Bui,"Toxic Exposure in America: Estimating fetal and infant health outcomes from 14 years of TRI reporting," *Journal of Health Economics* 29 (2010) 557-574.
**US PIRG Report, executive summary (22 January 2003).

Example of **CSS Progress**: An Integrated, Multi-tier Health Effects Testing Approach for Nanomaterials

1. Physicochemical Characterization

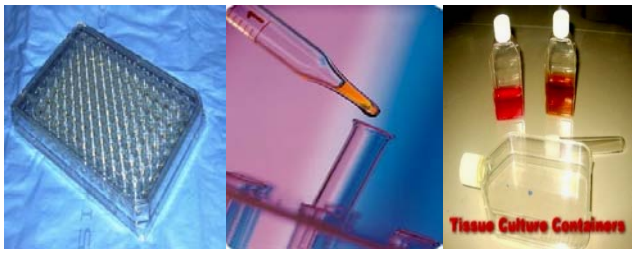
Selected specific nanoparticle types based on EPA and international (OECD) priorities



Well-characterized manufactured nanomaterials (vertical and horizontal testing)

2. Alternative Test Methods

(Non-Cellular and Cellular Based Assays)

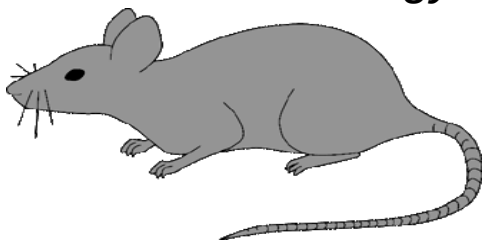


Collaborations
(NCCT; NTP; OECD)

-Screen/Rank
-Design *In Vivo* Testing

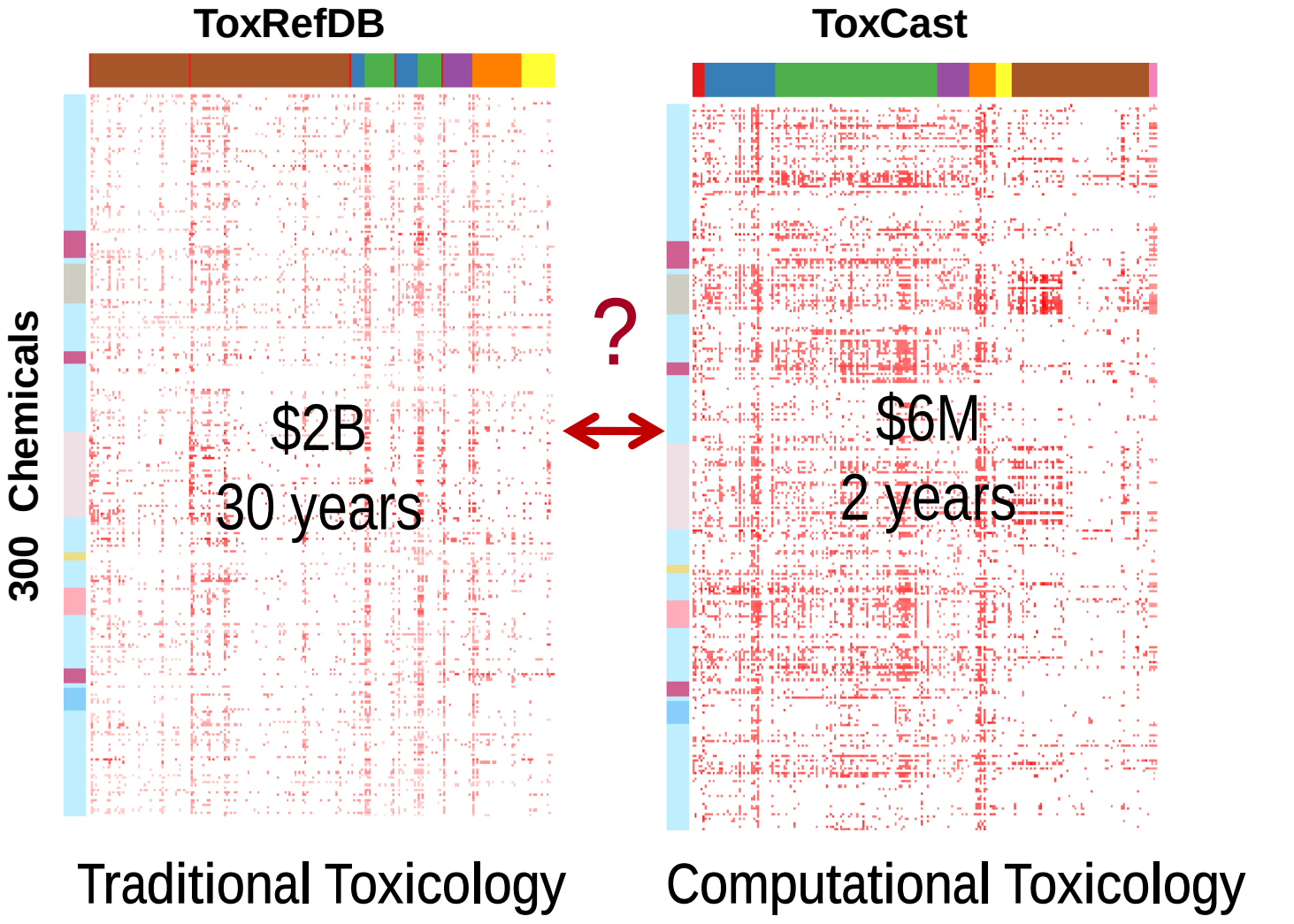
-Identify and Validate Alternative *In Vitro* Tests Predictive of *In Vivo* Toxicity

3. In Vivo Toxicology

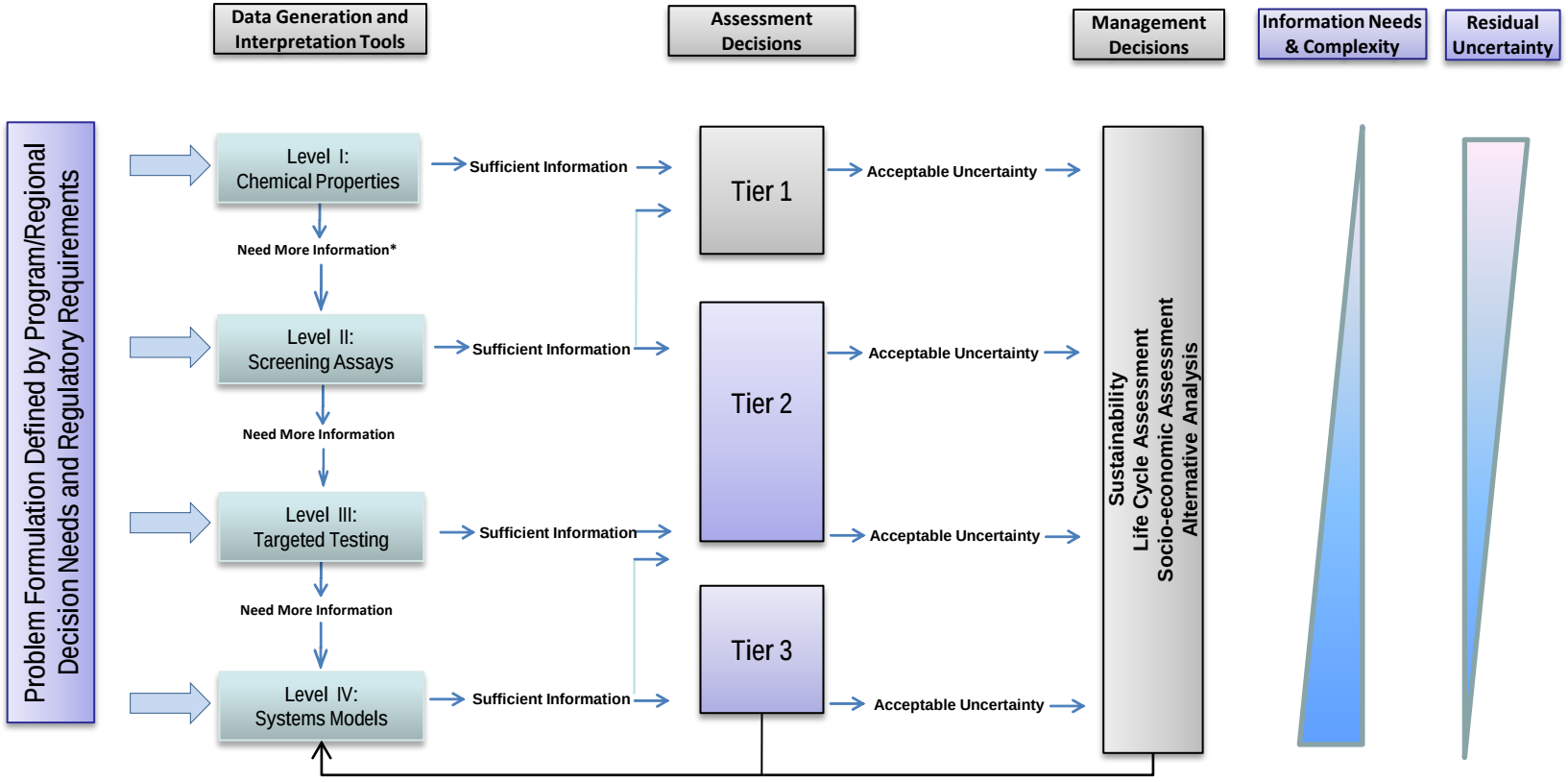


Collaborations
(NCCT; NTP; OECD)

Example of **CSS Potential**: ToxCast enabling more chemical assessments using less resources



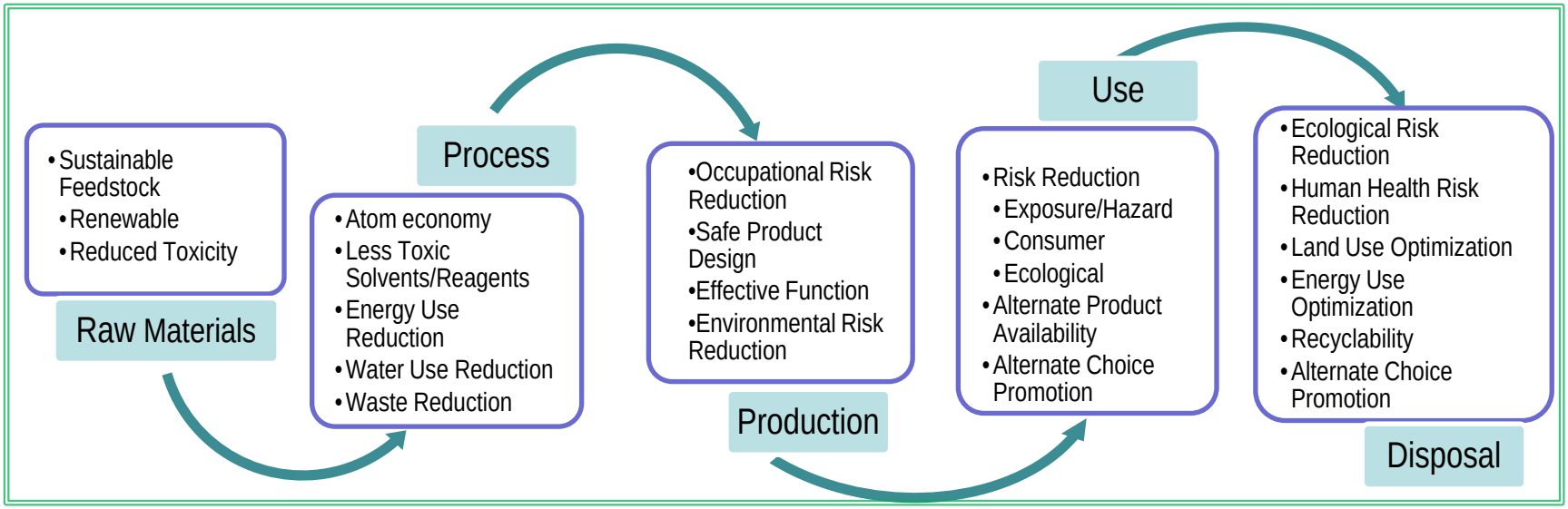
CSS Conceptual Model



Grand Challenges

- Digitizing and making available existing information
- Understanding the life cycle of chemical use and disposal, relevant to exposure and effects
- Improving dose reconstruction using biomarkers of exposure
- Identifying the critical biological pathways that are perturbed by environmental chemicals
- Capturing the complexities of exposure and dose in high-throughput assays
- Developing predictive models of hazard and exposure to prioritize further screening and testing
- Improving quantitative risk assessment and reducing uncertainty by using virtual tissues
- Applying 21st-century toxicology advances to both human and ecological assessment
- Scaling up the development of sustainable risk management approaches
- Providing more-effective technology transfer, translational science, and science communication

Considering Sustainability Across Chemical Life Cycles



Prevention Decisions
(future, new chemicals)

Management Decisions
(existing chemicals)

Focusing ORD Predictive Capabilities on a Systematic Approach to Product Development and Use

Supported by Existing Core Competencies

- Source-to-Outcome Measurement, Modeling, and Prediction
- Risk Assessment
- Risk Management Methods

With New/Enhanced Capabilities

- Life Cycle Analysis
- Green Chemistry/Green Engineering
- Computational Toxicology
- Systems Exposure/Systems Biology
- Susceptibility/Resiliency
- Next-Gen Risk Assessment

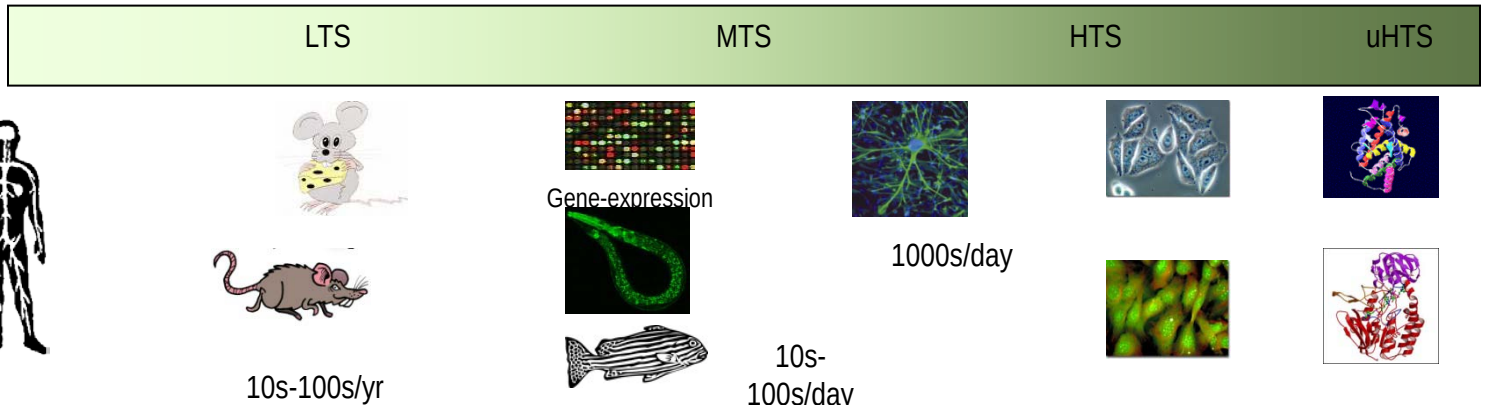
CSS Research Area 1:
Developing the Scientific Knowledge, Tools and Models for Integrated Evaluation Strategies

Problem

- Over 200,000 chemicals registered in European REACH; 75,000 chemicals in TSCA with very few evaluated for safety
- EPA cannot efficiently or effectively assure the safety of all chemicals using currently available evaluation and assessment approaches

Goal

- Develop the tools needed for efficient approaches that allow the integrated evaluation, assessment and management of thousands of chemicals



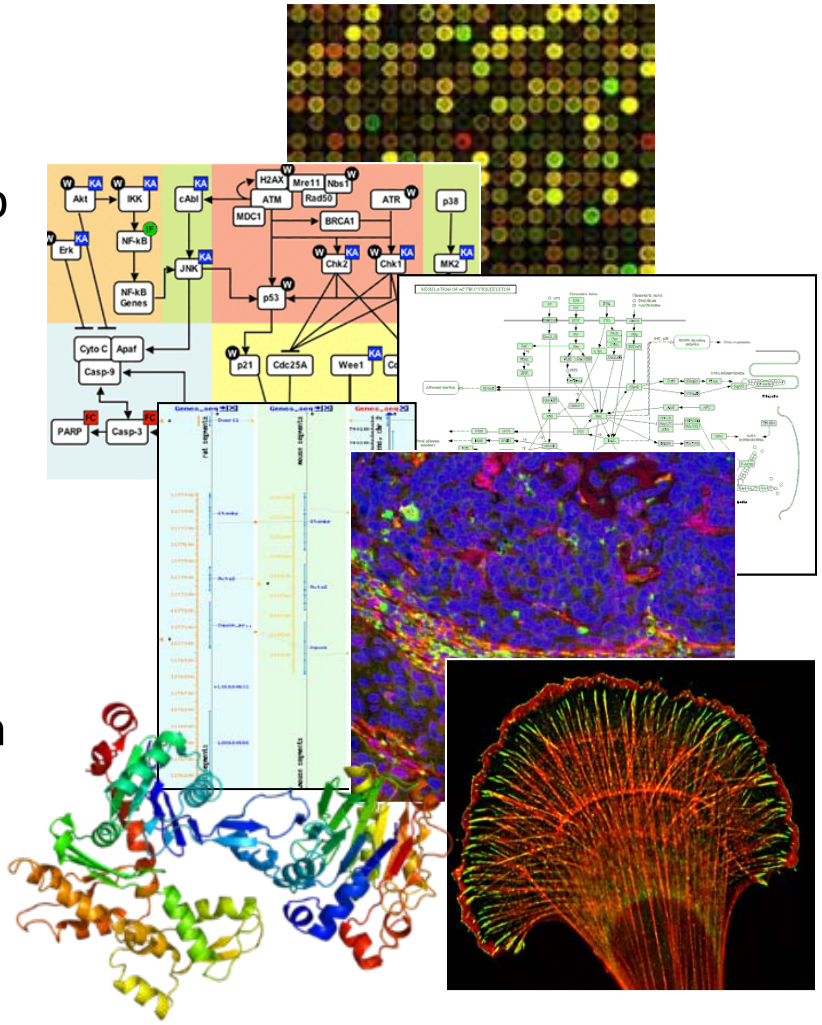
CSS Research Area 2:
Improving the Relevance of Assessment and Management Methods for Chemical Safety

Problem

- Our current assessment and risk management approaches cannot keep up with environmental decision-making needs

Goals

- Integrate next-generation risk assessment approaches across the Agency
- Facilitate management decisions that can be made faster and more efficiently, while reducing uncertainties about risks.



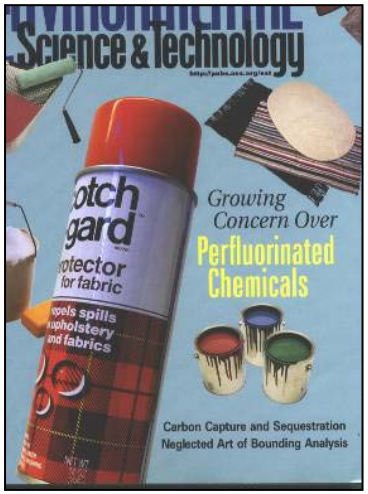
Photos courtesy of MIT Koch Institute

CSS Research Area 3:
Targeting High-Priority Research Needs for Immediate and Focused Attention

Problem. EPA has near-term critical research needs that are essential to fulfilling regulatory mandates.

Goal. A process to ensure that EPA's highest-priority needs are incorporated into the CSS program.

- Needs will be determined by annual (or regular) discussions between the senior managers of the CSS program and those of the EPA program and regional offices, informed by input from EPA stakeholders.



Your Input:
Providing Comments, Generating Ideas

We have created a web site to serve as a forum for providing, reading, and responding to comments on the CSS research program.

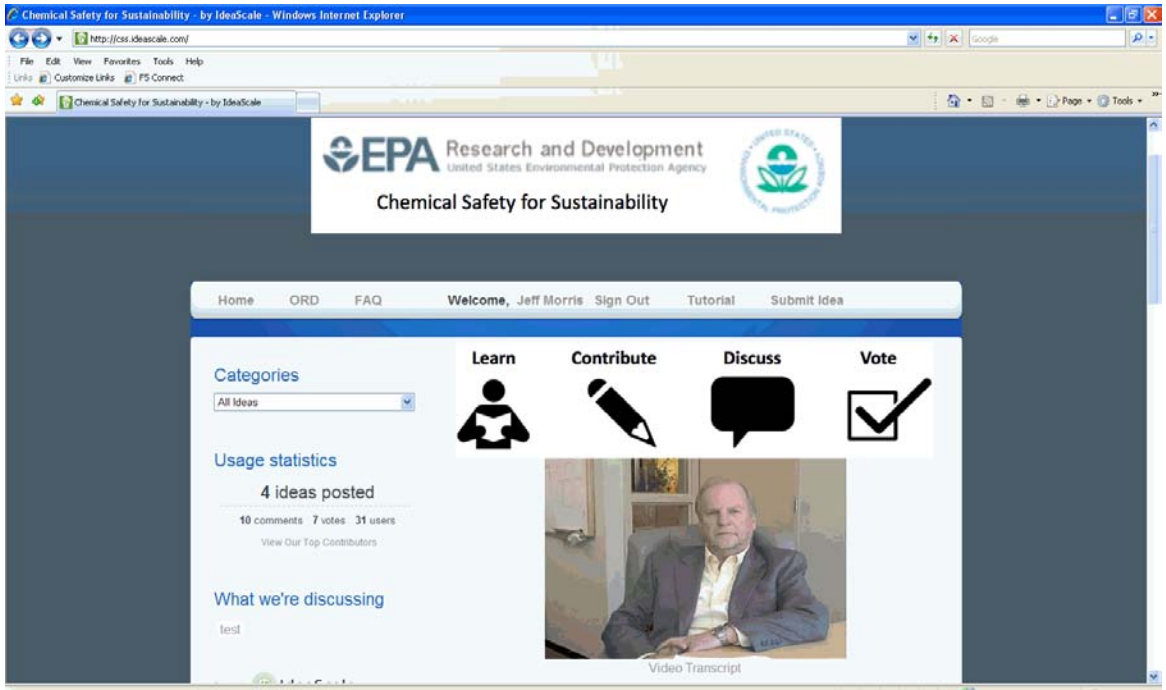
css.ideascale.com

Opens **today**

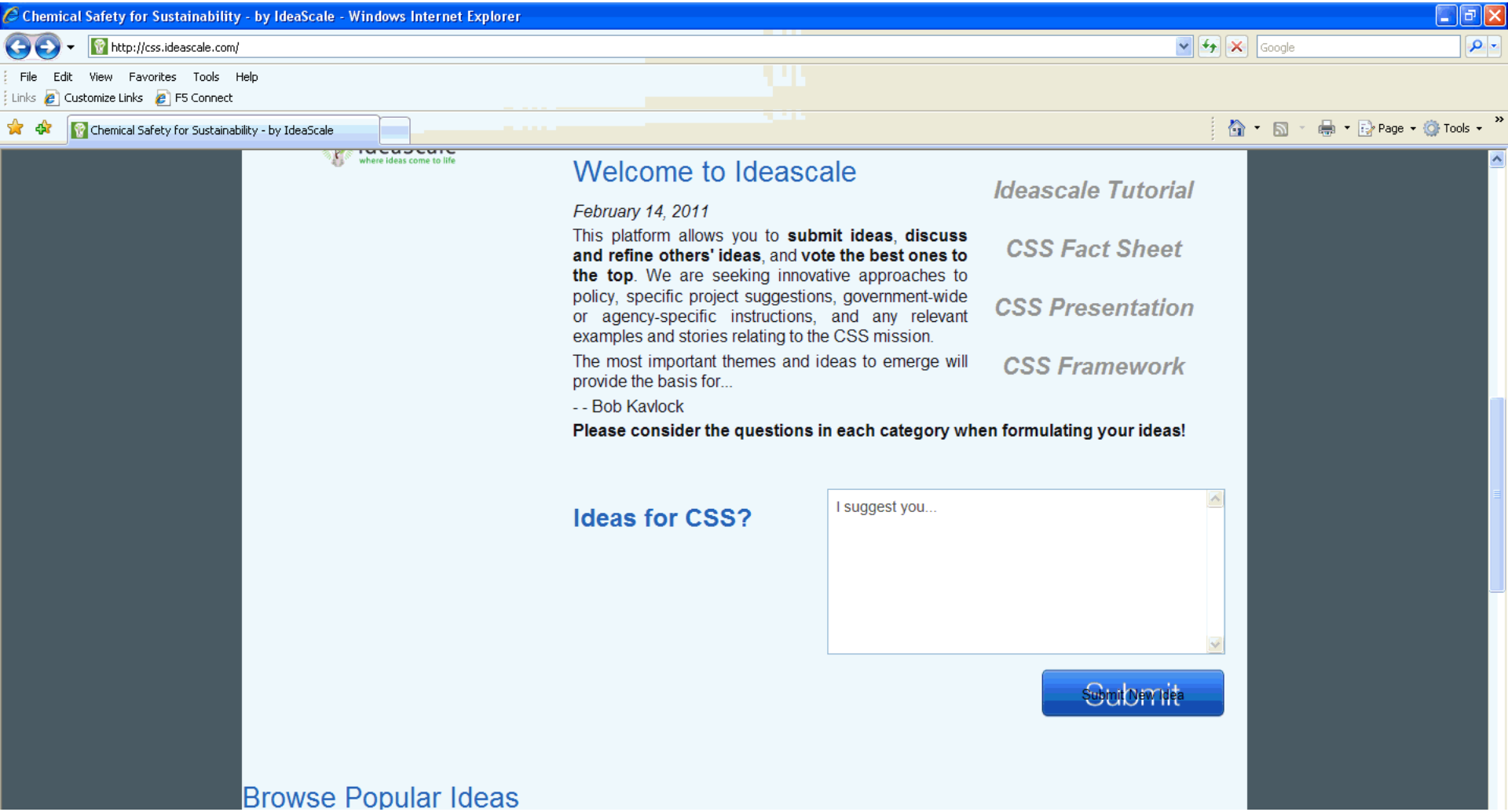
❖ Three-fold objective: (1) *inform stakeholders about research framework,*

(2) solicit input, and

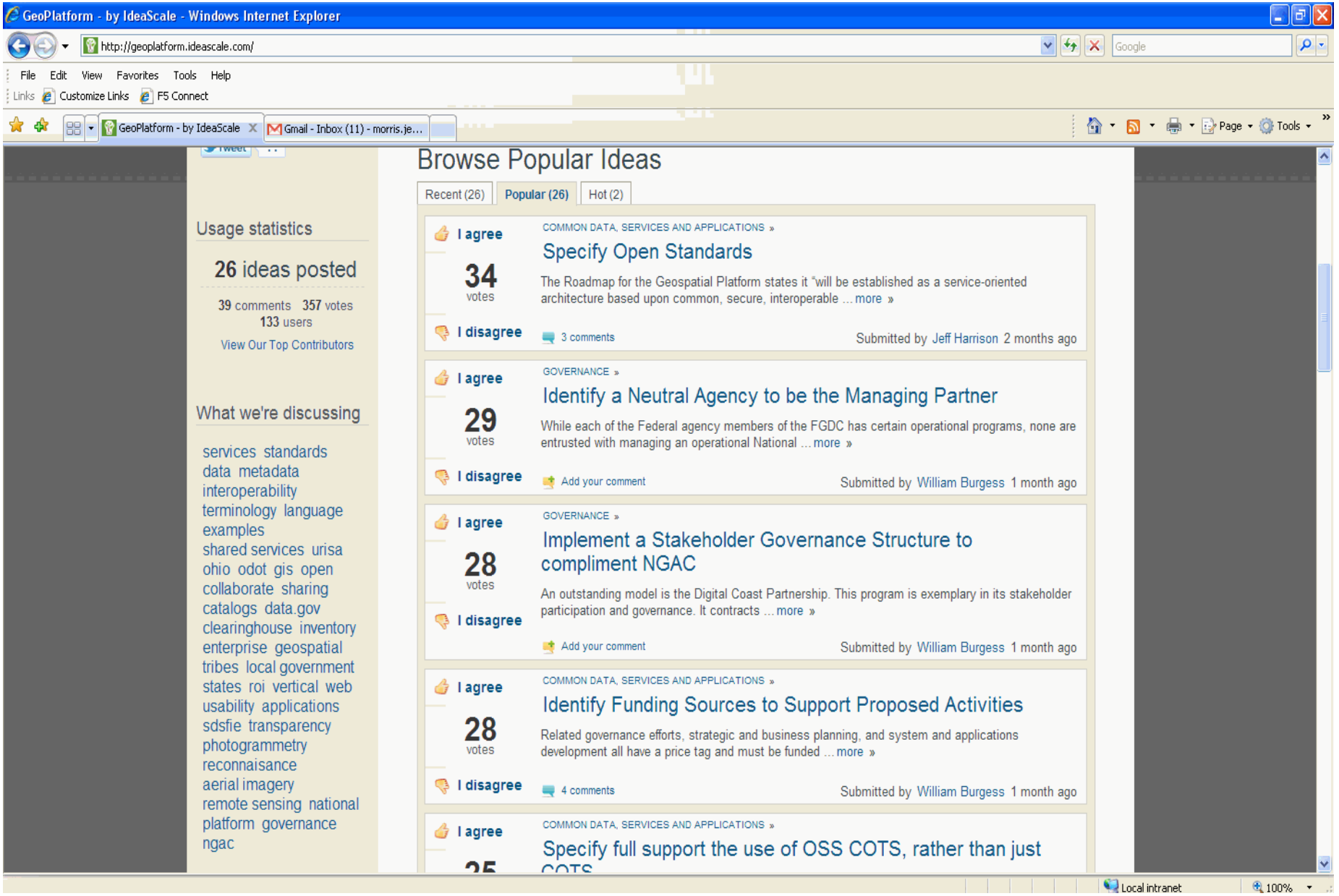
(3) generate ideas on how to best design, implement, and transparently communicate chemicals research at EPA.



Information on CSS Portal for Submitting Comments



More Than a Comment Site: An Idea-building Platform



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Timeline for CSS Program Development

Next Steps and How You Can Be Involved

Next Steps in 2011

February – April	Receive input and ideas
April – July	Use input and ideas to draft a Research Action Plan
July – September	Obtain expert review on key elements of RAP
October	Launch CSS as an EPA research program
October & beyond	Continually evaluate, evolve, and communicate

How You Can Participate

- Provide your input at the idea portal css.ideascale.com
- Similar webinar presentation will be given on in March 1 and March 15 webinar; see the ideascale portal for the latest information
- Pass this information along to others you believe would be interested