EPA United States Environmental Protection Agency

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

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Presentation to the joint meeting of the EPA SAB and ORD BOSC

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

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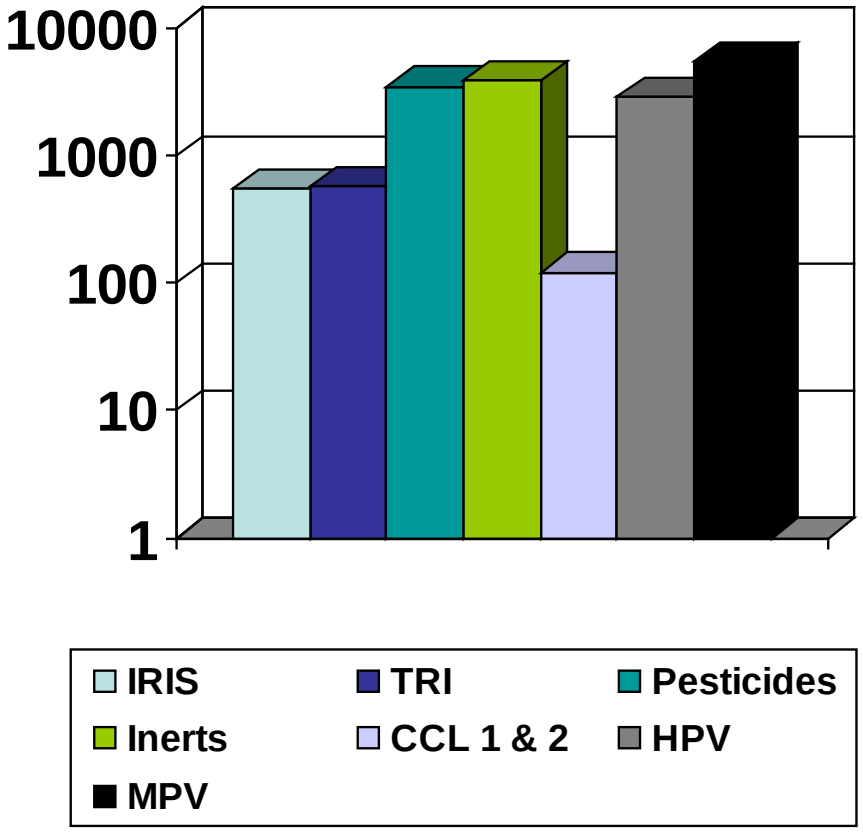
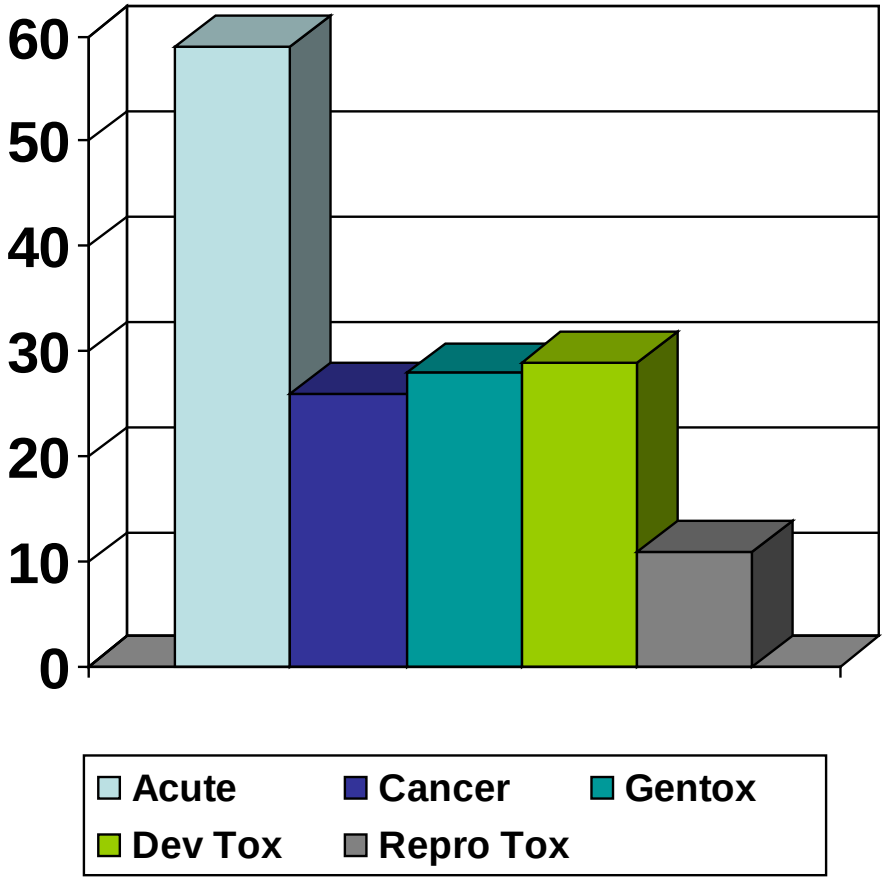
Many Chemicals



Little Data (%)



Judson et al, EHP (2009)

CSS Brings Together EPA's Chemicals- Related Research to Focus on 21st-Century Needs

- Understanding environmental impacts throughout chemical life cycles—from production to use to disposal/recycling.
- Enabling more, and more-timely, chemicals-related decisions by developing integrated testing strategies and data-generation approaches that are cheaper and faster, yet are more reliable and informative
- Targeting key complex issues such as characterizing mixtures of chemicals with respect to environmental impact, and understanding individual susceptibilities to chemical exposure over life stages.
- Identifying opportunities for applying green chemistry principles
- Interacting with the Human Health Risk Assessment Program to facilitate reduction to practice

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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.

Goals of the CSS

- To be a **program** dealing with Chemical Safety that:
  - Brings a critical mass to bear
  - Is integrated across ORD
    - > Lab/Center, in fact, >> Labs/Centers
    - Beyond the bounds of current interactions
    - Being co-dependent
    - Multiple multi-authored outputs
  - Promotes innovation and is catalytic and visible
  - Factors-in sustainability aspects

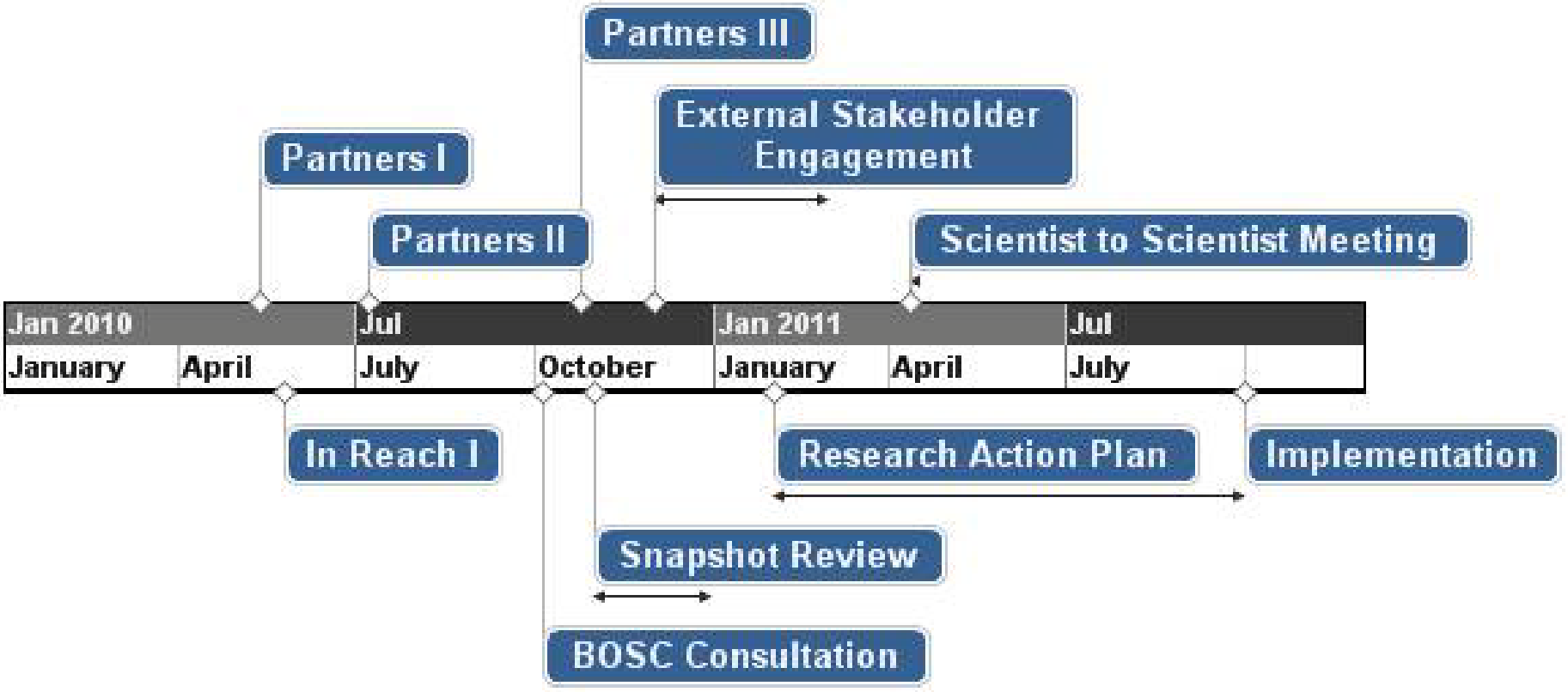
- To be **solution** oriented
  - Timely, relevant, and translated

- So that:
  - We can better protect the environment
  - And gain support for use of new scientific approaches

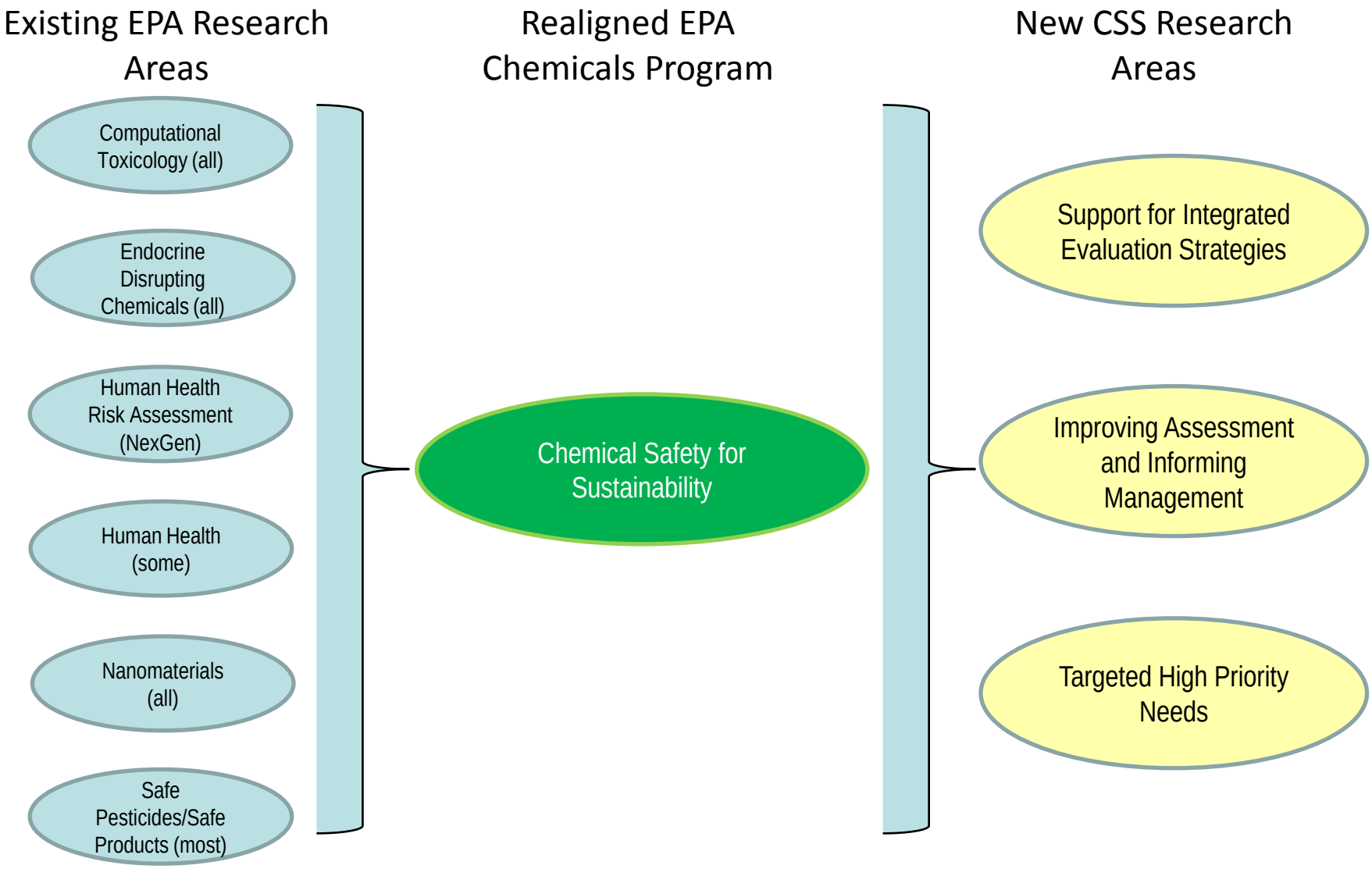
CSS Emphasis Areas

- Focuses on those chemicals (or their byproducts) over their life cycle that are intentionally manufactured for commercial use
- Research to support efforts in green chemistry and green engineering principles that would be used to design safer chemicals/products
- Includes impacts on both human health and ecological species
- Provides information needed to identify and address susceptibility and life stage issues
- Planning will interface with complementary ORD research programs (e.g., PCCL and SSWR, community/population health impacts with SHCR, chemical assessments with HHRP)

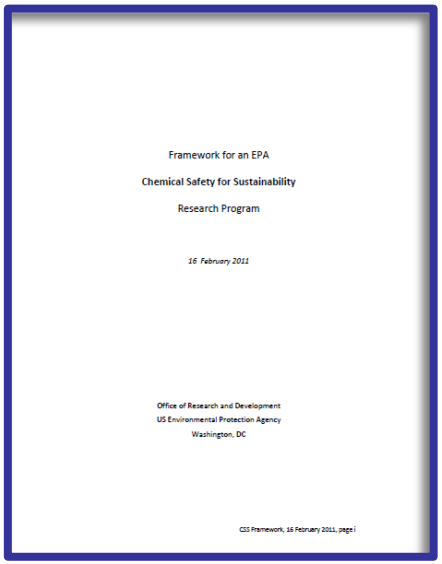
Timeline for CSS Program Development



Aligning EPA's Chemicals Research Activities



CSS Framework


Framework for an EPA

Chemical Safety for Sustainability

Research Program

16 February 2011

Office of Research and Development
US Environmental Protection Agency
Washington, DC

CSS Framework, 16 February 2011, page i

Developed in consultation with EPA Program Offices and Regions (3/2010-10/2010)

- Research needs and Key Science Questions to address
- Desired Outcomes

Drivers:

- Broadly applicable and integrative predictive approaches that cover the chemical's life cycle
- Efficient and effective evaluation assessment and management tools
- Fulfilling time critical regulatory mandates

Composed of all or partial elements of 6 current MYPs

Cross Agency Implementation Team has been formed to guide RAP development

Desired Key Outcomes: Addressed by Promoting Transdisciplinary Synergies

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

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CSS PROCESS

Framework
-NPD Lead with ORD and Partner Iterative Interactions
- Partner listening sessions
-Problem formulation
- EPA Context and Rationale
-Conceptual Model
-Research Areas, Science Questions, Expected Outcomes

Step Ones (n=230)
- Investigator Submitted
- Consisted of conceptual approaches to Framework issues
- Rows (Science) and Columns (Business)

Step Twos
-Organized Based upon Step One Discussions
- 8 Derived Thematic Topics
-~ 5 Pages in Length
-Describe Science Approaches, Projects and Outputs (short and long term)
- Facilitated by NPD, drafted by MI lead Investigator teams
- Vetted with Partners

Step Threes
-Facilitated by NPD and MIs, drafted by Investigator Lead teams
-For Each Task under a Project
- Commitment of WHO is doing WHAT by WHEN
-Reviewed by L/C and NPD
- Shared with Partners

Where We Are in the Process

The CSS Matrix

Product Focus Area → Framework Area ↓	Endocrine Activity	Nanomaterials	Commodity Chemicals	Water (CCLs)	Cross-Cutting Activities
Level I – Inherency					
Level II – Screening					
Level III – Targeted Testing					
Level IV – Systems Models					
Risk Assessment					
Risk Management					
Targeted Research					

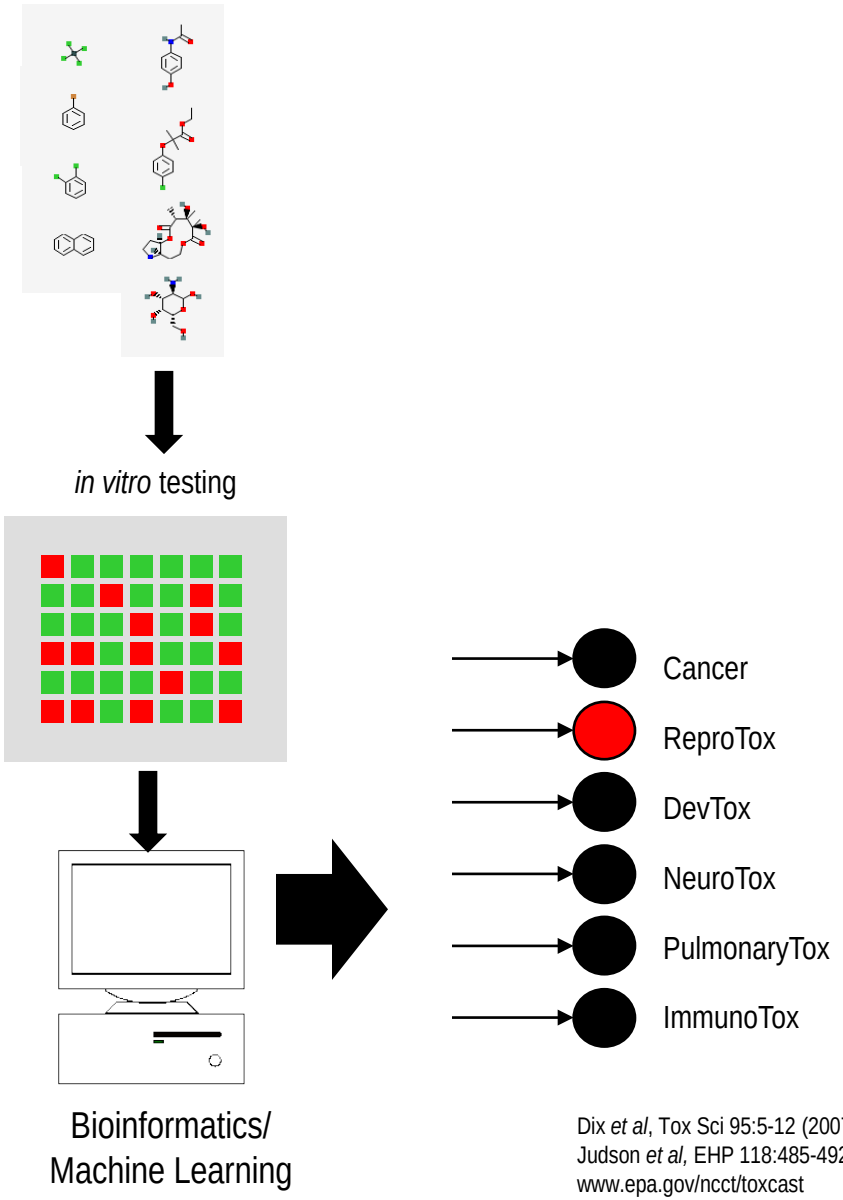
Key Steps to CSS RAP

- Step One: ORD scientist-to-scientist meeting (4/25-26) to present concepts to address Framework issues
  - 230 concept ideas submitted and discussed
  - After the meeting, identified 8 overarching themes
    - **Inherency, Biomarkers, Systems Pathways, Cumulative Risk, Life Cycle Considerations, Extrapolation, Dashboards, Evaluation**
- Step Two: Theme/Project descriptions were drafted by the L/Cs,
  - Reviewed by L/C senior management on May 20th
  - Revised and reviewed with partners on May 27th
- Step Three: (task-level descriptions) will be drafted during July and will form the core of the Research Action Plan
  - Will contain resources, outputs and milestones

A Signature Project: ToxCast Bioactivity Profiling

ATTRIBUTES:

- Less expensive
- More chemicals screened
- Fewer animals
- Solution oriented
- Innovative
- Multi-disciplinary
- Collaborative
- Catalytic
- Transparent



Dix *et al*, Tox Sci 95:5-12 (2007)
Judson *et al*, EHP 118:485-492 (2010)
www.epa.gov/ncct/toxcast

Key Next Steps

- Continual discussion and feedback of the CSS Implementation Team
  - Ensuring “must dos” are included in the RAP
  - Mapping high priority Step Ones to Themes/Projects/Tasks
- Responding to feedback from OMB and SAB/BOSC
- Determining Theme/Project/Task leads and developing Step Three task descriptions, outputs, and resources
- Working closely with Laboratory/Center management to ensure optimum workforce engagement and that the outputs are appropriate and meaningful

Summary - CSS Research Program is Being Developed:

- Through realignment of parts or all of 6 current research programs, to form a more-critical and multidisciplinary mass of resources to address chemical safety science needs
- To address the Administrator's priorities for chemical safety
- By using an integrated transdisciplinary research process
- By engaging Agency partners and external stakeholders throughout the process
- With the expectation that CSS will provide broad-reaching, game-changing results for how chemicals are tested, assessed, and managed

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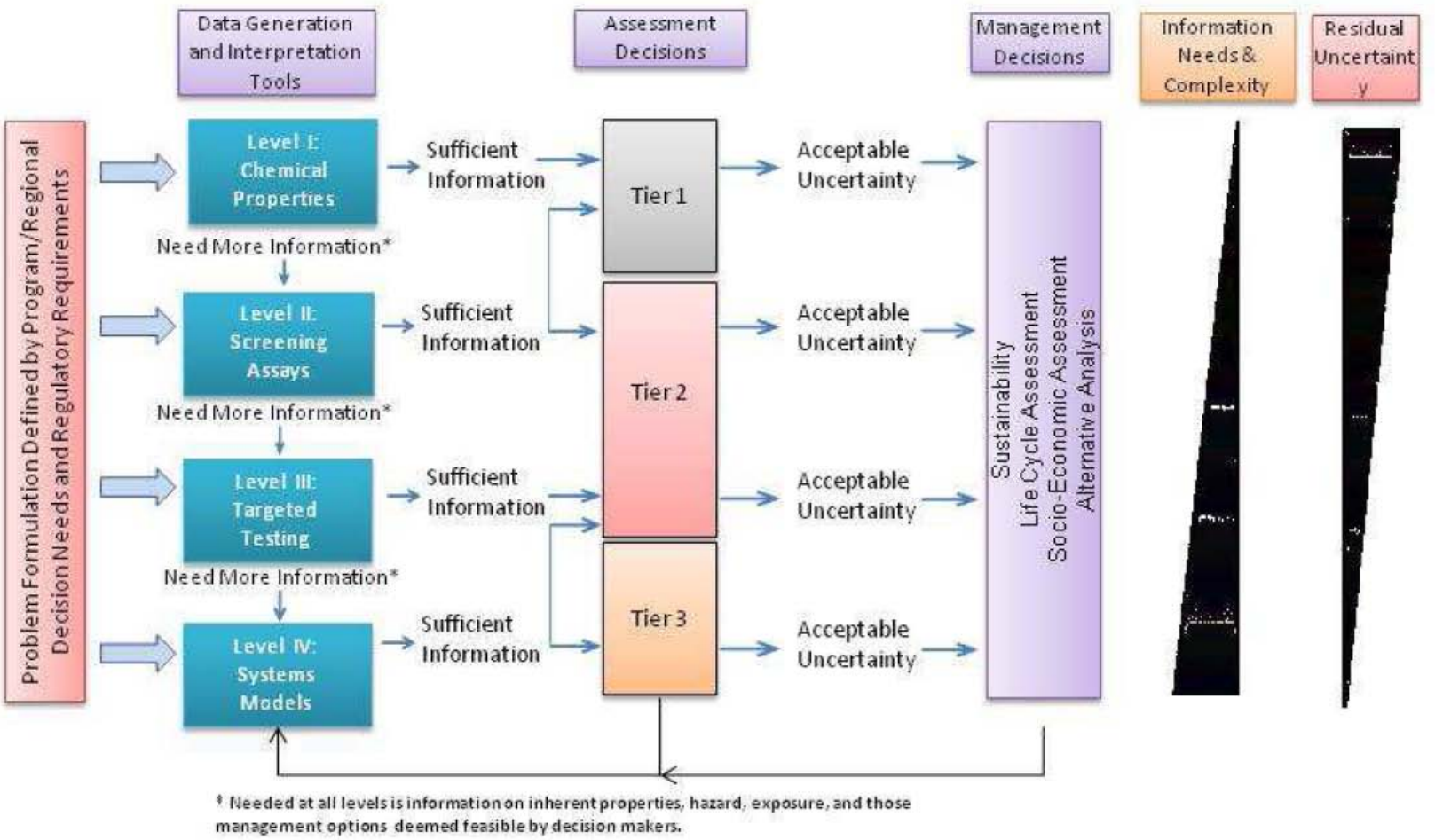
Supplemental Slides

CSS Conceptual Model



Life Cycle Considerations in Chemical Safety

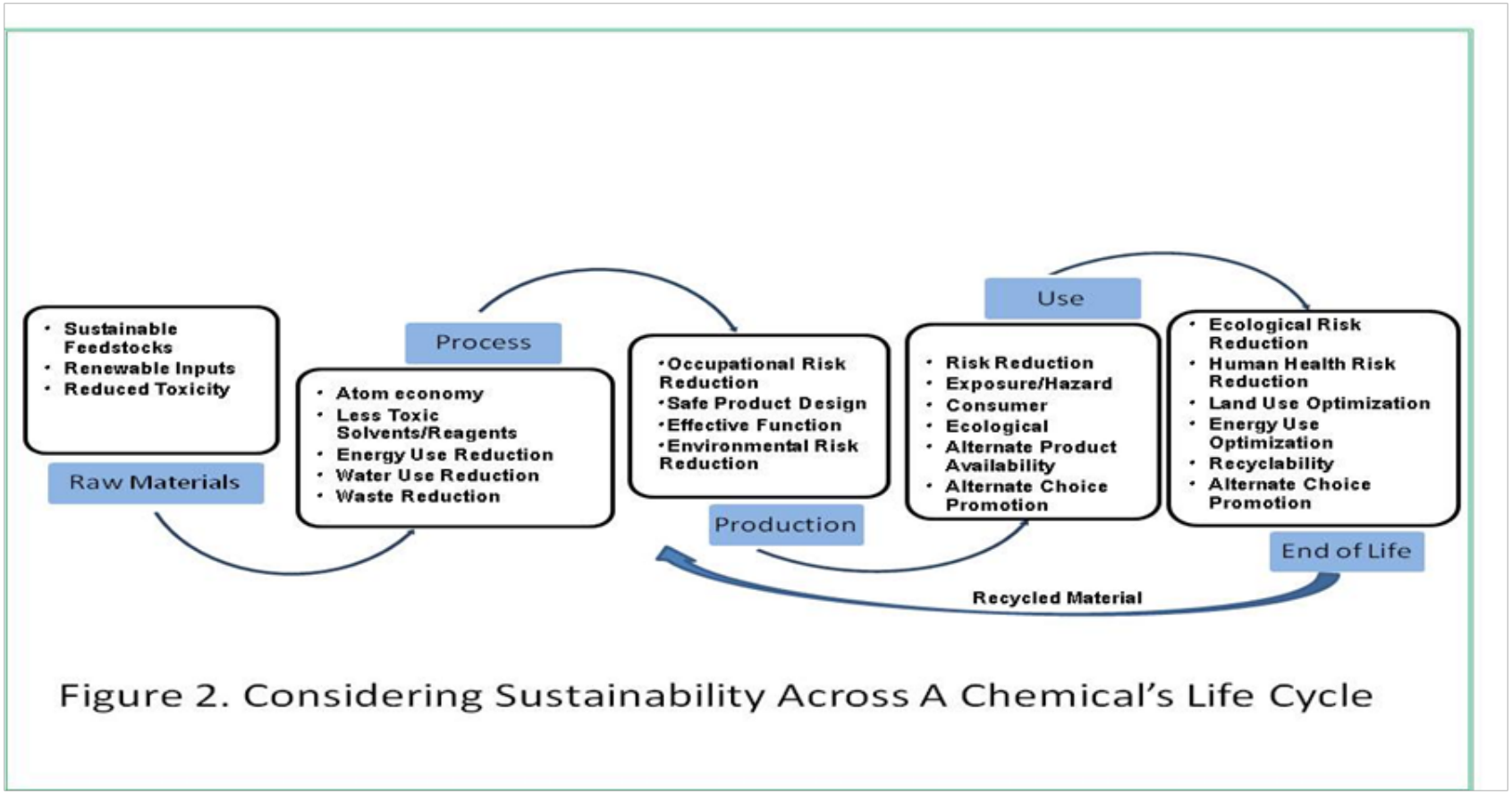
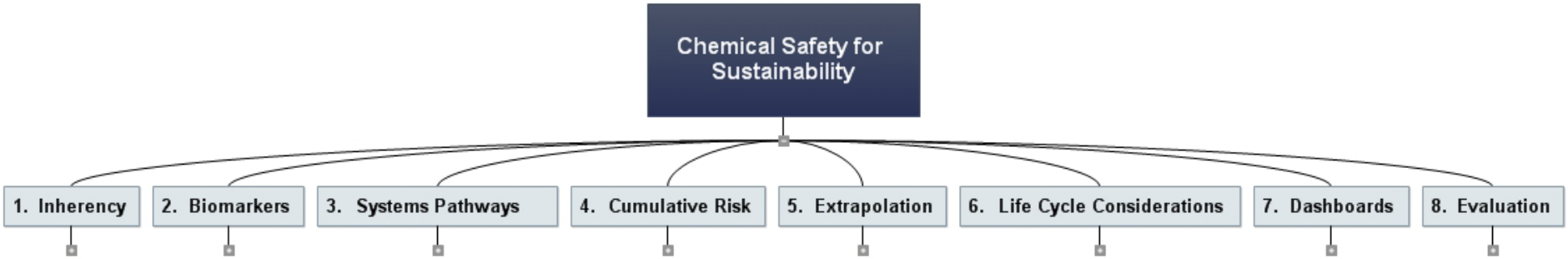


Figure 2. Considering Sustainability Across A Chemical's Life Cycle

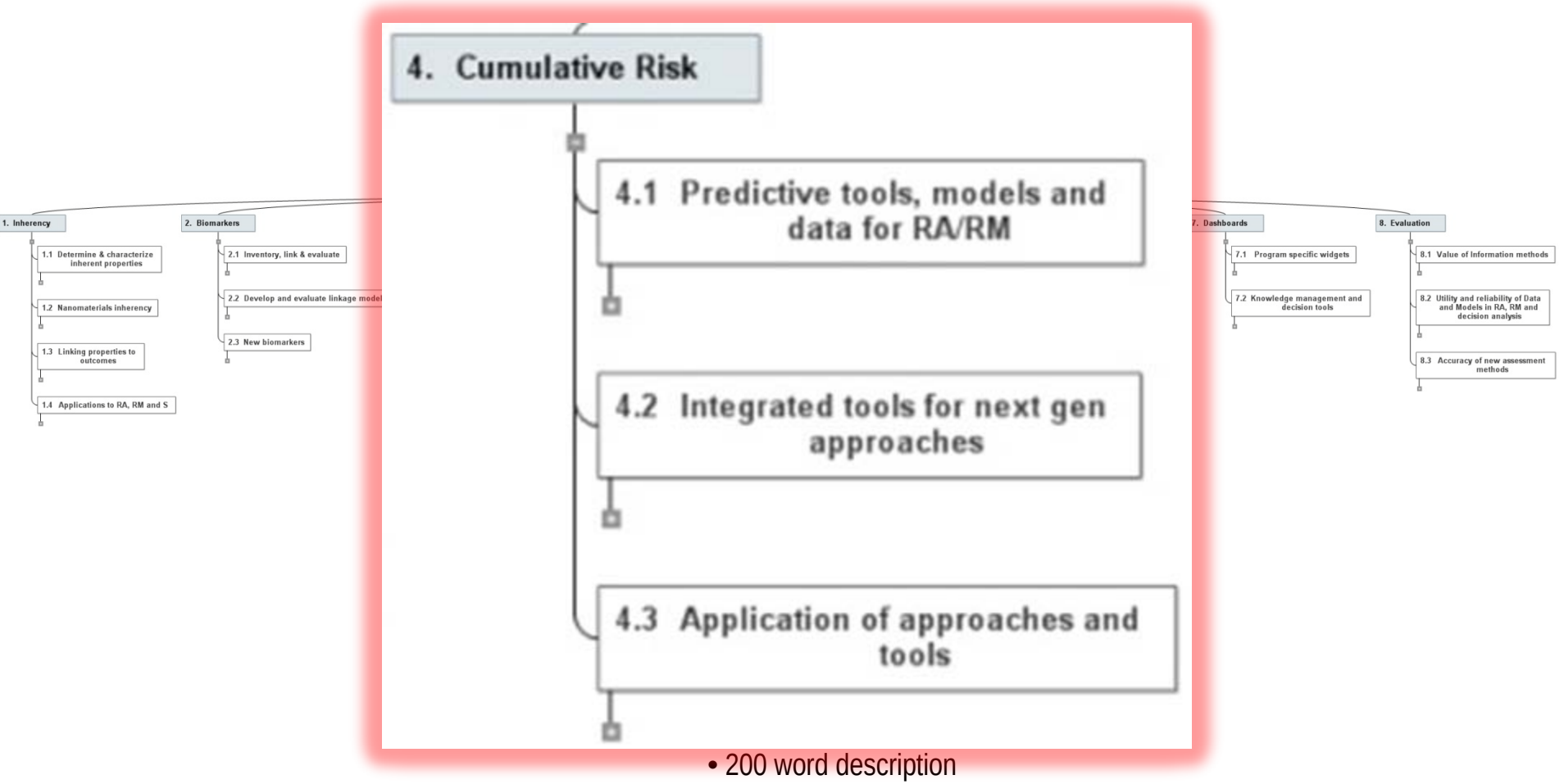
Step Two: Topic Level View



For each Topic:

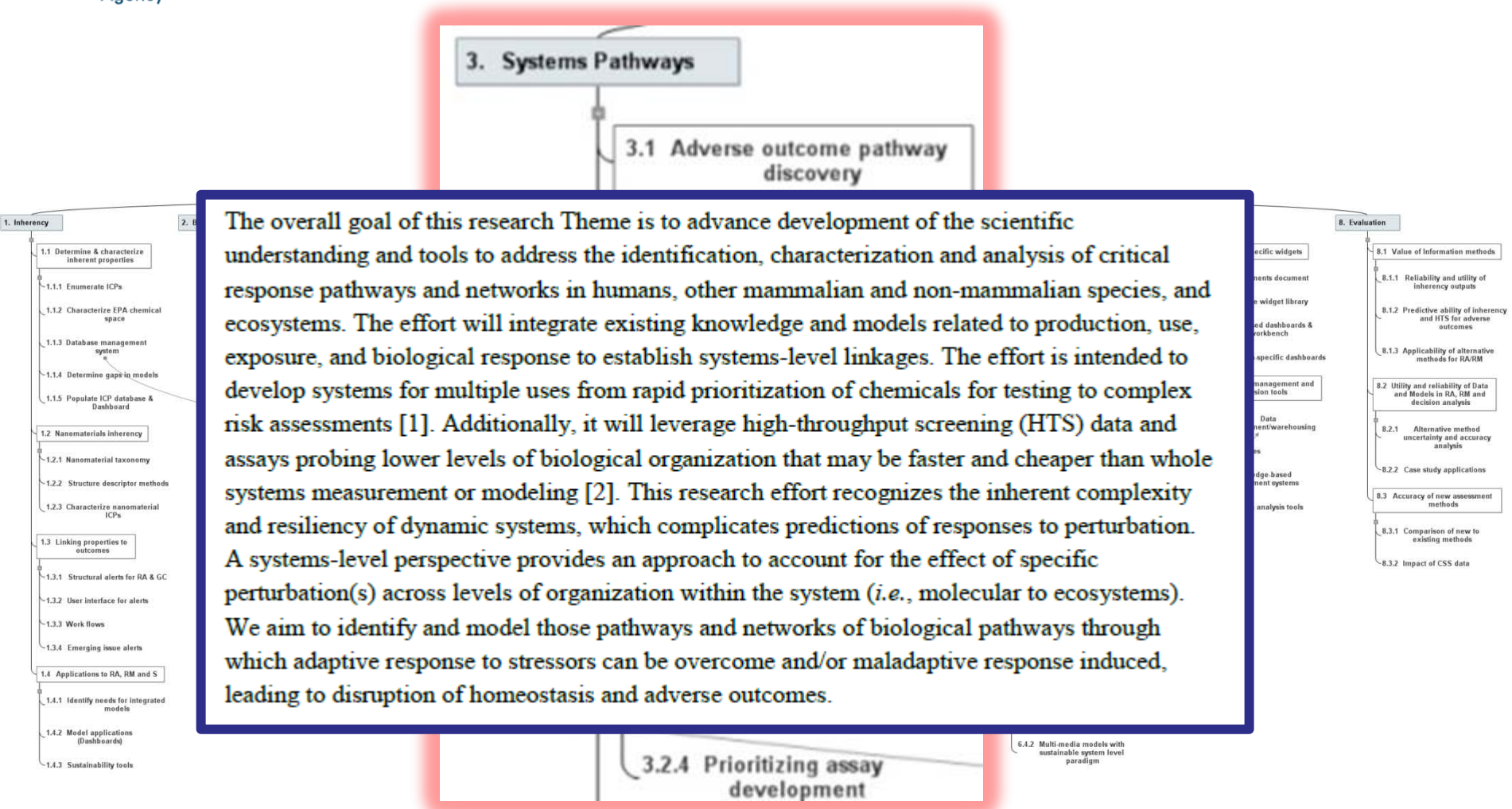
- A Champion (or Writing Lead)
- An FTE Allocation
- ~500 word description
- Linkage to Framework
    - Research Activity and Outcome ("Challenges")
- Extramural resources (aggregated from Projects)

Step Two: Project Level View



- 200 word description
- A figure showing intra and inter-relationships to Program
- Extramural resources (aggregated from Projects)

Step Two: Task Level View



- A Lead and team
- A 50 word description
- Key milestones (would come towards end of RAP process)
- Extramural Resources