Inherency

Systems models

Chemical Safety for Sustainability Break-Out Group

July 10-11, 2012

Biomarkers

Evaluation

Cumulative risk

Dashboards

Life cycle considerations

Extrapolation

BOSC / SAB CSS Break-Out Members

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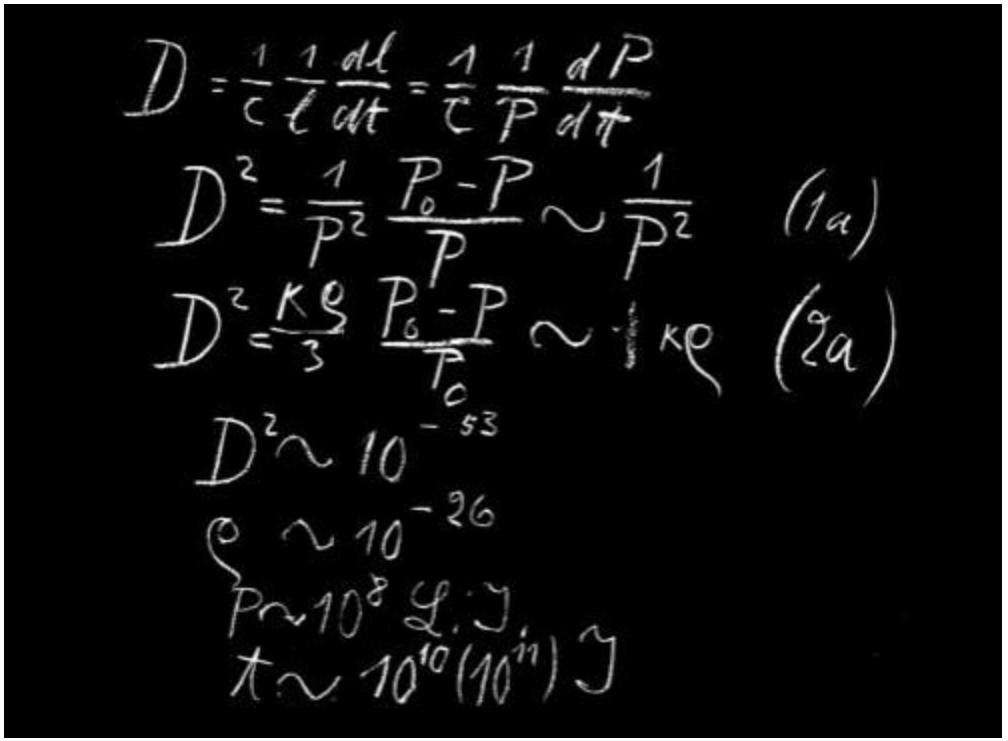
- Ed Carney (Dow Chemical), Rapporteur

Overall Impressions



Lots of Integration!!!

1. First Year Progress

- ***How are the ORD research programs progressing in the first year of implementation?***

"Impressive" "Phenomenal" "Exceeded expectations!"

Considerable progress toward a new, integrated management infrastructure to enable desired results (deliverables)

This, and The Plan, are incredible accomplishments of their own

Applaud inclusion of a framework and research directed to inform management decisions, not just risk assessment without connection with the CSS integrated program (eg life cycle considerations)

Too early to judge success in terms of specific deliverables, but early progress is encouraging. Emphasis on new tools (75%) is impressive.

- ***Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?***

All key elements are in the plan; many specific aspects affirmed

Exposure

- Greater presence in the plan than previously
- Not called out as a specific theme (might get more resources)
- Encourage even greater emphasis
- We think EPA should be able to measure human exposure

Cumulative risk

- Suggest highlighting how some tools from systems models theme will help address CR (e.g., common MoA).
- Like the integration of chemical and non-chemical stressors, socioecomonic factors

Ecosystems

- Plan should more clearly call out the emphasis on ecosystems

2. Sustainability

- ***How are ORD programs contributing to sustainability through their research plans and activities?***

Health and ecological health inform our understanding of sustainability, and inclusion in the definition is essential

Many examples of contributions from CSS program:
Use of high throughput tools to inform Green Chemical Design
Life cycle considerations (cradle to grave)
Life stages theme
Ecological aspects
Systems approach
Extrapolation approach (different levels of biological organization)

Recommendation from 2011 still holds - need to include metrics on how CSS contributes to sustainability

2. Sustainability

- ***What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?***

Be more clear about how the research impacts upon end users, such as risk managers, policy makers (value of the research for informing decisions)

3. Balancing Immediate Program Needs and Emerging Issues

- ***As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?***

Fortunately, EPA has means of accessing specialized expertise (e.g., external input) when needed

Integrated structure has prompted considerable re-training, enhancing the culture of continual learning

Ensure that every output is linked to a CSS theme

We support EPA's scenario planning exercise and willingness to make tough decisions and refusal to "dabble".

4. Program-Specific Questions

- ***Is the CSS program well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research?***

EPA is well positioned to support EPA needs in all three areas.
Key partnerships exist

General issues:

1) Approach for "Qualifying" assays for predictivity not described
2) Need to define normal range of variation vs region of adversity in toxicity pathways
3) Address use of targeted testing to complement/prove new computational/in vitro methods
4) Place greater emphasis on ADME and PBPK (e.g., metabolism, target tissue dose estimations) to integrate with high throughput methods

Nanotechnology

- Clarify whether research will compare the "parent chemical" vs its nano form (inherency theme)
- Ensure that EPA has the right models (e.g., in vivo models, fate and transport).
- Nano is a large field –articulate EPA's unique roles vs those of others

Hi throughput approaches

- Transparently articulate the approach to "qualify" the predictivity of new approaches. Put this before the BOSC / SAB.
- EPA should exert leadership in suggesting types of data which could be generated by organizations such as NTP and that would inform risk assessment

Endocrine

- The transition toward EDSP21 is critical not only for endocrine *per se*, but as a precedent for mechanism-based testing in general

4. Program-Specific Questions - CSS

- ***How well has the exposure component of the CSS research program progressed since its inception?***

Need even more research on estimation of consumer and incidental exposures

More specifically address how different deliverables apply to new vs. existing chemicals, High vs. Low production volume chemicals

Exposure provides an essential context and framework against which to evaluate new data

II. Integration Across Programs

- ***Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?***

Increasingly utilize the AOP concept as an inherently integrative process

Directly link science to regulators at regional office level (e.g., Duluth project on AOPs - female vitellogenin pathway linked all the way to population changes)

Highlight key examples of successful integration (Childrens's Health: Integration of chemical and non-chemical stressors)

Nitrogen – could be further integrated by incorporating community ground water exposure data

II. 2. Innovation

- ***How can ORD's initial innovation activities be improved to ensure continued and long-term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation?***

We applaud current program and support its further growth

Many benefits:

Innovation has become operational and ingrained in the culture of the CSS program. Fosters creativity, smart risk-taking

Double benefit of PIP program on efforts to increase integration

Consider further leveraging the top innovators to mentor future innovators and/or to promote further breakthroughs

Ensure that innovation gets applied and built upon