

Research to Risk Assessment Project Teleconference Summary Notes June 15, 2011



I. Opening/intro remarks:

Bill Suk (SRP):

- This project builds on the collaboration that SRP, ATSDR, and EPA have had for years.
- We have and need clear and firm senior management support in EPA, ATSDR, and NIEHS in this project.
- The design of this project is for the mutual benefit of all three agencies. How research is integrated into risk assessment is important. It's also important that SRP take EPA and ATSDR's research needs into account.

Beth Anderson (SRP):

The group present today is considered to be the core network for this project.

We have three over-arching purposes:

- To create an ongoing communication network. We'll add people as needed, including SRP grantees or other experts in government.
- To promote the near-term use of cutting-edge research science to further assist and advance the assessment of environmental/public health risks of hazardous substances in the environment.
- To foster an environment of mutual learning.

We know that there are significant issues in translating research into practice, especially in the field of risk assessment. Researchers and risk assessors have different incentives and often work with different time-frames. But this is going to be an on-going project and we intend to address these issues over time.

One of the key steps to achieving success will be to identify research that is most relevant and ready for application to improving risk assessment.

II. Opening remarks were followed by three agency perspectives:

Vince Cogliano (EPA ORD):

We should look at data gaps and uncertainty factors. There are a lot of targeted research programs where this would have a lot of benefit.

Three areas of particular interest:

- Develop more IRIS values. Often we have ingestion data, but not many inhalation studies. They're more expensive, but they often are needed. Also, it would help having distribution data for that route of exposure.
- Applying existing values to new scenarios. Usually, we deal with one chemical, administered for life. What happens in less than lifetime scenarios? We have simple methods now, but more would help. Many sites have a need for tox data on different isotopes—various chemical/compounds found at SF sites are different from what is found in IRIS.
- Many times different research approaches need to be applied as part of IRIS, i.e., chemical mixtures. Also, more is becoming known about susceptible populations, such as how might variations in population affect exposure/effect. IRIS struggles with this.

Kathleen Raffaele (EPA OSWER):

OSWER has similar interests to those that Vince raised:

- Many sites have chemicals where we have no data. Methods to help generalize from existing data would be good.
- We need better ways to screen and prioritize chemicals. How can we use the results of the new bioassays? How reliable are those assays? How does this translate to risk? PK is important—what does exposure mean to the person?
- Cumulative exposure is also important. Are there better ways to assess that? Is there information out there that we could be making use of?
- We have difficulty in translating epidemiology data into something usable. You have exposure, but not sure how much. Is there a better use of biomarkers? How does exposure relate to effects in epi studies? What level of change in biomarkers translates into an effect?

Steve Jones (ATSDR EPA HQ Liaison):

- How can we work together to continue the collaboration between SRP and EPA? Avoiding duplication of effort should be important as well as synergistically increasing our knowledge of toxicology.
- How can we incorporate this into community engagement work that all three agencies are doing? Folks from all four ATSDR divisions are involved in this.

III. Group Discussion was focused on two questions:

Question 1. What are the key obstacles to applying the latest relevant research to risk and health assessment?

- **Validation** is important, especially when talking about models or high-throughput screening. Expanding on validation, buy-in is important in the trenches with the risk assessors. People are reluctant to use risk assessment technology that doesn't have "official" weight behind it (e.g., a guidance). People can be a bit reluctant to move ahead without this.

- **Communication** is critical. Risk assessors aren't always aware of the latest science that may be applicable to risk assessment. Bench scientists are not always aware of what is needed for developing risk assessments.
 - Are there more systematic ways to share specific research gaps in the SRP RFA beyond what we do already, so potential grantees could be aimed at the most important questions? Or can grantees do something more about promoting impact on risk assessment?
 - Risk assessors need to know what science is available when we need to do assessments. Risk assessors also have difficulties accessing the appropriate scientific information, given the continuous flow of new studies. (It's hard to archive all that data in your head or a filing cabinet.)
 - We still have to deal with the human factor; risk assessors can have tunnel vision, where they limit their view of the site or situation. They are creatures of habit such that they've been doing something in a particular way for so long, and for a variety of reasons, they stick to the old ways rather than using the newest research.
 - Researchers and risk assessors have differing needs. It is possible to find ways to address both. There is often a lack of an early partnership between research and decision makers. Researchers are afraid their research is going to be applied and they won't be able to publish. Decision-makers are scared that it's so theoretical that it can't be applied. The obstacle is lack of collaboration at the beginning.
 - There is a missing critical piece between research and the field - sometimes referred to as advanced development - which focuses on taking some research from the lab to the field. In most research, it's neither defined nor assigned. Nobody owns it, so it doesn't get done. We need to address this in this project.

- **For biomonitoring and bio testing** - the throughput of research tests, and volume of specimens for research tests tends to be too large to be useful for a field environment. The time to get results back to people in the field is too long.

- With regard to inhalation **pharmacokinetics** - if risk assessors can convey some level of the specificity of their needs, they won't leave the grantee to guess what is needed.
 - We have been hearing a lot about biological, pharmacological, and other non-chemical stressors. There are exposure issues, still, especially with air exposures. What are people being exposed to?
 - In some cases, research is applicable. Basic toxicity /dose-response studies are good. Biokinetic data just aren't available. But perhaps a more holistic approach would be better. Perhaps we should look at kinetics as well as the dynamics.

- **Computational Toxicology** - We don't have a good handle on computational methods, and the QA that those methods are accurate. Frequently have a site with a chemical, and no information about that chemical. Could computational toxicology answer that need?

Question 2: What are the best actions that we could undertake to make this project most useful to you and your program?

- **Need for Mutual Education** - A lot of field people don't know what our SRP grantees are doing, so we should focus on how to present the research that SRP programs are doing. (There is probably a corresponding need to educate the risk assessors about the constraints that researchers have also.)
- **How to apply research** - One approach is to find a site where new research can be applied. But risk assessors have data gaps where information is needed....what if we start by asking the research needs question? (Another comment was made that SRP has been asking ATSDR and EPA for years for their research needs to factor into the next SRP RFA.)
 - SRP is interested in knowing what the present RA research needs are. After 20 years of work, what research results does SRP have that risk assessors can use? There needs to be an opportunity for expressing future research needs, but there's also a critical benefit in making use of what research results we have so far.
 - As a practical matter-this seems like a huge issue. It would be more practical to take a risk assessment issue (e.g., metals) and have subgroups focus on specific needs, and which parts of the catalog are relevant—so we could take some specific follow-up steps. In the past we've been trying to collect too many things from different areas. (This was seconded.) It would be good for those of us in the field to have a list/description of research in need of a problem to be applied.
 - SRP researchers are very eager to know how their work will have a practical application (some, anyway). This network could be an additional way to know where their work might be needed. A networking/virtual networking would be effective in that way...
 - The ongoing research may lack some of the details that risk assessors would need. What collaboration is needed so that the research we select fits the need risk assessors have right now?
 - Identifying areas that need additional research would be a good focus. Perhaps look at IRIS assessments- during that process, the public can comment on the draft assessment. Look for data gaps (and then comment). That could be a way of exchanging information between assessors and researchers.
 - Could a criteria document/draft IRIS document, and how to make comments on one, be a discussion topic at the SRP annual meeting?
- **Community Engagement** - EPA has a lot of limitations as far as surveys and addressing community issues. EPA is bound by information quality guidelines. Could this effort serve as a vehicle to collect information to assist assessments?
- With regard to **validation of models**...Could we address what may need to be standardized so that the model results could be used in a meaningful and informed way? There are useful models that have been developed over the years. We put everything on the SRP website so people can data mine. When we look at the SF website and your needs, we may come up with a better way to assess models and use them.

General comment:

A question arose whether any of the SRP researchers feel intimidated that any of their research might open them up to attack by industry? One participant stated that industry occasionally has gone after researchers in an aggressive and nasty way. But it was pointed out that the way the government approaches the research environment can make a big difference in reducing the vulnerability of researchers

IV. Next Steps – Beth Anderson:

- We will provide participants with links to our SRP web site. Areas that are of most interest will be highlighted.
- Our next step will be to go through the discussion notes from today, draft the meeting report, and send it around for you to make comments and suggestions.
- SRP will screen the ongoing SRP research and provide the participants with summaries as candidate research projects for future application to risk assessment. Participants will be asked to evaluate those candidate projects.
- SRP will also be exploring optional means of promoting mutual understanding among the participants to better understand the priorities and constraints of researchers, risk assessors, and health assessors.
- Participants are welcome to attend the SRP annual meeting on October 24 – 26 at the University of Kentucky in Lexington. If there are ideas on other venues we should be working with, please inform SRP.
- Translating research and scientific tools to be used in real world risk assessments is critical. One of the primary communication mechanisms has been meetings/conferences (internal and professional)...we are moving into a period where travel is going to be limited. We'll probably lose this major communication mechanism. So use of conference calls such as this and other communication tools will be critical.
- Getting feedback from the communities and industry will be important, and will constitute a different input that will feed into this network.
- For this project, we should be focusing on the research work that is ongoing and that can be applied in the short run. SRP is always interested in hearing future research needs, but as stated earlier, there's an ongoing process to request future research needs.
- It was noted that SRP researchers are attracted to the program because they want to see their research applied.