

Executive Summary

Endocrine Disruptor Workshop

September 19, 2002

Objectives:

The Endocrine Disruptors Workshop developed out of a need identified by the Tribal representatives of the Tribal Science Council (TSC) to:

- Provide information to Tribes about EPA's efforts with regard to the science and policy developments related to endocrine disruptors; and
- Provide information to EPA about Tribal concerns with endocrine disruptors resulting from a subsistence lifestyle.

Tribal Interests in Endocrine Disruptors:

- The TSC is particularly interested in understanding the current state-of-the-science at EPA relating to chemicals (pesticides, commercial chemicals and environmental contaminants) that might be disrupting the endocrine system of humans and wildlife.
- In general, Tribes are disproportionately impacted by chemical contaminants in the environment through their resource use practices relating to traditional lifeways; a common example being disproportionate fish consumption.
- The impact to Tribes when Tribal resources are contaminated extends beyond impacts to human health and the overall ecosystem to larger issues of Tribal culture, spirituality, and lifestyle.
- Tribes are interested in how to help move endocrine disruptor research forward, focusing on how to tie this research into Indian Country.

Science Related to Endocrine Disruptors:

Introduction to Endocrine Disruptor Compounds (Jerome Goldman, EPA/ORD)

Jerome Goldman of the Reproductive Technology Division of EPA's Office of Research and Development (ORD) National Health and Environmental Effects Research Lab provided a general introduction to endocrine disruptor science. (See Appendix 3) His presentation included:

- A review of endocrine system biology and function;
- Research findings regarding endocrine disruptors (i.e., experimental evidence, outcomes, modes of action, and classes of endocrine disruptor chemicals); and
- An overview of EPA's Endocrine Disruptor Screening Program.

Discussion

- TSC Tribal representatives identified several health conditions that have become prevalent within their communities, namely, hyperthyroidism and arthritis, and questioned whether such ailments could derive from the effects of endocrine disrupting chemicals. They also questioned whether Tribal cultural activities such as fasting could pose potential health risks by triggering a release/clearance of endocrine disruptors

within the body. Dr. Goldman noted that such health effects were part of a complex set of reactions within the body. While some endocrine disruptor research is trying to examine where specific substances are having a physiological impact, the evidence as to whether certain substances are having an adverse effect via an endocrine disruptive mode of action remains weak.

- While supportive of the current assays being conducted by the Agency, the TSC Tribal representatives noted that additional testing focused on low-level and cumulative exposures was needed.
- The TSC Tribal representatives expressed interest in working with the Agency on the issue of endocrine disruptor research, particularly in developing a more holistic, long-term approach to endocrine disruptor research and regulation. The TSC Tribal representatives noted that a new risk assessment paradigm they are developing, which looks at health and well-being and incorporates culture and lifeways practices, might be of benefit to long-term endocrine disruptor research.

History and Status of EPA's Programs Related to Endocrine Disruptors:

The U.S. EPA's Endocrine Disruptor Screening Program: Perspectives and Status (Gary Timm, EPA/OPPTS)

Gary Timm of EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Office of Science and Coordination and Policy provided an overview of EPA's Endocrine Disruptor Screening Program (EDSP). (See Appendix 4) His presentation included:

- An overview of how the Food Quality Protection Act (FQPA) of 1996, the Safe Drinking Water Act Amendments of 1996, and the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) shaped the EDSP;
- An explanation of the various modes of action through which endocrine disruptors take effect, stressing the importance of taking multiple modes of action into account in the EDSP; and
- A status of where the Agency is regarding validation and implementation of the EDSP.

Discussion

- Dan Kusnierz (Penobscot Nation) asked whether the assays being developed could be used to run screens on complex effluents rather than just individual chemicals. Mr. Timm noted that under the FQPA, the Agency is not required to look at additive effects until later, but that other areas within ORD are looking into these issues.
- There was discussion regarding the regulation of endocrine disruptors. TSC Tribal representatives asked at what point during the screening process chemicals would be considered sufficiently risky to be regulated. Mr. Timm explained that the current U.S. statutes are risk-based and that one must demonstrate that at low-levels there is unreasonable risk from a particular chemical. The Federal Food, Drug, and Cosmetic Act requires EPA to consider cumulative risks, that is those that operate according to a common mode of action, when assessing tolerances. This is especially significant for endocrine disruptors because endocrine disruption is a mode of action.

Endocrine Disruptors: What Research is EPA Conducting? (Elaine Francis, EPA/ORD)

Elaine Francis of ORD's Endocrine Disruptor Research Program provided an overview of EPA's current endocrine disruptor chemicals research program, including its goals, history, and future plans involving endocrine disruptor research. (See Appendix 5) She also provided a brief description of other current endocrine disruptor research efforts occurring across Federal agencies and internationally.

Discussion

- Dr. Francis noted that endocrine disruptor research is one of ORD's top five priority research areas, representing a high degree of visibility, interest, and coordination within the Agency.
- Chris Gannon (Confederated Tribes of Warm Springs) asked about current ORD funding options available to Tribes to participate in endocrine disruptor research. Elaine noted that such funding might become available through a broader environmental justice solicitation that will be released by the Agency. She later provided information on additional grants provided through ORD's Science to Achieve Results (STAR) program, which Tribes might be eligible to participate in. This additional information was presented during the closing discussion, as presented below.

An Overview of Endocrine Disruptor Science and Policy at EPA's Office of Water (Tony Maciorowski, EPA/OW)

Tony Maciorowski of OW provided an overview of EPA's Office of Water (OW) activities involving endocrine disruptor regulation and research. Early on, OW provided funding to inventory effluents and study treatment methods. Currently, OW participates on two EDSP workgroups: 1) priority selection for chemicals; and 2) the procedural rule. Future efforts, particularly at the state level, may focus on looking at how to address endocrine disruptor chemicals through the safe drinking water program.

Discussion

- TSC Tribal representatives questioned whether industry-specific, end-of-pipe assays would be developed. Mr. Maciorowski reported that such efforts are being considered, noting that EPA's research lab in Cincinnati, Ohio, is conducting research on endocrine disruptors in effluent, but that a lack of information still exists.

What's Up with EDCs in Region 9? Monitoring for Endocrine Disrupting Chemicals in California (Bobbie Smith, EPA, Region 9)

Bobbie Smith, the Region 9 Regional Science Liaison to ORD, reported on the state of the Agency's endocrine disruptor research ongoing in Region 9. (See Appendix 6) While endocrine disruptor chemicals currently are not specifically regulated because of endocrine disruption

effects under EPA's National Pollutant Discharge Elimination System, Region 9 is working with two Regional labs to develop biological monitoring plans for endocrine disruptor chemicals in surface waters and then conduct testing and validation. As a part of this effort, ORD is offering training and technology transfer, primarily to Tribal and state representatives, on a Fathead Minnow assay for estrogenic compounds exposure.

Discussion

- Rollie Hemmett (EPA Region 2) observed that the Regions, ORD, and OW have a biological advisory committee that might be able to assist in the effort.
- Arnie Kuzmack (OW) noted that this research could have broader relevance, having immediate application to microbial water treatment. He suggested that the training being planned for Tribal and state representatives could also be of benefit to many more senior-level scientists to get them caught up on the current state-of-the-science with regard to endocrine disruptor science.

Overview of EPA Endocrine Disruptor Budget

Overview of Budget Process for Endocrine Disruptor Program (Greg Schweer, EPA/OPPTS)

Greg Schweer of OPPTS's Office of Science Coordination and Policy provided an overview of the Agency's endocrine disruptor budget. (See Appendix 7) His presentation included the following:

- An overview of the 1993 Government Performance and Results Act and its impact on EPA's budget and planning activities;
- A summary of EPA's Endocrine Disruptor Program funding; and
- A discussion of the Agency's Endocrine Disruptor Screening Program expenditures.

Discussion

- Endocrine disruptor assay research currently is conducted around several fish (namely, the Fathead Minnow in the United States, the Zebrafish in Europe, and the Medaka in Japan) to develop standardized fish assays. Chris Gannon noted that many fish popular with Tribes would not be included in these standardized assays and suggested that a study be conducted with a fish, such as the Lamprey, which is popular with the Pacific Northwest Tribes as well as in Japan, to provide data relative to the other standardized fish assays being developed.

Closing Discussion and Action Items:

The TSC Tribal representatives identified a range of increased health effects in Tribal populations, including arthritis, polydactylism, lupus clusters, thyroid disorders, and increased cancer and diabetes rates. Agency representatives observed that the Agency would find Tribal observations and insights relating trends in birth defects, which could be correlated to high exposure scenarios in discrete Tribal populations, of keen interest and utility.

Rollie Hemmett noted that in many cases, as in the case of the St. Regis Mohawk Tribe, a number of outside epidemiological studies have been conducted on affected communities, but the information developed for the studies has never been returned to the Tribes in a form that is useful to them. The Agency needs to develop a guidance letter for conducting science studies in Indian Country that will help Agency staff develop and present data that is useful to the Tribe being impacted and include Tribes in all stages of the study in a respectful manner.

John Persell (Minnesota Chippewa Tribe) questioned what next steps would be pursued following the endocrine disruptor chemical screenings, asking whether reference doses would be developed. Mr. Timm explained that the Tier 2 data developed would drive the development of reference doses. Likely, the reference doses for carcinogens would be examined to determine whether they would be sufficient or whether new reference doses would be needed. The difficulty will lie in developing methods for testing dose response at very low levels, because, given the complex workings and feedback pathways of the endocrine system, researchers are not able to extrapolate down to a dose response curve from higher dose levels. Tribal representatives observed that once reference doses have been established, care must be taken when issuing health advisories, as Tribal members living a traditional lifestyle might not be responsive to the advisories.

Tribal representatives suggested that complex assays (a battery of complementary assays) that can measure for a variety of compounds would be most useful to Tribes (i.e., measuring the end flow of water from a source, rather than measuring for individual chemicals.)

Elaine Francis reported that ORD's STAR program will be issuing a request for applications (RFA) relating to exposure later in 2002. The RFA will be broad, covering biomonitoring of waterways, fish tissue sampling, methods for developing exposure studies, etc. She suggested that this might present an avenue for Tribes to get involved. Information on the current and future STAR RFAs can be found at: <http://es.epa.gov/ncer/rfa/#star03>.

Action Items from the workshop included:

1. TSC Tribal representatives were invited to ORD's Progress Review of Endocrine Disruptors Research Program being held in Research Triangle Park, North Carolina October 29-31, 2002. The workshop will bring together the scientists from the EPA labs and the grants office to discuss the scientific findings in the endocrine disruptor research area.
2. The TSC will look at how Tribes could potentially collect relevant data and see how they could plug into environmental monitoring assessments. This information will be included in OPPTS's Tribal newsletter.

**Tribal Science Council
Endocrine Disruptor Workshop
September 19, 2002
Washington, DC**

Attendee List

Name	Affiliation
Tom Baugh	EPA, Region 4, TSC Member
Mary Belefski	EPA, Office of Prevention, Pesticides and Toxic Substances
Norman Dyer	EPA, Region 6, TSC Member
Kesner Flores	Cortina Indian Rancheria, TSC Member
Chris Gannon	Confederated Tribes of Warm Springs, TSC Member
Rollie Hemmett	EPA, Region 2, TSC Member
Kheryn Klubnikin	U.S. Forest Service
Fran King-Brown	Southern Ute Indian Tribe, TSC Member
Gina Kneib	Sac and Fox Nation of Missouri, TSC Member
Dan Kusnierz	Penobscot Nation, TSC Member
Arnie Kuzmack	EPA, Office of Water, TSC Member
Andrew B. Lindstrom	EPA, Office of Research and Development
John Persell	Minnesota Chippewa Tribe, TSC Member
James Ransom	St. Regis Mohawk Tribe, TSC Member
Michael Rodgers	U.S. Department of Transportation
Keith Sargent	EPA, Office of Policy, Economics, and Innovation
Bobbye Smith	EPA, Region 9, TSC Member
Sherry Sterling	EPA, Office of Prevention, Pesticides and Toxic Substances, TSC Member
Claudia Walters	EPA, Office of Research and Development, TSC Executive Secretary
Felicia Wright	EPA, Office of Solid Waste and Emergency Response

Invited Presenters

Name	Affiliation
Elaine Francis	EPA, Office of Research and Development
Jerome Goldman	EPA, Office of Research and Development
Tony Maciorowski	EPA, Office of Water
Greg Schweer	EPA, Office of Prevention, Pollutants, and Toxic Substances
Bobbye Smith	EPA, Region 9
Gary Timm	EPA, Office of Prevention, Pesticides and Toxic Substances

Meeting Support

Name	Affiliation
Pat Tallarico	Marasco Newton Group
Karen Santora	Marasco Newton Group