

US EPA ARCHIVE DOCUMENT

## **Appendix R**

### **Compilation of Public Comment to the EDSTAC**

**October 31- November 1, 1996, Washington, D.C.**

Two opportunities were given for the members of the public observing the proceedings to comment on all aspects of the formation of the EDSTAC.

#### The First Day

Lynn Bradley, Director, Environmental Health, Association of State and Territorial Public Health Laboratory Directors, indicated that her organization has members interested in human monitoring and the related issues of how you deal with exposure. She recommended that EPA start thinking about addressing the human exposure concerns concurrently with the efforts to design a screening and testing program.

Chris Wilkinson of the Technology Sciences Group, Inc. related that, as a scientist, he is appalled with this process because law is mandating science and therefore science is under the gun. He also expressed concern about the perceived confusion surrounding the scope of the Committee. His advice was that since the law says EPA has to do one thing, develop a screen for estrogenicity, the Committee should deal with the law and then do the other tasks as time permits. The Committee's work could be utilized as a model for future efforts. He also suggested a set of steps the Committee should take: first, identify substances that have to go into a screen; second, complete the screens (a simple process that will raise flags); third, complete actual testing (dose-response issues); and fourth, bring in exposure because EPA will be doing a risk assessment.

Elizabeth Onon, who was not present at the meeting, asked that her comments be read into the record. Gary Timm of EPA read the letter. She asked the Committee to address the potential link between endocrine disrupters and the growing body of scientific knowledge regarding porphyria as relate to chemical disabilities. She further indicated that the nominees did not represent the victims of endocrine disrupters.

Stuart Cagen, Shell Chemical Company, indicated his support for the concept of what the Committee should produce. He suggested that the process has to include validation, interpretation, and an understanding of what EPA does with the results.

Steve Schraeder, National Institute for Occupational Safety and Health (NIOSH), expressed concern about the Committee only considering estrogens, especially as we now recognize that many of the effects we originally thought to be estrogens are actually anti-estrogens and anti-androgens. He suggested that the time is right for the Committee to go broader.

Mary Dadden, President, Long Island Breast Cancer Study, relayed her disappointment in how the information regarding the meeting was communicated. She requested that, in the future, notice be given at least four to six weeks in advance. In addition, she indicated her desire to see the discussions recognize the truly dangerous nature of chemicals and pesticides in the environment and their effects on humans. She suggested that the Committee consider opening at least two seats to consumer advocates who are not involved from a scientific perspective but can bring the concerns of the general public.

In response, the facilitator/convenor indicated that efforts to provide more notice will be made. He also indicated that the National Breast Cancer Coalition had offered to assist in coordinating efforts to involve disease-specific consumer interests in addition to breast cancer groups. One nominee added that the addition of consumer advocates to the Navy Breast Cancer Study had been very helpful and that this Committee should consider their inclusion. The idea of a communications work group, where concerns around the possibility of the public misunderstanding the results of screens and tests could be addressed, was raised. Another nominee added that the Committee seemed to be missing a representative of the people affected most by these chemicals and pesticides. The idea of moving the EDSTAC meetings around the country was raised as one way to include a wide range of perspectives and interests including consumer advocates. In addition, using the Internet to disseminate information was proposed, though its ability to disseminate information to a wide range of individuals was also recognized.

Alan Robeson raised the issue of testing mixtures. He indicated that a lot of people are concerned about pesticide runoff from agricultural lands and the combinations of pesticides. He recommended that, if the Committee moves its meetings around the country, they should go to a midwest city such as Chicago, Kansas City, or Des Moines in the spring.

John Berlau of Consumer Alert asked that the Committee consider consumer's interest, but added that there are different definitions of what constitute "consumer interests." He asked that the Committee look at the benefits of these substances as well as the negatives and said that consumers do not benefit from regulations developed without good science.

Miranda Henning, ChemRisk, suggested that, given the exposure issues as well as the fact that the information might be used in risk assessments, the Committee should involve a risk assessor.

Eric Juzenas, Health Policy Analyst, American Public Health Association, suggested that the Committee's environmental justice representation should be enhanced by adding some additional participants.

Rick Hind, Greenpeace, stressed that the Committee should keep in mind the issue of public disclosure and participants should volunteer information regarding their financial backing and/or interests as they relate to endocrine disrupter screening and testing if people want the process to be truly transparent. Relating to scope he said that the Committee should focus on looking at this through the lens of existing FIFRA and TSCA regulations. In addition, he felt that the Committee should not get caught looking at chemicals one-by-one.

Charlie Cray, Greenpeace, wanted the Committee to look at persistent organic pollutants. He also added that the Committee should incorporate, from an environmental justice perspective, some of the folks who represent the people who suffer as a result of the migration of these substances to the colder regions of the world (e.g., Alaska). He indicated that the public wants a list of products they should not buy and labeling that explains what is in a product. Other countries that have approached these issues, (e.g., Denmark) may be a useful source of information. If EPA is not going to develop these lists, he asked, who will?

Nelsa Ford asked whether all future meetings were going to be public now? EPA indicated that all EDSTAC meetings will be public, however, whether all work group meetings will be public remains to be determined.

### The Second Day

Maurice Zeeman, OPPTS, EPA, raised the issue of the Committee balancing ecological and human health issues because so much uncertainty exists regarding human health effects whereas we are more certain about ecological effects.

John McCarthy, American Crop Protection Association, commended the Committee nominees, EPA, and Keystone on their efforts. He raised three points: first, focus equally on human and ecological effects; second, look at all possible hormonal effect endpoints raised during the deliberations in parallel, while recognizing the statutory importance of specific ones; and third, the Committee should get on with the task at hand without getting too bureaucratic and use the Science Integration and Coordination work group in the future if necessary.

Layla Patarsi, Center for Food Quality, Food and Drug Administration, explained that food additives comprise a set of chemicals not currently regulated under TSCA or FIFRA, and asked that the Committee consider them in their deliberations.

Robert Fisher, National Council of the Paper Industry for Air and Stream Improvement, talked about the structure of the Committee and recommended that the group consider looking at how the EPA structured a process dealing with the Gulf of Mexico where many similar issues were addressed. They used a tiered process and included issue committees, a technical steering committee, and a management committee/policy review board. He also added that the meetings of the working groups should be open to the public for observation for two reasons, first, the private sector is often involved in research relevant to the issues being discussed, and second, the private sector is often involved in the decision making process and needs to know about the findings coming out of these efforts.

Bill Kelley, the Institute for Regulatory Policy, recommended the nominees develop a list of what can be done between the organizational meeting and the December meeting before leaving. He also raised serious misgivings regarding the name endocrine “disrupters” and suggested changing it to “disruption” or “effects” as the Committee is talking about a hazard screening process rather than risk assessment.

Elizabeth Reeves, requested the Committee consider using cell culture testing rather than animal tests. She added that the Committee should remember the ultimate stakeholder is the American citizen and the ecological issues should not be overlooked.

Mary Ann Dodden, expressed support for the evolution toward a broader definition of endocrine disrupters than just hormone disruption. If the definition says “only affect the hormone system,” she felt, the Committee will not examine the immune, reproductive, growth and neuro systems. She also stated that the Committee needs to recognize that other issues may be added to their discussions as their understanding of science evolves.

Elsa Ford, asked the Committee to commit to follow-up testing of past use and new use chemicals as pertains to endocrine disruption. Coordinated documentation, she added, is important in these types of efforts. Finally, she said that the public needs to know about the cumulative effects of chemicals and pesticides in the real world and asked the Committee not to focus only on single ones.

Patricia Fail, Research Triangle Institute, told the Committee nominees she had been working mainly on FIFRA issues for the past 10-15 years. After listening to the need for various screens

and tests during the past two days, she indicated that the Committee needs to take already existing data (from FIFRA companies) and validate the tests that exist and see if the chemicals that test positive are actually endocrine disrupters.

John Hines, an independent consultant, told the nominees that they need to address what product(s) they expect as a result of this effort. He also indicated that the discussions on prioritization of what issues to address were good. Regarding membership, he added, the Committee nominations seem to be carefully structured and will result in a fairly large Committee, so do not add too many more people.

### **December 12-13, 1996, San Francisco, California**

Lewell D. Brenneman, MD, Ph.D., expressed his point of view that few toxins in the environment are tested for cancer and hormone disruption. He outlined two approaches for dealing with manufactured chemicals such as carcinogens--acceptable risk and public health, and expressed concern about the fact that it is usually the consumer, rather than the producer, that has the burden of proving chemical toxicity. Dr. Brenneman urged the EDSTAC to develop long-term and generational testing approaches to endocrine disruption.

Joan Reiss, Project Coordinator of the Bay Area Breast Cancer Study, urged the Committee to develop outreach activities beyond their present scope, using several and varied means of communication. Ms. Reiss encouraged the Committee to be bold, swift, and innovative with its activities. She also stressed that small doses of chemicals can have an additive effect, and she urged the Committee to consider this when looking at screening and testing. Ms. Reiss went on to request that the Committee identify key geographical areas and criteria to start studying endocrine disruption; that new chemicals should be kept off the market until proven not harmful to humans and animals; that acceptable dose standards be shifted from levels for adult males to those acceptable for a newborn infant; and that synergistic effects of chemicals be analyzed.

Cindy Dyer of the U.S. Department of Agriculture, Food Safety and Inspection Service, commented that brominated flame retardants, which bioaccumulate, and are widely used in shipping cartons, are a prevalent class of chemical which needs to be scrutinized. Dr. Dyer stated her view that there is currently too much concentration on dioxin and PCBs in the scientific community, and that brominated compounds, as opposed to chlorinated compounds, deserve closer investigation. Dr. Dyer also urged the Committee to utilize exposure hazard database information.

Judy Brady, a member of the Cancer Prevention Coalition and the Women's Cancer Resource Center, urged the Committee to look at the safety of breast milk as it relates to endocrine disruption.

Keith Bowers, of the IFS Kaiser Consulting Group, Global Environmental Issues Unit for Eastern Europe and the former Soviet Union, made the suggestion that the EDSTAC consider identifying and reviewing data developed in other countries that might help or provide insight and fill data gaps in its own and other domestic efforts related to endocrine disruption. Mr. Bowers stated that issues such as endocrine disruption are transborder issues, and that societies all across the globe are concerned and working on the same matters.

Sandra Marquart, of the West Coast office of Mothers and Others for a Livable Planet, asked the Committee to consider the following priorities for testing: pesticides, plastics, solvents, and other products of major daily use. Ms. Marquart stressed her belief that this is an international issue, heavily influenced by trade patterns. She also encouraged the Committee to adjust its risk considerations from levels acceptable for adult males to finding the levels for the most susceptible organisms (e.g., infants), and to address issues of synergism and threshold levels. Ms. Marquart asked the EDSTAC to develop the most practical tests to find the greatest number of chemicals given its budgetary constraints. She urged EPA not to wait for final endpoints to be determined, but rather to take action and to extend public outreach to consumers at the first sign of possible problems with chemicals. Ms. Marquart further urged the Committee to hold future meetings as close to mass transit systems as possible.

Leslie Meister, of the Silicon Valley Toxics Coalition in San Jose, stressed the synergistic effects of chemicals in Silicon Valley laborers' and consumers' bloodstreams. Ms. Meister urged the Committee to use the "precautionary principle" in its decision making processes. She stated that issues of importance in the screening process include the determination of exposure thresholds for different populations (e.g., workers or children or *in utero* infants), and the identification of endpoints.

Davis Baltz, of Commonweal, asked the EDSTAC to look at the synergistic effects of chemicals. He suggested that, in order to streamline the EDSTAC's process, the Committee consider classes of chemicals as a whole when it is determined that several individual chemical members of that class pose problems. Mr. Baltz also stated that the validation of screens should provide information that is both useful and predictive, allowing EPA to enact policies and draft legislation that reduce exposure to hazardous chemicals. He, too, encouraged the Committee to adopt the use of a "precautionary principle."



Robert Gould, Associate Pathologist at the Santa Theresa Community Hospital in San Jose and a member of Physicians for Social Responsibility, urged the Committee to act promptly and to create a timetable for developing appropriate methodologies. Dr. Gould stated that screening and testing must be a part of an ongoing process of communication, and that the EDSTAC process should be completely open and transparent, including activities of the work groups. He asked the Committee to address estrogenic compounds; thyroid, androgenic, anti-estrogenic, and anti-androgenic effects; and additive and synergistic effects. Dr. Gould suggested EPA regulate whole classes of chemicals, and to use a “precautionary principle” as its guiding mechanism. He recommended that measures of high sensitivity and low specificity be used; that both wildlife and human health effects be considered; that background levels in humans should be taken into account; and that the EDSTAC study entire populations and communities.

Ritchie Fraley, a scientist at SRI International, stated that while receptivity measurement is cost effective and efficient, adherence to receptor-mediated tests could miss particular mechanistic indications. Dr. Fraley indicated that technologies such as accelerator mass spectrometry might prove helpful in the Committee’s work. She also asked how testing would be funded, and who would conduct the tests.

Jane Williams, of California Communities Against Toxics, stated that California is an industrialized state, subject to a wide range of impacts including dioxin contamination and effects from military facilities. She requested that the Committee address human health and ecological effects, as well as synergistic impacts. Ms. William expressed concern that a lack of connection to the policy making arena would render the process ineffective. She asked the Committee to consider the task of implementation in the course of developing its recommendations and develop recommendations in such a way that all producers and communities could understand and use them.

Please refer to Attachment F for textual statements provided by Dr. Brenneman, Ms. Reiss, Dr. Dyer, Mr. Baltz, and Dr. Gould.

### **Response to Public Comment**

The EDSTAC chair thanked the public for its comments and perspectives, adding that the degree of the quality of the comments at this meeting were exceptionally intelligent and helpful. Dr. Goldman explained that there would be four more meetings during this fiscal year in different parts of the country, and that EPA hopes to improve its outreach efforts and will coordinate a communications and outreach work group to assist in this effort.



Dr. Goldman stated that the endocrine disruption screening and testing process came about as part of legislation on drinking water standards and pesticides. She emphasized that the matter of real importance in the process is to do the necessary work using the best available science, and to do so in a framework that will help make policy decisions to help public health and the environment. Dr. Goldman clarified that the language in the standard in the new pesticide legislation is “a reasonable certainty of no harm.” She stated that the EDSTAC will take into account a multiplicity of exposures, and that other processes are also under way to advise and inform the agency in this matter.

Regarding the process of the advisory Committee, Dr. Goldman stated that all decisions made by the Committee will be made in the full Committee in open session, and that much will be brought to the Committee by work groups and individual scientists.

Dr. Goldman recognized that Toxics Release Inventory (TRI) matters are not of peripheral concern for her. She stated her belief in the need to link domestic efforts with international activities, and highlighted the fact that the Office of Economic Cooperation and Development (OECD), which has been working on issues related to the testing of chemicals, recently decided to address endocrine disruption issues. She also offered other examples of international efforts related to chemical pollutants, endocrine disruption, and persistent organic pollutants, and that the United States is presently working with Europe and Canada on long-range transport, global policy on populations, and the planning of a meeting at the United Nations Environmental Programme (UNEP) in January to discuss coordination of research.

### **February 5-6, 1997, Houston, Texas**

Due to changes in the schedule, some members of the public were able to provide comments prior to Dr. Goldman’s departure during the afternoon of the first day of the Houston plenary meeting. A period of two hours was also devoted to public comments later in the evening of the first day, during which nearly the entire Committee was present. A total of nineteen members of the public offered comments, twelve of whom also submitted written comments which can be found in the EPA Docket. This meeting summary attempts to capture the essence of the comments made by the public to the EDSTAC during both of those sessions. In addition, some members of the public who were not present at the meeting sent written comments to The Keystone Center. While these are not summarized below, they are also available through the Docket.

Sue Pope, a member of Downwinders At Risk and an advisory board member of the American Lung Association of Texas, expressed great concern over human health and ecological problems in her community seemingly attributable to endocrine disruption. In particular, Ms. Pope

chronicled health problems of her family and livestock alleged to stem from hazardous waste incineration at a cement kiln in her area. Ms. Pope entered into the Docket a video which included a television show about hazardous waste-related problems in her town, Winona, Texas. This segment is entitled "Winona Residents Demand Justice for their Children" and is available through the EPA Docket.

LaNell Anderson, a citizen from Channelview, Texas, detailed health problems in her community and family as a result of the effects of dioxin releases along the Houston Ship Channel. Ms. Anderson asked that the Committee make explicit its goals and expected steps for the implementation of its recommendations, and that State authorities be involved in the EDSTAC as appropriate. She asserted that the EDSTAC process merited close public scrutiny and monitoring, as its effects will have national impacts. Ms. Anderson encouraged full, impartial, firm, and informed participation by each of the Committee members in the EDSTAC process.

Brandt Mannchen commented on the composition of the Committee and encouraged awareness that no specific interest in the Committee have the ability to unduly influence the process. He said that he felt the Committee was not broad enough in its composition, especially with respect to community-based group representation, specific health problem/developmental effects group representation, and minority representation. Mr. Mannchen encouraged the EDSTAC to develop a screening and testing program that would be flexible enough to accommodate chemical synergies, additive effects, and new information as it becomes available.

Chavel Lopez, a member of the Southwest Public Workers Union in San Antonio, Texas, commented on the health problems surrounding areas adjacent to Kelly Air Force Base due to fuel and toxic chemical storage and toxic chemical dumping. Mr. Lopez, a member of a group of approximately 500 concerned citizens in Bear and Medina counties, raised concerns regarding contamination of the Edwards Aquifer. He also urged that the Committee include more representation of people-of-color.

LaNell Anderson read a statement written by Ms. Phyllis Glazer, President of Mothers Organized to Stop Environmental Sins (MOSES), which raised concerns about the effects of a hazardous waste incineration facility near the town of Winona, and expressed dissatisfaction with the requirements of State agencies in requiring testing for dioxins. In addition, Ms. Glazer's statement offered concern about the effects of other hazardous waste sites shipping waste to the incinerator for disposal and/or storage.

Jane Elioseff, of the Galveston-Houston Association for Smog Prevention (GHASP), an organization devoted to improving the air quality of the Galveston-Houston area, noted that the

Galveston-Houston area is a severe ozone non-attainment area with high levels of nitrogen oxide. She stated that this represented a large air quality problem for a suburban area. Ms. Elioseff said that GHASP, which receives funding from the W. Alton Jones Foundation to pursue its work, has determined that endocrine disruption is connected to air pollution and has just published a report on air quality in Houston, called "Danger in the Air," which she made available for the Docket.

Yolanda Johnson, a member of the Southwest Public Workers Union in San Antonio, Texas, expressed great concern with the generational effects of environmental contamination and endocrine disruption. Both she and her husband have experienced health problems, as have most members of their family raised near the fuel and chemical storage and disposal sites at Kelly Air Force Base. Ms. Johnson thanked the Committee for its work, and urged the EDSTAC to encourage greater communication and disclosure with respect to endocrine disrupting hazards.

Susan Pitman, Network Coordinator of The Chemical Connection, A Public Health Network of Texans Sensitive to Chemicals, commented that the Committee ought to consider chemically-sensitive persons and vulnerable populations in screening and testing for endocrine disruptors, rather than using healthy adult males as its benchmark.

Dominga Adams, a member of the Southwest Public Workers Union in San Antonio, Texas, detailed numerous ailments experienced by both herself and her husband, as well as by their children and grandchildren. Ms. Adams expressed doubt that her family's health problems were genetic, and indicated she felt they were caused by chemicals from Kelly Air Force Base. She also encouraged thorough governmental communication with the public in instances where health risks may or do exist.

Suzanne Martine Rohrer, of The Endometriosis Association, explained that she was diagnosed with endometriosis, discussed the effects of the disease, and outlined the consequent challenges in her life due to the disease. She urged the Committee to work diligently and asked that dioxin receive particular scrutiny, since high level exposure to dioxin has been associated with increased incidents of endometriosis.

Kim Phillips, former environmental chairman for the Texas PTA, said that she was grateful for and supportive of the Committee's work, and asked that children, rather than adult males, be used as guides for exposure effects. Ms. Phillips cautioned the EDSTAC that consensus processes can prove difficult, but that they are worth the effort. She outlined some of her organization's principal concerns with respect to endocrine disruptors, and urged the Committee to consider the synergistic effects of chemicals and to err on the side of caution.

Raul Villar, a retired welder from Kelly Air Force Base, commented on his family's health problems since living near Kelly Air Force Base, and expressed anger that the contamination of the area around his home had not been made publicly known prior to his purchase of the lot.

David Casen, of Save Whitewright and Tri-Counties (SWAT), said he was concerned about dioxins in his community, and deeply cynical about the consensus process of the EDSTAC. Mr. Casen stated that he feared the Committee's decisions would be made based on political considerations. He also expressed his concern caused by having representatives from chemical production companies on the Committee. Mr. Casen asked the EDSTAC to use mechanistic findings as suggestive but not limiting factors in screening and testing, and that the Committee adopt the "precautionary principle."

Virginia Castillo, a citizen residing near Kelly Air Force Base, asked that someone look into the causes of numerous health problems in the community adjacent to the Base.

Davis Baltz, a Research Associate with Commonweal, outlined eleven points. These points covered: using caution to determine when an effect was "adverse;" the importance of the EDSTAC's Principles Work Group, its charge, and its composition; deferral of chemicals in the screening and testing process; the importance of recognizing new information on endocrine disruption and chemical effects; the need for "a new paradigm" with respect to timing and exposure information; a re-evaluation of quantitative risk assessment; the encouragement of the use of the "precautionary principle;" the need for EPA to identify and allocate material resources to permit full participation and expression of all points of view within work groups; his desire to have a defined schedule of meeting dates for the duration of the EDSTAC process; the need for encouraging public education and comment on matters related to endocrine disruption from other countries; the importance of studying sex steroid- and thyroid-related effects; and, the need for screening, testing, and evaluating endocrine disruptors to become an ongoing responsibility of EPA.

Neil Carman, Ph.D., of the Sierra Club and formerly of the Texas Air Quality Board, presented comments from people near a site in Jacksonville, Arkansas, which expressed doubts about the fairness of health studies by the EPA and the Agency for Toxic Substances and Disease Registry. Mr. Carman also said he had little faith in the regulatory process. He urged the EDSTAC to look at synergistic effects of chemicals and to use the "precautionary principle."

Winifred Hamilton, Ph.D., of GHASP, stated that she felt most affected communities are not represented adequately in decisionmaking processes related to endocrine disruption. She said it was difficult to buy a non-contaminated house in Houston due to the prevalence of chlordane.

Dr. Hamilton urged the Committee to remain focused on health concerns, and offered caution that consensus processes not be misused. She continued by outlining principles she felt were important, including shifting the focus of acceptable levels of endocrine disruptors to protecting the most vulnerable populations (e.g., children and conceptuses *in utero*).

Judy Starns, a citizen from Channelview, Texas, outlined the impacts of contamination in her community, and expressed concern that her community has not been able to have a fair health study conducted.

Karla Lamb, a citizen from Channelview, Texas, outlined personal health problems since moving to Houston in 1975. She expressed anger and frustration at the deleterious effects chemical exposure has had on her health, and urged the Committee to help others in similar situations.

### **Response to Public Comment**

Dr. Fenner-Crisp thanked the members of the public for their comments. She stated that due to the mandate under which the EDSTAC was operating, the scope of the Committee's deliberations would likely have to start by focusing on the sex steroids, but that such a focus was not indicative of the EPA's research priorities.

Regarding the public request for a document detailing the state of the science related to endocrine disruption, Dr. Fenner-Crisp stated that the EPA has been working on such a document for one and one-half years. The document is currently undergoing review by EPA's Science Policy Council, and should be available on the World Wide Web and in hard copy through conventional avenues shortly.

Referring to public comments on the EDSTAC process and concerns with respect to consensus processes in general, the facilitator stated that comments on the Committee's process, even critical ones, are very welcome. With respect to the availability of information, he said that he hoped the use of the World Wide Web site would help meet the needs of the public, and added that the pace of the EDSTAC would hopefully decrease, thereby allowing members of the public an easier opportunity to track its deliberations.

Members of the Committee spoke to the concerns citizens raised about having representatives from chemical producing industries sitting on the EDSTAC. Some members firmly stated that there was, in no manner, a conflict of interest. In fact, Committee members pointed out, it is only in places like the EDSTAC that representatives of all interested parties can speak and share

commonalties as humans, and that a level of trust in the commonality of commitment would have to evolve.

Committee members also cautioned members of the public against putting all their hope in the EDSTAC as the solution to endocrine disruption or, more generally, to environmental contamination. They stated that the EDSTAC is only one part of a process to improve the situation, and that the limitations of science alone would likely present very real constraints to the effectiveness of the Committee.

#### **April 29 - May 1, 1997, Baltimore, Maryland**

Following a brief public reception hosted by the EDSTAC and attended by several members of the Committee on the first day of the plenary meeting, members of the public were invited to offer comments related to the scope and charge of the EDSTAC. The public comment session lasted longer than two hours, and allowed time for more than forty individuals to provide comment to Committee members, nearly all of whom were present. Due to the number of individuals seeking to provide public comment, all those who signed up to speak to the EDSTAC were requested to keep their comments to no more than four minutes in length. While this request may have caused frustration on behalf of some individuals, the intended and effected result was to allow all persons wishing to provide comment the opportunity to do so. Written comments submitted by members of the public may be found in the public docket (Docket Number--OPPTS-42189; phone 202-260-7099). This meeting summary attempts to capture the essence of the comments made by members of the public to the EDSTAC during the public comment session.

Thomas Hobbins, MD, from Physicians for Social Responsibility, commented that one of the most important recommendations offered by his organization is that Congress needs to provide a higher level of funding for endocrine disruption research. Dr. Hobbins related anecdotally the potential for paradigmatic shifts in thinking related to perception and actual awareness of health problems and risks. He urged the Committee to look at zero tolerance as a guide post rather than acceptable thresholds for risk.

Keith Bowers, of ICF, Inc., offered comments concerning international institutions working on issues of endocrine disruption. Mr. Bowers commented that the endocrine disruptor-related work being done by agencies and organizations such as the United Nations Environmental Programme and the OECD is being conducted in conjunction with their work on persistent organic pollutants. He stated that it was important for the EDSTAC to know how its work differs conceptually from the OECD's work, and that the Committee should look at non-persistent organic pollutant types of chemicals.



Gail LeMaire, Ph.D., of the Endometriosis Association, stated that there are currently millions of American women and girls with endometriosis, and expressed frustration at the lack of support for women with the disease, as well as the lack of information and research on the disease to date. Dr. LeMaire requested that more research be conducted on the relationship of chemicals such as dioxin, PCBs, and TCCD and their effects on the body. She added that studies should not simply examine instances of adverse effects, but should be proactive before such effects are manifested in the body. Dr. LeMaire concluded by stating that progesterone is noticeably missing from the EDSTAC's scope.

Anneke Davis, from the Maryland Conservation Council commented on the public information process of the EDSTAC. Recognizing that the Committee is under tremendous pressure to produce their deliverables, she stated that testing is going to take a lot of time and money, as well as public support. In order to accomplish this and to garner public support for adequate funding of the implementation of the EDSTAC's recommendations, Ms. Davis encouraged the Committee to keep groups of citizens concerned about endocrine disruption issues, such as the Maryland Conservation Council, informed. Furthermore, Ms. Davis encouraged the EDSTAC to draft its final report in a manner that will be intelligible to and usable by the general public. Finally, she urged that the Committee not forget that the effects of endocrine disruptors on ecological systems can have a tremendous impact on humans as well.

John Holtzman, of the Chemical Manufacturers Association noted his appreciation of the Committee's emphasis on insisting upon a scientific approach to its deliberations and deliverables. He noted that the EDSTAC's work will benefit the large number of studies currently being conducted in the field of endocrine disruption.

Carolyn Burrige, of the Maryland Chemical Industry Council complimented the members of the EDSTAC on their progress, and noted the timeliness of the Committee's work given the attention endocrine disruption is getting in state and national legislatures. However, she expressed concern that the state of the science on endocrine disruption is not yet sufficiently advanced to allow the formulation of sound public policy related to the subject. She encouraged the EDSTAC to emphasize the need for solid science and facts in its work, and to appropriately apply its limited resources toward this end.

Susan Gilson, from FMC Corporation, expressed support for the work of the EDSTAC, and encouraged the Committee to develop recommendations useful to professionals in fields affected by endocrine disruption, referencing her position as an industrial hygienist as an example of such fields. In addition, she noted interest in the work of the STWG in gauging dose responses, as well as other tools the work group employs.



John Casana, an environmental engineer, stressed his desire for the EDSTAC to use a scientific approach to quantifying risk and decision making in its work; to make a conscious decision as to what degree of uncertainty is acceptable in its recommendations; and, if there is greater uncertainty than appropriate, to devise a way to get to an acceptable level of uncertainty for a defensible position for future generations.

Grace Ziem, MD, Ph.D., requested that the EDSTAC seek testimony from physicians who are treating humans suffering from problems related to endocrine disruption when making recommendations for screening and testing. Dr. Ziem encouraged the Committee members to be sensitive to frustrations that can occur in the interface of academics and physicians, and asked that the Committee allow as much flexibility as possible in its recommendations for physicians to treat their patients according to their own judgment.

Linda Roberts, an employee of Chevron, requested that, whenever possible, the public have access to documents discussed at the plenary meetings in advance of such meetings to allow for appropriate comment and understanding of the issues. She expressed appreciation for Dr. Goldman's comments with respect to validation and encouraged the Committee to develop clear criteria for interpreting the results from screens and tests. In addition, she noted that, as data from screens and tests are collected, it would be useful to check this data against known endocrine disruptors to see how predictive the testing was. Ms. Roberts also requested the Committee to be sensitive to the issues of dose selection, and to hold more discussion with respect to the issue of zero tolerance.

Ajax Eastman, a former member of the Maryland Conservation Council, expressed concern about the development, production, and release of potential endocrine disrupting chemicals during the time it takes for the EDSTAC to reach consensus on a screening and testing program for EPA. He questioned whether a science or policy measure existed to slow or stop the introduction of such new chemicals until the Committee's recommendations are developed. Mr. Eastman also expressed concern that the CF would allow issues such as risk assessment and cost/benefit analysis to put greater priority on economic matters than human and ecological health.

Pat Lane noted great concern about the health consequences of the incineration of medical and municipal wastes. Ms. Lane expressed appreciation for the publicly open and flexible process being used by the EDSTAC in developing its recommendations. In addition, she commented that terms such as "risk assessment" and "parts-per-trillion" are perhaps not clearly or fully understood by the general public, and that such terminology takes on international implications when used in reference to chemicals used around the world. Furthermore, Ms. Lane noted that the public's perception of risk is a critical element in effective communication and protection, and asked the

Committee to use any influence it had to encourage medical facilities to sort their waste and reduce the incineration of PCBs.

Lisa Carlson and Kirstin Smith, both medical students at Johns Hopkins University and members of the student chapter of Physicians for Social Responsibility, presented a joint statement and expressed both concern that only two systems--the gonadal and thyroidal systems--were mentioned in the Committee's scope, as well as hope that the Committee would expand its scope beyond estrogen-, anti-estrogen-, androgen-, anti-androgen-, and thyroid-related effects. Ms. Smith read a statement from the student chapter of Physicians for Social Responsibility which called for: (1) larger studies on humans and animals looking at chemical effects and synergies; (2) the burden of proof to be placed on manufacturers to prove the safety of chemicals before marketing them; (3) the use of small doses in testing for endocrine disruption; (4) restrictions on medical waste incinerators and annual monitoring by EPA of waste from every incinerator for levels of mercury and dioxin; and (5) aggressive education of the public by EPA on endocrine disruption.

Phyllis Glazer and Sherre Holmer, of Mothers Organized to Stop Environmental Sins (MOSES), detailed the story of Winona, Texas, where a well was driven through the local aquifer for the injection of hazardous waste into the ground, which resulted in contamination of the aquifer. They commented that, in most cases, those affected by endocrine disruption lack political power, and urged that any screening and testing program should make use of anecdotal information from affected persons who live or have lived within two miles of facilities which store, produce, or dispose of hazardous waste. Furthermore, Ms. Glazer and Ms. Holmer requested that the screening and testing program developed by the Committee take into account the synergistic effects of multiple chemicals, due to their view that the regulation of exposure to single chemicals is a matter of regulatory convenience. They recommended that the screening and testing program focus on: the most vulnerable life stages; both human health and the environment; and the transference of chemicals through bioaccumulation and human relationships (e.g., breast feeding). In addition, they recommended that: information about the potential harm of any substance be released from the Committee to the public at the earliest opportunity; the Committee place emphasis on the certainty of safety. They noted that the endocrinological effects do not necessarily follow a linear relationship, and that current levels of acceptable risk burden populations of minorities. Finally, they urged the EDSTAC to practice good science without allowing an uneven balance of representation on the Committee. In accord with this, they recommended that the Committee membership be restructured to decrease the number of agency and industry representatives.

Albert Donnay, executive director of MCS Referral and Resources, addressed the definition of “endocrine disruptor” as discussed by the Committee. Mr. Donnay commented that the inclusion of the notion of “adverse” in the definition overlooks the fact that there are many endocrine disruptors that may produce beneficial or therapeutic effects, and that effects of endocrine disruptors may vary by individual. He encouraged the Committee to remind the public that such beneficial endocrine disruptors do exist. In addition, he asked the Committee to not only include the young and developing in recommended field studies, but to also include elderly animals. Mr. Donnay also encouraged the Committee to consider its definition reference to exogenous substance, stating that light can have an effect on hormones (e.g., diurnal cycles). Finally, he asked that the EDSTAC clarify their definition inclusion of “(sub)populations” to identify what the smallest subpopulation that needed to be considered was.

Gwen Dubois, MD, of Physicians for Social Responsibility, stated that the consideration of groups and classes of chemicals rather than of individual chemicals in the screening and testing program was very sensible. She urged the Committee to not be reticent to recommend action on information of harmful endocrine disruption to ban certain chemicals. In addition, Dr. Dubois expressed hope that the Committee’s recommendations would address exposure to multiple chemicals, and asked the Committee to consider the hazards of medical waste.

Raymond Yang, a professor of Toxicology at Colorado State University, applauded the endurance of the EDSTAC members through the course of difficult deliberations. He expressed his view that the figure regarding the number of chemicals released into the environment used by the Committee was low, and encouraged the Committee to give serious consideration to the issue of mixtures in all of its deliberations, products, and recommendations.

Bruce Baird Struminger, a student at Johns Hopkins University Medical School, expressed concern regarding the way that EPA formed the EDSTAC. He stated his view that the Committee lacked a clear sense of consensus on the definition of “endocrine disruptor” and noted that, while simplicity is good where appropriate, the emphasis in the definition should be on accuracy. Mr. Struminger stated that the issue of endocrine disruption is a complex one, and that a simple definition would not help protect the public health. He urged that scope be enlarged to include additional hormones, and expressed his feeling that policy on endocrine disruption is getting ahead of the clinical science on the issue. He expressed dissatisfaction with the level of education on endocrinology in medical schools, as well as the lack of communication about the issue of endocrine disruption in endocrine journals. He asked the Committee to take a precautionary stance in its recommendations and, given the growing and irreversible bioaccumulation levels of dioxins and PCBs, to place the onus on industries to prove their products do not compromise human health.

Audrey R. McMahon, from the Learning Disabilities Association, stated that maternal thyroid dysfunction is a very serious endocrine disruption issue. She further stated that EPA research has clearly related PCBs to diminished thyroid function and subsequent effects on humans, including embryonic development. Ms. McMahon expressed her view that developmental disabilities are epidemic in the United States, and added that she hoped the Committee's recommendations would help this situation.

Mimi Cooper, of the League of Women Voters in Baltimore, expressed her hope that chlorines and the burning of dioxins would be affected by the Committee's work and would eventually be brought under control.

Yataka Aoki, from Johns Hopkins University Public Health School, stated that it is difficult for members of the general public to understand what Types I and II errors are, and asked the Committee to use commonly familiar language in its recommendations and final report.

Erica Wexler, a science teacher from South Baltimore and a member of the Community Advisory Panel, commented that it was important for the EDSTAC to follow a scientific process and take all the advice and views into account as it proceeds with its tasks. She added that the Committee should identify the best screens and tests, validate them, and implement their use.

Greg Merrill, from the Chlorine Chemistry Council, noted a threefold increase in state legislation that make reference to endocrine disruption, and that those who were responsible for creating many of the regulations and laws, particularly at the state level, are looking to the EDSTAC for guidance. He stated that it was important that the foundations EDSTAC establishes and the principles adopted be based on sound science to ensure confidence in their implementation.

Davis Baltz, of Commonweal, described journal articles about gender maturation and exposure to certain chemicals. He stated that, as reflected by research in the popular press; evidence of endocrine disruption is increasing. Mr. Baltz expressed hope that the Committee would draw the conclusion to increase research and prevent exposure. He stated that members of the public have a right to know about the EDSTAC's activities, and that plenaries should continue to be conducted across the country to allow input from different geographical areas.

Ann Mulligan, National Coordinator for The DES Cancer Network, stated that DES-affected persons represent one of the few populations known to be affected by endocrine disruption. She urged the Committee to construct a new paradigm for endocrine disruption, and to adopt zero risk and precautionary principles. Ms. Mulligan described generational effects of DES, adding that DES is still being given to women in other countries and the affected population, therefore, is

a global one. She commented that traditional risk assessment failed those exposed and needs to be revisited, noting that another chemical, AZT, currently being prescribed to pregnant women shows DES-like effects.

Alyce Ortizar, of the Well Mind Association of Greater Washington, detailed cancer rates and breast cancer incidence stating that she was troubled by the fact that companies that have caused endocrine disruption seem to be benefiting from treating endocrine disruption. She urged the adoption of zero tolerance beliefs, and the shifting of the burden of proof onto industry.

Carolyn S. Van Pelt, of DuPont and the American Crop Protection Association, applauded the Committee for its process and for the work performed thus far.

Daniel Pontious, from the Maryland Public Interest Research Group, stated that the information shared with the public is only as good as the testing that is done to generate that information. He expressed his appreciation that the Committee would be looking at multiple chemical exposures, and encouraged the use of caution and scrutiny in looking at low-dose toxicity of some chemicals.

Keary Cope, a student at Johns Hopkins University, suggested the consideration of certain metabolites in the Committee's work.

Alan Noe, of the American Crop Protection Association, noted that the large number of public commenters indicated a high level of interest in issues related to endocrine disruption. He commented on the role and benefits of pesticides in the American agricultural sector, and discouraged the use of the precautionary principle. He also urged that science "drive" the EDSTAC process.

Lara Shane, of Responsible Industry for a Sound Environment, expressed her belief that the EDSTAC process is a great one to bring people from the different sides of the spectrum to come together in productive discussion and action, and offered the Committee her wholehearted support.

Valerie Jewitt, from the American Crop Protection Association, commented that her family had been impacted by the incidence of breast cancer, and said she supported getting all affected parties involved in the EDSTAC process. She encouraged the use of sound science in effecting the parties' mutual goal of making the environment safer for all life, and added that she looked forward to when this type of process is commonplace in decision making.

Charles Cangerni, of Reliance Fire Protection, discussed the role of small business in the United States, noting that they do not generally have the same employment and financial resources as large companies. Mr. Cangerni urged the Committee to keep small businesses in mind when recommending screening and testing techniques.

Melissa Sheridan, a member of the Endometriosis Association, stated that she suffers from the disease, and told the Committee that the EDSTAC's work is vitally important and very appreciated.

Gail McPherson, an American Agri-woman and farmer, expressed great concern regarding her feeling that the general public was characterizing the agricultural sector as polluting and causing disease. She urged the public and the EDSTAC to remember the role of the agricultural sector in the development of the United States.

David Fisk, a medical student at Johns Hopkins University and member of the student chapter of Physicians for Social Responsibility, stated that endocrine disruption was a major topic of discussion at a recent national conference in Chicago. He urged that the burden of proof rest on chemical manufacturers and incinerator operators.

Polly Walker, MD, encouraged the adoption of zero exposure and precautionary principles and a new type of risk assessment. She stated that the long lasting and irreversible effects of endocrine disruption are unconscionable. Dr. Walker further stated that unless the real levels of potential harm are put into the equation of risk assessment, new technologies will not be developed to address them. She encouraged the Committee to consider the synergistic and additive effects of chemicals in endocrine disruption.

Victor Perez, a medical student at Johns Hopkins University and a member of a south Baltimore community, stated that his community receives disproportionate effects from hazardous waste. He noted that amphibians tend to be the first type of organisms to be noticeably affected by environmental changes due to their breeding patterns and aquatic life. Similarly, he stated that inner-city and urban populations have emerged as somewhat of an indicator species for humankind, especially in reference to endocrine disruption. He encouraged the Committee to seriously consider such populations in its deliberations.

### **Response to Public Comment**



Judy O'Brien, Associate of The Keystone Center, thanked the members of the public for their comments and asked Committee members if they had any comments, clarifications, or questions related to the public comment.

With respect to Dr. Ziem's comments, one Committee member noted that the continued need to integrate the work of the EDSTAC with practitioners is one that has been reiterated by Committee members themselves throughout the EDSTAC process. In addition, it was noted that the EDSTAC is not charged with developing clinical tests to assess endocrinological wellness, but rather experimental toxicology related to endocrine disruption.

Regarding the interface between science and public policy, one Committee member noted the difficulties attendant in banning or regulating chemicals already on the market. With respect to the Alar scare, another Committee member noted that the scientist presented the Alar information correctly, but the media blew the information out of proportion. Due to this unpredictability, the Committee member urged the EDSTAC, and the COWG in particular, to try to anticipate potential public relations/perception problems to the greatest extent possible.

With respect to the EDSTAC's scope, Dr. Goldman commented that the Committee is not responsible for setting standards or for advising EPA on how to set them. Nor, she added, is the Committee responsible for medical waste incineration issues. Dr. Goldman noted, in the convening phase, many Committee members advocated for taking as comprehensive a strategy as possible to address the widest possible scope of hormones. However, given the time pressures of accomplishing the tasks and mandated deliverables, certain hormones were necessarily selected as a starting point for the Committee's scope. The EDSTAC's recommendations will, however, provide a general framework for EPA to use as new information comes forward in the application of screening and testing programs for a variety of hormonal endpoints and mechanisms.

Regarding public comments about research, Dr. Goldman noted that the EDSTAC can make recommendations concerning research and studies to be done, but that the Committee would not be performing any research or studies itself. In response to comments regarding regulated agency membership on the Committee, Dr. Goldman noted that the Agencies that generate waste are not part of the EDSTAC, but that many agencies represented on the Committee are indeed regulators.

One Committee member replied to comments regarding the EDSTAC's scope and industry onus and burden of proof, noting that the industry representatives on the Committee are sincerely concerned that everything that is produced in their industry is safe for humans and the environment. He added that, with respect to scope, the hormonal areas identified as foci for the Committee's work are those where the Committee members believe the EDSTAC has the greatest



chance of making solid decisions and recommendations given the deadlines and the current state of the science.

Another Committee member addressed Dr. Yang's comments regarding the consideration of mixtures stating that, while there may not yet seem to be a great deal of discussion on the subject at the plenary level, much work on mixtures was taking place at the work group level, and would eventually be brought before the full Committee.

Another Committee member pointed out that there is, indeed, representation on the EDSTAC by physicians who are treating patients with endocrinological disorders.

Dr. Goldman thanked the public for their thoughts, and expressed her appreciation of the public's attention and patience in observation of the involved, and sometimes intricate, discussions of the EDSTAC. One Committee member urged members of the public to look to their own communities, not the Committee, to find the solutions to community problems. Dr. Goldman echoed these sentiments, adding that she recognized the value of and need for inter-community communication and encouraged communities affected by endocrine disruption and hazardous waste to begin to engage each other in dialogue.

After the public comment period, several EDSTAC members expressed their recognition of the troubling health and environmental consequences of endocrine disruptors, but urged the public to recognize that the charge of the EDSTAC is to develop a screening and testing program for endocrine disruptors. Committee members encouraged future public comment on thoughts and ideas specifically related to the development of an effective, strategic, and efficient screening and testing program, rather than testimony related to the effects and perils of diseases and endocrine disruption. Public comment opportunities at the Chicago plenary and future meetings may, therefore, be designed to facilitate this type of discourse.

### **July 15 - 16, 1997, Chicago, Illinois**

Following the Committee's deliberations on the first day of the plenary meeting, members of the public were invited to offer comments related to the scope and charge of the EDSTAC. The public comment session lasted over two hours, and allowed time for more than forty individuals to provide comment to Committee members, nearly all of whom were present. Due to the number of individuals seeking to provide public comment, all those who signed up to speak to the EDSTAC were requested to keep their comments to no more than four minutes in length. While this request may have caused frustration on behalf of some individuals, the intended and effected result was to allow all persons wishing to provide comment the opportunity to do so. Written

comments submitted by members of the public may be found in the public docket (Docket Number--OPPTS-42189; phone 202-260-7099). This meeting summary attempts to capture the essence of the comments made by members of the public to the EDSTAC during the public comment session.

Patricia Speth, a concerned citizen who comes from a family of farmers, expressed concern that the agricultural industry may be adversely impacted by endocrine disruptors, prior to gaining additional information about their effects. She expressed her support for the EDSTAC process and suggested that the approach this problem should be deliberate and practical and urged that solutions not be based on emotionalism or “junk science.”

Joe DiGangi, of Greenpeace in Chicago and formerly a corporate scientist, spoke to the issue of risk assessment. He urged the Committee to reopen the risk assessment discussion within the Committee’s deliberations because he feels as though the Committee has an obligation to show to the public there is a disparity of views on this issue. He also would like to see industry take on the burden of proof to demonstrate the safety of new chemicals.

Brett Hulsey, of the Sierra Club, mentioned his role on the FACA for water monitoring and expressed concern about the fish people consume today and the lack of knowledge about fishing advisories that exists and the potential for harm because of that lack of knowledge. He supports due diligence for companies, particularly to handle the high costs associated with cleaning up polluted areas. Finally, he urged the Committee to be conservative and make screens as extensive as possible that go beyond adverse affect.

Mark Richie, of the Institute for Agriculture and Trade Policy, an organization that is concerned about pollution and health concerns, particularly due to airborne chemicals, which may render products produced in an organic manner polluted, suggested that multiple layers of impacts are of great concern, as is the eroding market niche for organic products due to this pollution. He cautioned the Committee to take the precaution that is necessary to protect public health, but to also remember that decisions are being made to protect other industries as well.

Ellen Kauffman, of the Endometriosis Association in Chicago, stated that she was there representing women with endometriosis and related information about the disease and some concerns of those women who have it. She indicated that studies have shown that a transfer of toxins can occur in-utero and during breast feeding, and the hormonal effects in children of mothers with the disease are increasingly being realized. Ms. Kauffman related that there are 5 1/2 million cases of endometriosis today and is estimated to occur in 10% of women of

reproductive age. Endometriosis is affecting women at younger and younger ages with greater severity--the costs of this disease are high.

Davis Baltz, of Commonweal, Inc., spoke directly about the screening and testing program, suggesting that chemicals in the Stop Box should undergo a random sampling process in order to ensure they have not been placed there erroneously. He also suggested breast milk should be tested. Regarding Production and Use data, he supported breaking these out into two separate categories because use information is quite different than production information. Mr. Baltz expressed his support for the public's right to know about these issues every step of the way, which includes a comprehensive educational effort.

Rob Christie, Director of Public Affairs for FMC Corporation, expressed concern both personally and professionally about the work of the EDSTAC. He related his opinion that any direction the Committee takes with public policy in this area should be based on sound science and he urged the Committee to remain focused on their tasks, in order to reach the deadlines ahead of them.

Jackie Hunt Christensen, of Health Care Without Harm, asked the Committee to do the following: 1) recommend to EPA that chemicals such as dioxins be phased out immediately, rather than go to tier 2 testing; 2) testing of chemicals used in medical products should be reviewed, as well as products produced by health care facilities; and 3) make it a priority that chemicals that cross the placenta or are present in breast milk should be tested.

Lynn Fahey McGrath, manager of risk assessment for Hoechst Corporation, a multinational chemical company, said there is a clear need for chemical products to pose a minimal risk to consumers and the environment. She urged against the publication of premature results and their effects (e.g., poor deselection choices), noting that in Europe, positive results from a screen can result in deselection. Her experience working in Europe has broadened her perspective on these issues, and she encourages the Committee to incorporate greater coordination there. She also encouraged the Screening and Testing Work Group to reevaluate baseline data and, at a minimum, allow flexibility for data required in other countries.

Jack Weinberg of Greenpeace discussed some of the policy implications of the decisions EDSTAC has already made. He noted that the concept of endocrine disruption used at the Wingspread Conference was broader than that used by the EDSTAC and very useful because it captured a range of mechanisms that operated at very minute concentrations. Mr. Weinberg recognized that, for pragmatic reasons, the EDSTAC limited the scope of its efforts to three hormonal systems, but asked the Committee to make clear to the public that the extent of

endocrine disruption was not circumscribed nor fully addressed by consideration of the three hormones in the EDSTAC's scope.

Linda Roberts, of Chevron, directed her comments to the Priority Setting Work Group. She indicated that Chevron has had some experience with SAR models and, in terms of their utility and use, she suggested that the accuracy of SAR output is a function of the degrees of structural similarity between the untested chemicals and the tested chemicals. Regarding Option 3 of the PSWG's presentation, she urged the work group to clarify what is meant by High, Low, and No Data, especially in terms of production and use. For the No Data option, she supported using the term "inadequate information". Regarding the Stop Box, Ms. Roberts suggested that there is not much of a distinction between 20,000 and 40,000 chemicals, because many will not be tested in our lifetime. She urged the Committee to evaluate the chemicals they do want to test and design the program to incorporate them. Regarding the STWG activities, Ms. Roberts encouraged the use of validation in the biological variability of the process. She suggested it would be helpful, for example, to know how reproducible the endpoints are, how many animals are needed, and whether the results are reproducible in good lab. Finally, regarding dose response, she asked for guidance from the STWG on the sizes of doses it thinks is appropriate, particularly for the high and low doses.

Joanna Hoelscher, Director of the Illinois office of Citizens for a Better Environment, thanked the Committee for holding a meeting in Chicago and for the opportunity to comment. She urged the EDSTAC to not lose sight of the broader mission of protecting public health and the environment in both the short term and the long term, and therefore encouraged the use of the "precautionary principle". Ms. Hoelscher then made specific comments directed toward PSWG and COWG. To the PSWG, she said the CF must take into account the fact that there are already significant amounts of information in the literature on chemicals already known to be endocrine disruptors, and there should be a mechanism to fast track these in order to eliminate exposure. She also stated that traditional risk assessment methodologies are inadequate to protect public health, which should be included in the CF. Finally, she suggested prioritization be given to certain chemicals based on bioavailability and persistence. To the COWG, she requested that scientific uncertainty not be considered tantamount to an assumption of no danger.

Michael Murry of the National Wildlife Federation directed his comments to the PSWG as follows. First, he suggested the uncertainty that exists with SARs has to be an issue when looking at toxicological effects. Second, regarding the log  $K_{ow}$ , he suggests that increasing the  $K_{ow}$  means increasing the bioaccumulation of chemicals and there is no reason why there should be an upper limit on  $K_{ow}$ s. Third, Mr. Murray suggested that there are two potential sources of breakdown products from plants--monomers and dimers--and the only way to control discharge of them is to

control discharge of their parent compounds. Finally, regarding exposure data, he encouraged evaluation in a precautionary way because 2000 new chemicals are introduced each year and some processes are still behind and testing old chemicals that were banned 20 years ago.

Sarah Janssen, a medical student who is a member of Physicians for Social Responsibility, raised several concerns regarding potential endocrine disruptors. Specifically, she is concerned about toxic releases from a local toxic waste incinerator as well as about endocrine disruptors in the air, water, and ground. A main concern lies with her future potential patients and the ramifications of these chemicals being emitted into the environment. Ms. Janssen commended the Committee for its intention to screen and test mixtures and encouraged them to look at low doses. She also urged for an increase in federal funding for the development of more sensitive assays.

Mark Holmer, of the Chemical Industry Council of Illinois, provided some general comments to the Committee. He stressed the importance of remaining objective when examining such issues and urged that sound science be applied. He praised EPA for reaching outside of its own employees to create the Committee and for assembling such a diverse group. Finally, he urged that science lead EPA to whatever regulatory path they take.

Ed Gunderson, chairman of regulatory affairs for the Chemical Industry Council of Illinois, suggested any policies developed be based on sound science, be technically realistic, and serve to protect the public health and the environment. He urged that protocols for the Screening and Testing program provide conclusive data demonstrating beyond any doubt that an adverse effect could result from a realistic exposure route. Mr. Gunderson also encouraged the use of a scientific, dosage-risk-based approach to developing the program.

Lynn Lawson, with the Multiple Chemical Sensitivities: Health and Environment, described health effects she presently experiences due to chemical sensitivity and lifestyle changes she has made to limit exposures to such chemicals. Many of the chemicals indicated in personal blood tests, she asserted, appear on lists of suspected endocrine disruptors. Ms. Lawson asked the EDSTAC to: 1) address the endocrine disrupting potential of mixtures first in their screening and testing program; 2) consider new chemicals guilty until proven innocent; 3) “sunset” chemicals known, or likely, to be endocrine disruptors, noting her feeling that any threshold for such chemicals is too high.

Marjorie Fischer, of the League of Women Voters, stated that chemicals in the environment should not impinge public health, especially the health of children. She added that the current position of the League of Women Voters on pesticides is that exposures to people should be reduced and that nontoxic alternatives to these pesticides should be used. Ms. Fischer noted that

many suspected endocrine disruptors would appear to be pesticides and would, therefore, seem to be of interest to the League due to its interests, stances, and publications. She expressed appreciation of the inclusive definition of endocrine disruptors tentatively being used by the Committee, and urged that zero tolerance parameters be imposed on endocrine disrupting chemicals, especially in light of effects caused by fetal exposure to such chemicals.

Cecile Sastre, from the Endometriosis Association, asked the EDSTAC to remember the real effects diseases attributed to endocrine disruptors are having on humans. She described symptoms and illnesses related to the disease of endometriosis, and noted that evidence indicates certain chemicals are responsible for endometriosis and a myriad of other diseases. Ms. Sastre told the Committee she is personally afflicted by endometriosis, and described the effects the disease has had on her life, including severe chemical sensitivities, difficulties finding employment due to the hazards of workplaces, as well as other lifestyle complications. She urged the EDSTAC to set zero tolerance standards, and to consider the synergistic actions of chemicals.

Dr. George Raab, former chair of the Species Survival Unit of the Chicago Zoological Society, commented on the synergies of chemical compounds affecting species. In particular, he sought to report recent information on the phenomenon of declining amphibian populations in several parts of the world. Although, he admitted, the ultimate causal effects and factors to which these declines may be attributed have not yet been satisfactorily identified, he noted that some declines indicate there might be endocrine disruption or distortion effects at work, especially in parts of Central America. Dr. Raab urged the financing of studies on these declines and effects on the broadest scale possible.

Jim Houston, with the International Joint Commission's Canadian Section in Ottawa, reflected on the interface between efforts directed toward endocrine disruptors in his country and in the United States. He noted that the earlier Canadians are involved in similar activities and are informed by the United States on its efforts, the more efficiently the problem may be addressed.

Charlie Cray, of Greenpeace, stated that the fact that the Committee is focusing on developing a screening and testing program should not delay current federal or state actions to phase out products proven to cause endocrine disrupting effects. He noted there was a need to support policies on endocrine disruptors even when uncertainties exist. Mr. Cray described current European studies indicating the timeliness of phasing out the use and production of certain chemicals. Particularly addressing the endocrine disrupting potential of chemicals in medical products, Mr. Cray noted that allegedly safe alternatives are available and urged their use. He encouraged the Committee to talk about releases and exposures of potentially endocrine disrupting chemicals from common products into waste water and other media.



Chuck Elkins, an environmental consultant, commented that the Committee's T1S design sounded fairly sophisticated and seemed consistent with the current state of the science and with similar efforts. However, he expressed caution that a decision to use either one or a very small number of decision makers to decide what testing would be done in a tailored approach could prove to be a bottleneck in the screening and testing process. Mr. Elkins asked that the Committee pay particular attention to communications issues in the sorting and prioritization process, as these stages of the program could be misunderstood by both the public and decision makers.

Mary Beth Doyle, from the Ecology Center of Ann Arbor, thanked the Committee for conducting a meeting in the Great Lakes region, and for the Committee's hard work. She encouraged the Committee to adopt the "precautionary principle" in its program, and to insure chemicals are tested thoroughly before being released into the environment. With respect to hormone disruptors, she noted the inclusion of the word "adverse" in the working definition concerned her, and urged the EDSTAC to develop a broader definition. In addition, Ms. Doyle expressed concern with the Stop Box, noting her feeling that the scientific tools currently available to screen and test for endocrine disruptors are too crude to send a chemical substances or mixtures definitively to the Stop Box. Rather, she requested that such chemical substances or mixtures be assigned to a low priority group. Furthermore, Ms. Doyle suggested that the EDSTAC "groundtruth" chemicals sent to the Stop Box to ensure the accuracy of the screening and testing program. She also said that community concern over a chemical substances or mixtures should be sufficient to pull a chemical out of the Stop Box for re-entry into the screening and testing program.

Penny Richards, the Learning Disabilities Association of Illinois, Inc., expressed concern about the impact of agricultural chemicals on the lifestyle and health of humans, and especially on her developmentally disabled child. Specifically, Ms. Richards noted concern regarding hormonal disruption due to fetal exposure, and urged the EDSTAC to promote and protect children's health. She urged the Committee to adopt the "precautionary principle," adding that chemicals should not have a "civil right" of being considered innocent or harmless until proven guilty. She stated that no permission had been given by any human for a chemical body burden.

David De Rosa, from Greenpeace in Chicago, expressed his concern caused by the recognition that, due to realistic constraints, all chemicals cannot be tested for endocrine disruption. Therefore, he noted, he hoped that scientists would be able to learn from the EDSTAC's screening and testing program how to make educated guesses about classes of chemicals, and that scientists would apply that knowledge in anticipating any effect, not just adverse effects. Mr. De Rosa stated that the screening and testing program should look at chemical substances or mixtures, as well as their breakdown products, with which people come into contact on a daily



basis. He encouraged the prioritization process to use production volume figures, and requested that any chemical proven to be an endocrine disruptor be banned.

Bill Holland, of Illinois Public Interest Research Group, stated his concern about the potential hazards of minute doses of endocrine disrupting chemicals, noting that damage from exposure may not be apparent until much later in an organism's development process. He stated that his organization urged the adoption of both the "precautionary principle" and zero exposure tolerances. Mr. Holland added that industry should be responsible for showing that their chemicals are safe before approval, use, and release into the environment. Furthermore, he requested EPA make significant and easily understandable efforts to educate the public on endocrine disruption issues, chemicals being tested, and the endocrine disruptor screening and testing process.

Angel Cohoon, also of Greenpeace, offered great concern regarding the effects of endocrine disruptors on early stages of development, especially due to fetal exposure from chemical substances or mixtures present in pregnant mothers. She urged the Committee to consider using the "precautionary principle" and to immediately phase out any chemical proven to be an endocrine disruptor. Despite economic and practical difficulties, Ms. Cohoon expressed confidence that scientific ability existed to eliminate proven endocrine disruptors.

Barbara Alexander Malarky, of the Waste Handlers Network, praised Illinois EPA's efforts on hormone disruption publications to date. She urged that the Committee's prioritization process place significant emphasis on the cumulative and synergistic effects of endocrine disruptors, and that it not look at chemicals in isolation. Ms. Malarky expressed concern regarding the effects of waste incinerators, especially from the disposal of dioxin and cows, due to the potential for interaction of airborne endocrine disrupting chemicals.

Tracy Easthope, from the Ecology Center of Ann Arbor, recommended to the Committee that all proceedings of the International Joint Commission and their science advisory board be included as part of the official proceedings of the Committee. She noted that persistence is an important criteria to consider in the screening and testing program, and that testing should be sensitive sentinel species as an "early warning system" in order to avoid economic and human health/environmental costs. In addition, she questioned the scientific ability to send a chemical definitively to the Stop Box as indicated in the Conceptual Framework. Ms. Easthope encouraged the Committee to look at research indicating that the timing of exposure has significant implications for endocrine disrupting effects, including synergies and seasonal variations, due to the fact that toxicity differs depending on stage of development and health of the organism at the time of exposure (e.g., fetal exposure from mother's body burden). She

expressed concern about: limitations on exposure detection due to the state of the science; the Committee's working definition of an "endocrine disruptor"; and the potential for a lack of clarity about screening and testing results (e.g., whether or not a chemical substances or mixtures is an endocrine disruptor if results of T1S or T2T are mixed). Finally, Ms. Easthope emphasized the importance of risk assessment considerations in the Committee's development of a screening and testing program, as well as the need to constantly reevaluate the effectiveness of whatever tools are designed to address the endocrine disruptor issue.

### **Response to Public Comment**

Dr. Goldman noted that while the Committee is not yet, as a whole, in agreement on the role of risk assessment and its use in regulating chemicals, discussion on the subject had not at any point been constrained or inhibited. She asked members of the public to remember that this, in addition to other issues, are still at a level of tentative agreement, and not to characterize all of the EDSTAC's deliberations as firmly agreed upon.

In response to one commenter's request that the EDSTAC look at the international context and regulatory practices in the European Union as it proceeds in its deliberations, Dr. Goldman indicated this was an issue for the STWG to consider. However, she cautioned that some testing data used by European authorities might not be available for the EDSTAC's screening and testing program due to confidential business information constraints and to differences in evaluation methods.

With respect to international harmonization and coordination issues, Dr. Goldman reminded the Committee and members of the public, that EPA and the EDSTAC have begun to cooperate with other international organizations on endocrine disruption issues. Specifically, interaction is currently underway with the OECD, with one of EPA's specific goals being the structuring of the Committee's work to make its efforts available to the OECD, and vice versa.

She also highlighted recent and ongoing international coordination efforts with the Summit of Eight, where an environmental agenda was put together for protecting children on an international level, including the consideration of endocrine disruption. In addition, the United States is involved in the International Program for Chemical Safety, an international effort that will involve the coordination and collaboration of research on matters of chemical safety and endocrine disruption.

With respect to comments regarding the Committee's tentative definition of an "endocrine disruptor" and its decision to focus its efforts on a defined set of endpoints related to estrogen-, androgen-, and thyroid-related effects, Dr. Goldman agreed with one commenter that the Committee should take care to recognize that these hormones did not constitute the full extent of potential endocrine disruption. In addition, she noted that, while the EDSTAC will focus on the three specified hormonal systems, the Committee plans to develop broader guiding principles for a broader application of the screening and testing program to consider endocrine disruptors in general.

With respect to the issue of screening and testing mixtures, one EDSTAC member noted that the issue is being taken very seriously, and is presently being addressed by the PSWG. Although a specific formula for addressing mixtures in the sorting, priority setting, screening, and testing processes has not yet been developed, it was indicated that more information would likely be available on the issue in upcoming plenary meetings.

Several Committee members expressed their appreciation of the public comments, noting in particular the scientific and policy-related sophistication of the remarks. Committee members, in response to some of the public remarks, noted their recognition of the multiple and sensitive issues tied to communication, and reiterated their intention to give this aspect of the screening and testing program great attention.

#### **October 7-8, 1997, New York, New York**

Following the Committee's deliberations on the first day of the plenary meeting, members of the public were invited to offer comments related to the scope and charge of the EDSTAC. The public comment session lasted over two hours, and allowed time for approximately twenty-five individuals to provide comment to Committee members, nearly all of whom were present. Written comments submitted by members of the public may be found in the public docket (Docket Number--OPPTS-42189; phone 202-260-7099). This meeting summary attempts to capture the essence of the comments made by members of the public to the EDSTAC during the public comment session.

Frank Stoppenbach, a resident of the Hudson Valley, noted that he was concerned about the presence of PCBs in his community and about the impacts on small communities of chemical exposures. He encouraged the consideration of fetal and developmental exposures in the EDSTAC screening and testing program. Furthermore, Mr. Stoppenbach encouraged that data regarding endocrine disruptors generated by the screening and testing program be made as

publicly accessible as possible. He expressed concern, as well, about the use of SLAP suits in his community.

Greg Koontz, director of regulatory affairs for the Chemical Producers and Distributors Association, described benefits of the products supported by his organization. He encouraged support for efficient, cost effective responses to environmental problems commensurate with the problems they are meant to address. He noted concern about the impact of regulatory actions on small businesses, as well as cost impacts from such regulation. Mr. Koontz questioned the scope of the endocrine disruption issue, as well as the accuracy and ability of assays to detect designated endpoints. He encouraged the Committee to clarify the definitional and utilization issues of false positives and negatives, and urged a balanced approach to risk assessment.

Ralph Magin, a research and development scientist with the Albermarle Corporation, expressed his support for toxicity testing requirements that afford increased public health protection. He noted the broad array of assays under consideration, and encouraged the Committee to be pragmatic in its selection process. He also noted that toxicity screening and testing is a decision-oriented process and should be characterized by relevant and reliable endpoints and methods, upon which clear interpretations of results can be made. Mr. Magin stated that those who review and interpret the testing results will not likely be research scientists, and that opportunities to clarify ambiguities will not be forthcoming once the EDSTAC process is concluded. He questioned the present potential scope of screens under consideration by the STWG, and encouraged the group to be pragmatic and to use validated assays in the screening and testing tiers to ensure, among other things, that resources are not expended to study chemicals of little concern.

Laura Whatley, with American Cyanamid Company, recognized the need to know about endocrine disrupting chemicals, and recommended the development of a deliberate, practical approach to do so, in order to save time and resources. She furthermore encouraged the Committee to base its recommendations on sound, verifiable science so that future policy would be based on that sound science.

Geri Barish, president of the Long Island Breast Cancer Coalition and a member of One in Nine, a breast cancer support and advocacy group, noted concern about the growing chemical use of developing countries and the breast cancer rates in these countries. She offered DDT use in India as an example of this, and noted the lack of public access to politicians, scientists, and education regardless of culture.

Ed Sabo, New York coordinator for the Chlorine Chemistry Council, stated his support for the EDSTAC process, noting that the endocrine disruptor issue is a complex subject with limited scientific information on which to base public policy. He commented that the goal of achieving consensus on a screening and testing program requires staying focused, and urged the Committee not to lose focus by wanting to develop a list of endocrine disruptors. He indicated that such development was not a part of the EDSTAC's mission. Mr. Sabo expressed his feeling that chemicals entering the screening and testing program through the nominations process should undergo screening through the same criteria as all other chemicals. Finally he stated that diligence will ensure that laws and regulations will be based on sound science.

Linda Roberts, of Chevron Research and Technology Company, commented that *in utero* tests should be included in the screening and testing program as definitive testing. In addition, she noted that definitive testing should more thoroughly characterize toxicity, and that *in utero* assays would be a benefit in doing this. Ms. Roberts indicated her preference that laboratories expend resources on such testing rather than on screens.

Mary Dauden, with the Coalition Organized to Protect the Environment, stated that the first and foremost role of government is the protection and quality of human health. She expressed support for the use of *in utero* developmental assays examine responses in populations at greatest risk, from pre-natal fetuses to infants to the elderly. She said that fetuses are exposed to many chemicals which can cause cancer and mental disabilities.

Walter Schroeder, of the Nassau/Suffolk Landscape Gardeners Association, Inc., on Long Island, said that the EDSTAC was doing a great job for the most part. He noted awareness of breast cancer incidences in his community, but indicated that the determination of pesticides as causative factors in breast cancer is not clear cut. Mr. Schroeder cited the retraction of the Tulane study and Steve Safe's article as examples of the continuing debate over the effects of endocrine disruptors, and encouraged the Committee to act prudently.

Diana Hinchcliff, executive director of the New York State Chemical Alliance, indicated her support of the EDSTAC process and her hope that the Committee's goal will be accomplished in an objective manner. Ms. Hinchcliff cited the public's likely misinterpretation of lists and past examples of misuse or misunderstanding of lists as reasons to avoid developing lists of chemicals or to deliberate at length on the use of chemicals. Rather, she suggested the Committee create an endocrine disruptor screening and testing program based on the best available science to determine which chemicals have endocrine disruption potential, and to do so carefully, expeditiously, and judiciously, bearing in mind issues related to implementation.

Hamdy Balba, with Uniroyal Chemical Company, referenced the adverse effects of many endocrine disruptors in urging the Committee to use an analytical and methodological approach in creating its screening and testing program. He suggested the establishment of a database for all documented and suspected industrial and natural chemicals with endocrinological properties. Mr. Balba encouraged the development of a reliable assay for confirming endocrinological activities to assist the regulatory agencies in prioritizing chemicals for screening and testing and protecting public health and the environment. Finally, he advised the Committee to be aware of possible antagonistic, synergistic effects of chemicals.

Joe Gregella, executive director of the Long Island Farm Bureau, noted that farmers are extremely concerned, as are commercial applicators, of any potential impacts of pesticides. He stated that he hoped the EDSTAC could help instill public confidence in the government by reintroducing sound science to policy. Mr. Gregella urged that science dictate the decisions made by the EDSTAC. He acknowledged the emotional aspects of the debate over the endocrine disruption issue and urged for the development of studies that can be verified and validated by peer reviews and reproducibility. Furthermore, he noted that public policy needs to balance many variables, including economic and social concerns, but he hoped it would do so guided by sound science.

Jim Lamb, a toxicologist with Jelnecks, Schwartz, and Connelly, commented that the design of the entire system needs to be built with primary objective of being able to do a risk assessment on adverse effects on the endocrine system, noting his belief that the “adverse” qualifier was critical. Mr. Lamb also stated that *in utero* testing is critical to the endocrine disruption argument, but urged that it be conducted in the testing tier, not in the screening tier. He stated his support for a bypass option for chemicals to go straight from prioritization to testing, contingent upon the design of a comprehensive testing tier.

Davis Baltz, with Commonweal, asked whether degradation products and metabolites be captured by the assay battery of the screening tier of the screening and testing program, and expressed concern regarding the perceived difficulty of moving a chemical out of the “Hold” box. He questioned the ability of the Committee to focus testing on the hypothalamus-pituitary-gonadal (HPG) axis, given the rapidly emerging and developing state of the science related to endocrine disruption. Regarding the screening battery, Mr. Baltz commented that the battery needed to maintain flexibility to address issues not anticipated by the Committee. He also noted his belief that the addition of an invertebrate assay to the screening and testing program was critical to support EPA’s goal of protecting the environment. Mr. Baltz noted that the issue of how to address commonly found mixtures had not yet been agreed upon by the EDSTAC, and indicated his concern about the chemical body burden issue. He asked how new chemicals would be



handled by the screening and testing program, urging that they be handled more stringently and that they be screened and tested right away. Commenting on the nominations process, Mr. Baltz indicated his support for the concept of giving the public a process to offer input into the screening and testing program, and noted his belief that a separate set of criteria should be established to gauge the merits of the chemical nominations.

Marian Feinberg, of the South Bronx Clean Air Coalition, referenced concern regarding childhood cancer incidences and prenatal sensitivity in requesting that screening and testing tiers agreed upon by the Committee capture the broadest possible mechanisms. Ms. Feinberg asserted that inner-city communities are being heavily impacted by endocrine disruptor-related illnesses, and urged that the roots of transmission (e.g., ingestion, inhalation) of such diseases be examined. She also commented on an alleged lack of union representation on the Committee and in the audience, as well as a lack of representation by impacted community representatives. She encouraged the Committee and the COWG to develop publicly accessible and intelligible language in presenting the EDSTAC's deliberations and recommendations.

Jim Moore, executive director of the New York Coalition for Alternatives to Pesticides, encouraged the EDSTAC to adopt the precautionary principle. He indicated his desire for the onus to be on manufacturers to prove the safety of chemicals, or to offer compelling reasons for bringing products to market that transcend doubt. He cited DES, DDT, and thalidomide as examples of science policy failures that did not determine safety prior to release, and noted that science should not dominate public policy but that it should be a part of policy making. He commented that the Committee's definition of "adverse" effects is too narrow given the lack of knowledge in the field, and stated that the EDSTAC's top priority should be a true understanding of the true mechanisms of endocrine disruption. Mr. Moore stated his desire for a greater emphasis on research into endocrine disruption issues.

Christian Klossner, with the New York Public Interest Research Group, noted his concern regarding the increasing use of pesticides in this country and their effects on endocrine systems. With respect to priority setting, he stated his belief that the prioritization criteria should be: chemicals that are implicated by current toxicological or endocrinological data; chemicals that bioaccumulate or are persistent; likelihood of exposure; consumer products; and child exposure. He indicated that he felt pesticides fit all of these categories and should, therefore, be of priority for the endocrine disruptor program. Regarding screening and testing, he requested that the Committee include assays and tests designed to encompass developmental and fetal life stages. Mr. Klossner indicated his support for the EDSTAC's careful consideration of conventional risk



assessment, and encouraged the Committee to examine chemical synergies. He asked that the onus of proof of chemical safety lie with the chemicals' producers.

Wanda Cohen asked the Committee about timeframes, required resources, and risk management issues related to the screening and testing program. In addition, she questioned how new information would be integrated into the process, and whether endocrine effects beyond estrogen, androgen, and thyroid would be addressed. She also asked about the development of the chemical nominations process and public accessibility of information coming out of the screening and testing program. Ms. Cohen commented that she was unsure how multisystem effects such as multineurological effects, degradation products, intermediates, and metabolites would be accounted for in the priority setting criteria. She asked about additional legislative authorities that might be applicable to the EDSTAC's work, such as the Clean Air Act. Ms. Cohen questioned how the process of updating databases of information would take place and how the databases would be kept useful and accessible to the public. She also commented that exposure is not necessarily equivalent to effect.

Bill Sanock, with the Cornell Cooperative Extension, commented that he works closely with breast cancer groups, as well as pesticide users, and noted that those who use pesticides have great concern about their safety and support the Committee's work to provide more information. He stated the need to use good, practical science in the process, and asked how the EDSTAC would communicate results and recommendations of the screening and testing program to the public. He encouraged the Committee to approach risk assessment and exposure issues using common sense and practical research.

Judith Helfund, with the DES Cancer Network, stated that Long Island has the highest rate of DES exposure in the country, and indicated the region's required attention on related issues. She offered a very detailed account of personal physical problems due to DES exposure as a youth, and urged the Committee to adopt the precautionary principle to avoid future incidences similar to her own. In addition, Ms. Helfund asserted that transgenerational impact of DES exposure and endocrine disruption was a reality, and should be considered as the effects would be manifested long after exposure. She stated that information is needed to make informed decisions and to give consent to exposure.

Minna Barrett, professor of environmental psychology at the State University of New York, stated that her mother had died of thyroid and breast cancer. She encouraged the Committee to include lifespan scrutiny and mechanisms (especially with respect to fetal exposure), synergistic chemical reactions (including low dose exposure and inert synergies) health implications for endocrine sensitive cancers and other diseases, and synchronicity, bioaccumulative, and persistent

considerations in the endocrine disruptor screening and testing program. She encouraged the EDSTAC to include an analysis of developmental endpoints in the screening and testing tiers to catch effects of chemicals to which neonatal children are often exposed. Ms. Barrett stated her perception that many of the endocrine disruptor issues had been perpetuated by the economy, and indicated her sense that industry is suspect. She commented that low risk allowances are not acceptable, and that only no risk situations would be acceptable.

### Response to Public Comment

Lynn Goldman thanked the public for their comments, noting that they reflected the serious challenge to the Committee and EPA to protect human health and the environment, and to do so in ways that are effective, cost effective, and practical. She stated that she expected a mutually beneficial outcome for both economic development and environmental protection if the EDSTAC was successful in reaching its goals. With respect to public access to information, Dr. Goldman commented that efforts have been made to develop an endocrine disruptor Web site and to keep it updated.

With respect to the retraction of the Tulane study, Dr. Goldman indicated her belief that the portrayal of the situation surrounding the retraction had been inaccurate. She noted that, while that particular study had been withdrawn because it cannot be reproduced, other studies exist in the literature supporting the synergy of endocrine disrupting chemicals. Furthermore, she commented that the legislation that started the EDSTAC process was introduced several months prior to the publication of the Tulane study.

Dr. Goldman commented on the obvious thoughtful preparation by commenters, and recognized their efforts. She reiterated that the EDSTAC process has been a science-based process from the very outset, and that it would continue to be so. In response to some comments, she noted that EPA is engaged in activities to address the rising rates of childhood cancer.

One Committee member responded to Mr. Baltz' concern with respect to the handling of mixtures by noting that the subject was being addressed by the PSWG and that the issues of identification, prioritization, and technical aspects of how to screen and test mixtures still needed to be discussed.

Dr. Goldman, in response to public comments about the inclusion of an *in utero* assay in the screening and testing program, commented that there is no debate in the Committee about whether it should be part of the process, but rather where in the process it should be included (i.e., T1S or T2T). With respect to prenatal detection of childhood cancer, she commented that

while the concern is valid, it is not within the scope of the EDSTAC but that other EPA offices are addressing the issue. Regarding public comments about missing or inappropriate Committee representation, she stated that not all EDSTAC members were present at the New York meeting, but that the EDSTAC did have union representation and environmental justice representation, and that membership on the Committee from industry was important and vital for consensus. Dr. Goldman noted that environmental protection has often been done in an adversarial manner with industry, but that the EDSTAC represents a coming together around a common interest and in good will.

Some members of the public commented critically about the location of the New York plenary as being inconvenient and inaccessible by mass transportation. Dr. Goldman acknowledged these criticisms and offered an explanation of why the meeting had to be held in the determined location. However, she indicated that future meetings would try to address the public's concerns.

Committee members summarized for the public some of the COWG's efforts, and the work group's goals of making all Committee communication palatable, understandable, and clear for the public. It was also noted that a survey had been widely distributed by EPA on communications issues related to the EDSTAC, and that copies of the survey were available for those who desired to complete the forms. Members of the COWG expressed interest in hearing from the public how to efficiently and effectively communicate with and to the public, and encourage members of the public to assist COWG by offering suggestions.

David Parkinson, a Committee member, referenced his years of working with steelworkers and other union groups, noting that he, indeed, did lend a union perspective to the EDSTAC, counter to public statements to the contrary. He noted his current affiliation with occupational and environmental health clinics in the New York area, funded partly by state, and his desire to work with environmental groups in the area to design something they can do for themselves to test and monitor health concerns. In addition, Mr. Parkinson indicated the willingness of the clinics to assist patients who are sick and need evaluation given an environmental problem even without health insurance.

One Committee member thanked the public for their comments, and acknowledged her appreciation as a scientist for the calls from observers for policy based on sound science. In addition, she acknowledged the need to balance science with other factors to create sound public policy. She noted that repeatability and peer review are of great importance to the EDSTAC, and her appreciation for the public's encouragement of the adoption of the precautionary principle.

EDSTAC members indicated their support for a public nominations process, in recognition of the importance that the public have a continuing role in the endocrine disruptor screening and testing process. Members of the Committee noted their intention to scrutinize similar programs already in place at other organizations or agencies in the design of the EDSTAC's process.

Industry representatives on the EDSTAC encouraged the public to overcome their mistrust of the sector by focusing on the Committee's product, and by remembering that many scientists working with industry have spent a great deal of time training to learn about the issues without malintent. It was stated that public input is very important to the EDSTAC process, and that industry representation is present because industry has a responsibility, as a stakeholder, to be involved in the consensus-building process.

### **December 2-3, 1997, Orlando, Florida**

Ellen Bregg, of the Coalition to Stop Children's Exposures to Pesticides, urged the EPA to allow independent laboratories to perform testing in addition to that done by the EPA. She expressed concern about the use of pesticides in urban areas and the effects of low dose exposures to malathion and pesticides. Ms. Bregg said she would like to see more educational information about pesticides. She stated she wants to know which chemicals will be addressed by the screening and testing program, whether chemical effects will be looked at individually or cumulatively, and whether there will be a focus on the effects at the developmental stage. Ms. Bregg added she would like to see press releases providing updates on the Committee's progress.

Greg Koontz, Regulatory Affairs Manager for the Chemical Producers and Distributors Association, emphasized the burden of the screening and testing program needs to be commensurate with the gravity of the adverse effects caused by endocrine mediated toxicity. He indicated chemicals with health, safety, or other benefits should not be sacrificed through regulatory overkill, and the demands of an endocrine screening and testing program should be flexible to reflect the seriousness of the threat as demonstrated by science. Such a program, Mr. Koontz stressed, should be efficient and cost-effective. He expressed support for further research into potential endocrine disruptor effects from low doses but opposes a test program including low dose testing unless the need for it is substantiated by good science, and then only if the hypothesis applies generally to chemicals and not just exceptional cases. He expressed concern with the testing program possibly increasing overall risks to public health by reducing the availability of certain chemicals or by scaring the public into not using particular products (for example, mosquito-control chemicals, the use of which aids in preventing cases of viral equine encephalitis.) Mr. Koontz suggested using a nomination approach, whereby chemicals would

proceed through the normal priority setting process. Mr. Koontz finished by saying the EPA, if needed, should ask Congress for more time to implement a sensible approach.

Chuck Elkins, an environmental consultant with Jellinek, Schwartz, & Connolly, Inc., presented five ideas. First, the success of EDSTAC will not be based upon how many chemicals are screened, rather on whether the information coming out of the program is useful. Second, while chemicals are in the program they are highly vulnerable as a full data set is not available until the chemical in question gets to the end of the program. Third, each stage of the program needs to be clearly defined (e.g., what is screening). Fourth, only EDSTAC has the credibility to make recommendations and, in so doing, they need to write their words carefully, work on principles, and avoid using lists. Fifth, too many chemicals should not be forced into the program at the beginning as the system will break down if chemicals do not get through the program quickly.

John Brennan, a high school biology teacher from Orlando, Florida, discussed his concerns about the influence of the media regarding the level of attention the issue of endocrine disruption receives. He commented that although some sensationalism pushes the issue, which can be beneficial, it is important to take a reasoned approach and consider all sides. As an example, Mr. Brennan pointed out both the benefits (e.g. possible safeguard against lime disease) and detriments (e.g. health risks from exposure) of applying insecticide to a child. He encouraged the Committee to keep an open, scientific mind about the issue of endocrine disruption and not let the press influence its decisions.

Nancy Stephens, Executive Director of the Florida Manufacturing and Chemical Council, emphasized the need for the Committee to balance the importance of chemical use with the safety issues associated with such use. She requested the Committee not be persuaded by political and emotional agendas, but rather address the issue of endocrine disruption on a scientific basis. Ms. Stephens suggested the Committee provide EPA with a “tool box” with which the Agency can evaluate chemicals.

Suzanne Spencer, representing the Northeast Florida Chapter of the Sierra Club, stated there is an urgent need to develop a screening and testing program to detect endocrine disruption in humans, fish, and wildlife. She brought a letter from Maurice Coman, Chair to the Northeast Florida Group, Sierra Club, discussing the link between dioxin and related chemicals to cancer and reproductive, immunological, and developmental dysfunction. Ms. Spencer also brought correspondence from the Food and Drug Administration involving consumer exposure to dioxin through food sources. She noted the need to do significantly more research concerning the health effects of environmental hazards on children, and added the threat to children will persist until this happens.

Davis Baltz, of Commonweal and member of the EDSTAC Communications and Outreach Work Group, reminded the Committee that over the past year it has heard from a broad cross-section of Americans concerned about the implications of endocrine disruption, including the following: Sierra Club; Endometriosis Association; cancer survivors; learning disability networks; consumers; environmental justice representatives; mothers; pregnant women; farmers; ranchers; gardeners; unions; small business; environmental consultants; veterinarians; the League of Women Voters; and, individual citizens. Mr. Baltz noted a common theme to be concern for children and added, it should be remembered, that as adults, we impose risks on our children without their consent. He reminded the Committee of its agreement regarding the definition of 'screening' as "the application of assays to detect the potential for endocrine disrupting properties of chemical substances and mixtures." Mr. Baltz emphasized that, for the promotion of children's healthy development, the EDSTAC must include a means for establishing developmental endpoints for low doses at the 'screening' phase.

Betty Mekdeci, Director of the Association of Birth Defect Children Inc. (ABDC), indicated the greatest examples of how exposure to herbicides increases the likelihood that a child will suffer from a disability or birth defect, are the children of Vietnam veterans. She spoke of an analysis, performed by ABDC and the New Jersey Agent Orange Commission, which identified disabilities in 800 children of Vietnam veterans compared to 400 children of non-Vietnam veterans and noted further evidence suggested the effects could be transgenerational. Ms. Mekdeci said the types of problems included; chronic skin disorders, benign tumors/cysts, cancers, emotional/behavioral problems, chronic fatigue, tooth problems, and others. Ms. Mekdeci expressed concern with the lack of accurate exposure data on herbicides.

Andy LaVigne, Executive Director of the Florida Fertilizer and Agrichemical Association, stated extensive testing is performed on agricultural chemicals and pesticides before these products are used. He said no scientist will give a determination of zero risk regarding the use of a specific chemical because there are so many variables potentially impacting the effects related to use. Mr. LaVigne said claims of pesticides not being well tested before registration and release for public use, and claims they are not specifically tested for estrogenic activity, are not true. He noted EPA requires each pesticide be thoroughly tested for its potential to cause adverse effects, including hormone disruption. Mr. LaVigne requested the Committee not use a "paparazzi science" approach but rather develop a screening program based on the best available scientific data.

Pam Williams, of the Endo Association, indicated that dioxins are one of the most toxic compounds known to man and are linked to endometriosis and other health problems. Ms. Williams said ninety percent of human dioxin exposure is from meat and dairy products because the animals from which these products originate, are exposed to dioxins via pesticides, herbicides,



plastics incineration (PVC), and pulp and paper production processes. Ms. Williams urged the Committee to consider the following questions: how much is too much; can the current levels of dioxins already present be reduced; are there other ways to do what we are doing; and, what effect will these changes have on the future of humanity?

Keith Branly, Vice President of Research and Development of Micro Flo, a small pesticide formulating business, stated the need for the burdens to equal the benefits which result from pesticide regulation. He noted many small businesses are impacted by toxicity testing and the demands of a screening and testing program need to be viable and cost effective. Mr. Branly added testing and screening requirements should not deprive the public of the use of products with clear health benefits. Regarding the issue of low-dose testing raised in T2T, he said he feels it is not cost-effective and is premature until a low-dose testing hypothesis is accepted by the scientific community.

Katie Holmes, an aquatic toxicologist, requested the Committee verify the practicality, not just the theory behind, the studies it recommends be used to analyze potential endocrine disruptors. Ms. Holmes encouraged the EDSTAC to consult with individuals who run relevant studies dial, and are aware of the scientific and practical issues associated with the tests. She expressed particular concern regarding the mysid life-cycle, fish life-cycle, and avian reproduction studies being considered by the Committee.

Jeannie Economos, of the Farmworkers of Florida, expressed concern about farmworker exposure to pesticides and related health effects. She stated chemicals are being screened on an individual basis when, in fact, people are exposed to all kinds of chemicals over time and therefore, the cumulative effects associated with chemical exposure should be considered. Ms. Economos commented on the high incidence of miscarriage among farmworkers and said she wants to see studies performed on this particular sector in order to evaluate the long-term effects of chemical exposure.

Lukner Millen, speaking on behalf of farmworkers, indicated there are still many instances where pesticides are being used in the vicinity of workers. He told a story of a female farmworker who was working in the fields when she broke out in a rash all over her body and was unable to identify the pesticides to which she had been exposed. Mr. Millen commented that exposure problems persist and he wants the persons responsible for exposing farmworkers to pesticides (e.g., spraying the fields while workers are present) to be held accountable for their actions. He closed by saying he is counting on the Committee to act to change this situation.

Joy Cummings, a Florida rancher and farmer, explained she was a chemicals sales representative until she realized the harmful effects associated with chemical exposure. After moving to her farm she found her community was contaminated. Ms. Cummings remarked that people are eating fish contaminated with dioxins, female fish are taking on male sexual characteristics (as are some female humans in the community), and there is a high rate of children with learning disabilities as well as a high rate of leukemia. She stated she worked on a dioxin FACA and is still worried about the dioxins which she believes are probably caused from chlorine. Her message to industry was to stop dumping poisons and to stop using chlorine.

Linda Young, Southeast coordinator of the Clean Water Network, stated she was also speaking on behalf of Margaret Williams of the Citizens for Toxic Exposure, a group located in southern Florida which evolved due to concern about citizens' health. She emphasized the public health must not go unprotected because of scientific uncertainties and encouraged the application of the precautionary principle. Ms. Young also noted the need to assess the effects of chemicals on the most vulnerable populations, including the fetus.

Lisa Doig, of the Farmworkers Association of Florida, Inc., stated she strongly suspects a direct relationship between exposure to pesticides and worker outbreaks of rashes, welts, bumps on the body, birth defects, and miscarriages. She commented on cases where women farmworkers experienced rashes, believed to be caused by chemical exposure, and then subsequently had miscarriages. Ms. Doig suggested an in-depth study into the cause and effect relationship of pesticides and public health threats, and making available to the public the results.

Estaban Caro Jr., a farmworker, stated that as a common worker he is exposed to a number of different pesticides and suffers from itching and swelling skin. He said the farmworkers are aware of their exposure to such chemicals on a daily basis. With the help of organizations like the Farmworkers Association, Mr. Caro explained, workers have been better able to get needed information about how to protect themselves from pesticide exposure and how to get treatment once exposure occurs. He expressed concern about how the exposure will affect him and other workers in the long run and asked the Committee to do whatever possible to make the farmworkers lives a little better.

### **Response to Public Comment**

Dr. Lynn Goldman thanked the public for their comments and reminded them of the Committee's scope. She expressed concern about the fern industry and indicated more attention needs to be focused in this area. Dr. Goldman noted the need for the Committee to understand the extent of exposure possible and to understand that laws and regulations do not always work as they should.

