Chapter One

Introduction

Do Not Cite, Quote, or Distribute

April 3, 1998

I. Overview

A growing body of scientific research indicates that many man made industrial chemicals and pesticides may interfere with the normal functioning of human and wildlife endocrine or hormone systems. These endocrine, disruptors may cause a variety of problems with development, behavior, and reproduction.

Although many pesticides and some industrial chemicals have undergone extensive toxicological testing, it is unclear whether this testing has been adequate to detect the potential for these chemicals and pesticides to be endocrine disruptors or whether additional testing is needed for the U.S. Environmental Protection Agency (EPA) to assess and characterize both human health and ecological risk. Notwithstanding recognition that the scientific knowledge related to endocrine disruptors is still evolving, there is appropriate widespread agreement that the development of a screening and testing program.

This report contains the [consensus] recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC). This chapter describes the origin of the EDSTAC, including its mission, purpose, makeup, and outcome. It also describes the work groups that were established by the EDSTAC and the chapters that follow, which are the products of these work groups and the Committee as a whole.

II. The EDSTAC's Origin

Reflecting increasing scientific knowledge about and concern for endocrine disruption, in April 1995, EPA convened a workshop to craft a strategy for assessing the risk of endocrine disruption and to define research needs in the areas of human and ecological effects. A second workshop was convened in June 1995 to further define the research needs for ecological effects.

In May, 1996, EPA sponsored a stakeholder meeting to further define its response to the issue. Attendees urged the Agency to address screening and testing issues, and stressed the essential need for broad stakeholder involvement in what was recognized as an evolving program. Three months later, in August 1996, Congress passed both the Food Quality Protection Act (FQPA) and amendments to the Safe Drinking Water Act (SDWA). Both of these laws contained provisions that call for the screening and testing of chemicals and pesticides for possible endocrine disrupting effects. Specifically, these laws require EPA to:

> *"develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect as the Administrator may designate."*

These laws required EPA to develop and present to Congress a screening program by August 1998, to implement the program by August 1999, and to report on the program's progress by August 2000.

As a result of the May 1996 meeting and the passage of FQPA and SDWA, EPA formed EDSTAC. EPA charged the EDSTAC with providing advice to the Agency on how to design a screening and testing program for endocrine disrupting chemicals. In part because deliberations about forming EDSTAC predated enactment of FQPA and amendments to the SDWA, both EPA and the EDSTAC itself decided not to limit the Committee's deliberations to the types of chemicals, hormonal systems, or effects specifically covered under these statutes. The scope of the EDSTAC's effort is further explained in Chapter Three, which sets forth the Conceptual Framework within which the recommendations fit in the chapter that follows.

The EDSTAC was composed of 39 individuals representing various stakeholder groups and scientific expertise. The members included scientists and other representatives from: EPA, other federal agencies, state agencies, various sectors of industry, water providers, worker protection and labor organizations, national environmental groups, environmental justice groups, public health groups, and research scientists. Committee members were asked to serve as members of the EDSTAC by EPA, following a four-month convening process conducted by the facilitation team. A list of Committee members and alternates is provided in Appendix A.

As a federally chartered advisory committee, all EDSTAC plenary meetings were open to the public. A total of eight Committee meetings were held, starting with an organizational meeting that took place in October 1996 and the final plenary (which will be) in June 1998. The majority of these plenary meetings were held in different locations across the country including San Francisco, Houston, Chicago, Baltimore, Orlando, New York, and Washington, D.C. Numerous work group meetings and conference calls were also held. A public comment session was held at each Committee meeting in order to provide all members of the public an opportunity to comment to Committee members about the EDSTAC process and development of the screening and testing program. A wide diversity of constituents expressed interest in the actions of the Committee and the issue of endocrine disruptors, including: advocacy organizations, disease-impacted groups, environmental groups, environmental justice networks, farmers and farm workers, governmental

organizations, industry, environmental and health non-governmental organizations (NGOs), trade unions, students, effected or "downstream" industries, and concerned citizens.

The Committee organized itself into four work groups: the Principles Work Group, the Priority Setting Work Group (PSWG), the Screening and Testing Work Group (STWG), and the Communications and Outreach Work Group (COWG). Each work group was facilitated by a member of the facilitation team with technical assistance from EPA, and consisted of Committee members, as well as other individuals who were not members of the Committee but were asked to participate in the EDSTAC process because of their particular expertise and perspective. A list of the members for each of these work groups is included in Appendices B (Principles), C (PSWG), D (STWG), and E (COWG).

III. About the EDSTAC Report

[NOTE TO READER: The paragraph that follows is tentative, pending the final outcome of the EDSTAC's deliberations on the draft final, and final versions of its report.]

The EDSTAC Report was developed through a deliberative process that encouraged the development of consensus solutions to complex problems and issues at both the work group and committee levels. The work groups were the primary drafters of the chapters of the final report. Discussion papers and drafts of these chapters were presented by the work groups to the Committee. The Committee then discussed the issues raised by these discussion papers and drafts and developed the final consensus, which is reflected in this report.

Chapter Two of this report will provide the reader with background information on the function of the endocrine system, the issue of endocrine disruptors, and the complex statutory and chemical universe within which priority setting and screening and testing must be accomplished. It is intended to provide a context for those not well versed in either the scientific or regulatory basis of this very technical issue. It is hoped that this chapter will provide the reader with an understanding of the basis for the EDSTAC's recommendations that follow.

The EDSTAC formed the Principles Work Group to further develop and refine a set of principles that the Committee "brainstormed" at its first plenary meeting in San Francisco. The Principles Work Group helped to create a document that was called the EDSTAC Conceptual Framework (CF). This document, which was made public in May 1997, has been revised slightly from the original version and is now included as Chapter Three of the EDSTAC's (draft) final report. Initially, the CF was intended to inform, focus, facilitate, and expedite the work of the EDSTAC work groups. In its finalized form, the goal of the EDSTAC Conceptual Framework is to provide broad guidance to EPA regarding the development and implementation of its endocrine disruptor screening and testing strategy.

Chapter Four presents the work of the Priority Setting Work Group. It addresses the need to set priorities for endocrine disruptor screening and testing. It builds upon the information contained in the Background chapter regarding the universe of chemicals that need to be considered for endocrine disruptor screening and testing, and shows how these complexities are addressed in the recommendations for sorting and priority setting. The PSWG was tasked by the EDSTAC to address the following:

I. Specify types of information that should be gathered and analyzed to sort and prioritize chemical substances and mixtures for screening and testing;

A.

II. Develop criteria that can be used to evaluate the quality, adequacy, and reliability of the information that will be used in sorting and prioritizing chemical substances and mixtures for screening and testing;

A.

III. Develop criteria for sorting chemical substances and mixtures into four possible next steps, including: 1) hold screening and testing; 2) prioritize for Tier 1 Screening; 3) go to Tier 2 testing; or 4) go to hazard assessment;

A.

IV. Develop criteria for setting priorities for Tier 1 Screening. These criteria will address the relative order of priority in which chemical substances that are sorted into this category will actually proceed to Tier 1 Screening; and

A.

V. Suggest how information used for priority setting should be combined with screening and testing results to generate a "weight-of-evidence" determination for proceeding from screening to testing or from testing to hazard assessment.

A. Chapter Five describes the work of the Screening and Testing Work Group (STWG), which was charged with developing recommendations on approaches for conducting screening and testing within the overarching framework set forth in Chapter Three. The EDSTAC charged the STWG to develop recommendations on:

B.

I. the specific assays to be included in a standardized Tier 1 Screening battery;

I. guidance for using available information to generate a "weight-of-evidence" determination for moving a specific compound from screening to testing;

A.

II. guidance for how to tailor specific Tier 2 Testing; and

A.

III.

a process and criteria to standardize and validate screens and tests.

The Communications and Outreach Work Group had a threefold purpose: 1) to assist in the coordination and input on overall outreach and communication efforts surrounding the EDSTAC plenary meetings; 2) to develop recommendations for the EDSTAC report on communication issues regarding the screening and testing program; and 3) to review draft recommendations and the draft report of the EDSTAC with the objective of ensuring effective communication to both EPA and the public. The recommendations of the COWG for task 2) above can be found in Chapter Six of the report, along with a description of the efforts undertaken by the group regarding ongoing communication efforts of the Committee throughout the process, as well as ensuring effective communication of the report itself.

Chapter Seven, the final chapter of the report, summarizes some of the key features of the EDSTAC's recommendations that will affect the timeline for EPA's implementation of the proposed screening and testing program.