Chapter One

Introduction

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I. Overview

A growing body of scientific research indicates that 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, this testing may have been inadequate to determine whether they interact with the endocrine system and 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 is needed.

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, composition, and outcome. This chapter also describes the work groups established by the EDSTAC and the other chapters of the report, 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, EPA convened a workshop in April 1995 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 develop 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 calling 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 a screening program by August 1998, to implement the program by August 1999, and to report to Congress on the program's progress by August 2000.

As a result of the May 1996 meeting and the passage of the FQPA and the SDWA, EPA formed the 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 the EDSTAC predated enactment of the FQPA and the 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 the recommendations of the following chapter.

The EDSTAC was composed of 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, national environmental groups, environmental justice groups, public health groups, and research scientists. Committee members were asked by EPA to serve as members of the EDSTAC, 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 ten Committee meetings were held, starting with an organizational meeting in October 1996 and the final plenary in June 1998. The majority of these plenary meetings were held in different locations across the country, including San Francisco, Houston, Baltimore Chicago, New York, Orlando and Washington, D.C. Numerous work group meetings and conference calls were also convened. Public comment sessions were held at seven of the ten Committee meetings in order to provide 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, affected 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). Work groups were facilitated by members of the facilitation team with technical assistance from EPA. Each work group consisted of Committee members, as well as other individuals who were not members of the Committee but who 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

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 for 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 provides 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. The chapter is intended to provide a context for those individuals 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. 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 final report. Initially, the Conceptual Framework 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 addresses the need to set priorities for endocrine disruptor screening and testing, and builds upon the information contained in Chapter Two regarding the universe of chemicals that need to be considered for endocrine disruptor screening and testing. Chapter Four also shows how various complexities are addressed in the recommendations for sorting and priority setting. The PSWG was charged by the EDSTAC to address the following tasks:

- specify types of information that should be gathered and analyzed to sort and prioritize chemical substances and mixtures for screening and testing;
- develop criteria for evaluating the quality, adequacy, and reliability of the information that will be used in sorting and prioritizing chemical substances and mixtures for screening and testing;
- 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 (T1S); (3) go to Tier 2 Testing (T2T); or (4) go to hazard assessment;
- develop criteria for setting priorities for T1S. These criteria will address the relative order of priority in which chemical substances that are sorted into this category will actually proceed to T1S; and
- 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.

Chapter Five describes the EDSTAC recommendations regarding development of a screening and

testing program within the overarching framework set forth in Chapter Three. The work of the STWG, established by the EDSTAC to assist in developing guidance regarding development of the screening and testing program, formed the basis for Chapter Five. The EDSTAC charged the STWG with developing recommendations on:

- the specific assays to be included in a standardized T1S battery;
- guidance for using available information to generate a "weight-of-evidence" determination for moving a specific chemical substance or mixture from screening to testing;
- guidance for how to tailor specific T2T; and
- a process and criteria to standardize and validate screens and tests.

The Communications and Outreach Work Group's purpose was threefold: (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 the second task can be found in Chapter Six of the report, along with a description of the efforts undertaken by the work group regarding ongoing communication efforts of the Committee throughout the process, as well as ensuring effective communication of the report itself.

Chapter Seven includes all of the Committee's recommendations, made in Chapters Three, Four, Five, and Six. Each set of recommendations can also be found at the end of their respective chapters.