Chapter Six

Communications and Outreach

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I. Introduction

The EDSTAC recognized early on, that effective communication about the endocrine disruptor screening and testing program and its results, would be critical to the success of the Endocrine Disruptor Screening and Testing Program (EDSTP) (Heckler, 1985; Banquet, 1985; Chilton, 1989; NRC, 1989; NRC, 1994; NRC, 1996; NRC, 1983). To address this need, the EDSTAC created the Communications and Outreach Work Group (COWG), which was charged with three principal tasks:

1. providing advice on the coordination of the overall communications and outreach efforts surrounding the EDSTAC process;
2. developing recommendations to be incorporated into the EDSTAC final report on communication issues regarding key decision points of the Conceptual Framework and implementation of the EDSTP; and
3. improving the understandability of the final report and any other materials distributed by the Committee.

A significant portion of the work completed by the COWG during the EDSTAC process fell under the first task – coordination and input on overall communications and outreach efforts surrounding the EDSTAC plenary meetings. Activities of the work group included: providing feedback to EPA on the public comment period session; developing the *Description of the EDSTAC Charge,* which was used by EPA to describe the process to the public; recommending to EPA that the Agency coordinate an outreach mailing to interested and potentially interested parties; assisting in the subsequent assembly of materials for the mailing; and discussing additional outreach efforts for EPA and the Committee. Included in the EPA outreach mailing was a questionnaire developed by the COWG and disseminated to over 1,500 addressees. This questionnaire was created in an effort to obtain information as to the public's interest in the EDSTAC and its activities during the Committee's existence, as well as to help in future outreach efforts by the Agency. The information received in response to this questionnaire will assist the Agency in determining the most effective way(s) to communicate with those individuals and organizations interested in the EDSTAC process. A summary of the results of the survey can be found in Appendix T.

The recommendations provided in this chapter focus primarily on the second of these three tasks – developing recommendations to be incorporated into the EDSTAC final report on communication issues regarding key decision points of the Conceptual Framework and implementation of the EDSTP. In some instances, however, communication recommendations regarding key decisions of the Conceptual Framework and the EDSTP are included elsewhere in the report where they are more appropriate.

The work group's efforts surrounding the third task above – improving the understandability of the final report and any other materials distributed by the Committee – included: review of the Priority Setting and Screening and Testing Work Group chapters to ensure communication issues

are addressed where appropriate; development of language appropriate for distribution to the public describing various aspects of the screening and testing program; and development of background materials describing the basic science of the endocrine system, as well as reasons why the EDSTAC was created by EPA, for use in Chapter One of this Report.

II. Need for Communication

The EDSTAC Conceptual Framework, which has been described elsewhere in this document, is premised on a phased or tiered approach to decision-making regarding screening and testing chemical substances or mixtures for endocrine disruption. Under this approach, increasingly more specific and precise information produced in each tier is used to reach key decisions, which begin with judgments as to how chemicals and mixtures should be selected for movement into the screening and testing stages (i.e., priority setting). This will lead eventually to judgments about whether a chemical or mixture may or may not interact with the endocrine system (i.e., T1S) or produce endocrine-mediated adverse effects (i.e., T2T) for the hormone systems currently addressed by the program (i.e., estrogen, androgen, and thyroid systems (EAT)).

The first steps of the program utilize broad criteria relating to exposure- and effects-related information for the purposes of sorting and prioritizing chemicals for T1S. Criteria for moving a chemical into screening are less restrictive than criteria used later in the program to move chemicals from screening into testing or, similarly, from testing into hazard assessment. The purpose of using less restrictive criteria initially is to ensure that chemicals which may cause endocrine activity are not missed in early steps of the program, when information less specific for evaluating interaction with the endocrine system is used to make decisions. Thus, because the information gathered becomes more specific as a chemical moves through the EDSTP, the criteria for progressing through the program need to be more restrictive. Such increasing rigor will focus attention and resources on those chemicals and mixtures most likely to cause endocrine-mediated adverse effects.

When little or no effects data on a chemical are available, additional information to guide sorting and priority setting decision making will come from the results of High Throughput Pre-Screening (HTPS), as described in Chapter Four. The T1S battery is intended to identify, through the application of various assays, whether a chemical substance or mixture may interact with the EAT components of the endocrine system and, if so, to forward such compounds to the testing phase of the program. T2T is intended to determine whether a particular compound does or does not produce endocrine-mediated adverse effects and whether it should, therefore, be subjected to the hazard assessment phase of decision-making.

Communication is most important when decisions are made to move chemicals from one step in the process to the next (i.e., from initial sorting to priority setting, to screening, to testing). The tiered approach is constructed so the Agency will have increased certainty, with each progressing tier, that a chemical does or does not disrupt the endocrine system for the hormone systems currently addressed by the program. It is important for EPA to clearly communicate the

limitations that must be placed on the interpretation of information from the EDSTP, as well as the meaning and implication of its decisions.

One significant concern identified by the Committee is that information could be misused to label chemicals as "endocrine disruptors" prior to the existence of evidence to support such a claim. Such potential misuse of information could lead to unnecessary and undue concern, along with a failure to focus society's attention on those substances that are most likely to be endocrine disruptors. Such a result could, in the end, create problems serving the interest of no one. This, therefore, necessitates that the public and other interested stakeholders be provided with accurate information about the meaning of the EDSTP results. The recommendations provided in the remainder of this chapter seek to emphasize the importance of communication as EPA moves forward with implementation of the EDSTP.

III. Recommendations

A. Principles to Guide Implementation of a Communications and Outreach Strategy

EPA should develop and implement an effective communications and outreach strategy for the EDSTP, as this is an element vital to the program's success. EPA should follow a set of principles regarding implementation of the communications and outreach strategy, which include:

- Both the process and results of the EDSTP should be open and transparent.
- The results of the EDSTP should be interpreted and communicated within the context set forth in the EDSTAC final report.
- The limitations and uncertainties of the available data and the results of EDSTP should be articulated clearly when the screening and testing program is discussed.
- As new scientific evidence emerges, the uncertainties and limitations of the data may also change. These changes should be communicated clearly.
- EPA should develop quality assurance processes to assure that any database maintained for the public relative to the EDSTP is accurate and current.

B. Basic Features of the Communications and Outreach Strategy

It is anticipated that the EDSTP will produce an abundance of information shortly after its initiation, some of which may be preliminary and difficult to interpret. As results of the program are generated, it will be imperative for EPA to make them available to the public in a timely manner and to provide guidance on their interpretation (while recognizing there may be legitimate disagreement as to the appropriate interpretation).

This program of communication and outreach should consider the following four issues:

1. What should be communicated?
2. To whom should information be communicated?
3. How should information be communicated?
4. When should information be communicated?

The following discussion further addresses these four issues in detail.

1. What Should be Communicated?

The EDSTAC has focused on several aspects of the program, described below, about which EPA should be prepared to provide information. Where appropriate, the Committee has provided suggested language that could be used to communicate such information to those interested in the issues and the outcomes of the EDSTP.

a) Description of the Endocrine Disruptor Screening and Testing Program

The EDSTAC determined that one of the central issues for EPA's communication and outreach efforts is the explanation of the screening and testing program itself. Committee members recognized the importance of explicitly describing what information generated by the EDSTP means and does not mean, so as to avoid misinterpretation and misperception of the information. This potential problem was identified as a major area of concern by Committee members.

To address this concern, an explanation of the various components of the EDSTP is provided below in less technical terms than is found throughout the report. This, it is hoped, will help minimize miscommunication about the EDSTP and/or its results. Each phase of the EDSTP, (i.e., priority setting, screening, and testing) is briefly described. The Committee envisions such language filling a variety of needs for EPA and others. For example, it could be used in the following ways: to fill requests of the Agency for information about the EDSTP and, more specifically, what it means when chemicals reach certain steps in the process; as background information in the development of booklets or brochures about the screening and testing program; in EPA outreach mailings; and as information placed on EPA's Web site. The language below could also be used more widely, as Committee members and others seek to explain the EDSTP to their constituencies.

Steps of the EDSTP

The following examples were developed by the Committee to explain each phase of the EDSTP.

PRIORITY SETTING PROCESS

During the priority setting process, existing information is gathered and evaluated on new and existing chemical substances and mixtures to determine their priority to be set aside, screened, tested, or forwarded to hazard assessment. Information on exposure and human health and ecological effects, as well as statutory requirements about chemicals, will be used by EPA to set priorities. The exposure-related information and criteria will include: biological sampling data; environmental, occupational, consumer product, and food-related data; data on environmental releases; production volume; and fate and transport data and models. The effects-related information and criteria will include: toxicological laboratory studies and databases; epidemiological and field studies and databases; predictive biological activity or effects models; and results of high throughput pre-screening.

Since most chemicals lack adequate data on human health and ecological effects for purposes of priority setting for endocrine screening and testing, the EDSTAC recommends that chemicals produced in amounts equal to or greater than 10,000 pounds per year, as well as pesticides, be subjected to High Throughput Pre-Screening (HTPS) assays. These assays are intended both to provide a cursory assessment of the chemicals' potential to interact with estrogen, androgen, and thyroid receptor systems and to assist in the effort to set priorities for Tier 1 Screening (T1S). Using a limited number of assays that are appropriate for automated processing and that rely on robotics technology, HTPS is designed to generate results quickly and inexpensively. HTPS results, by themselves, will not be sufficient to make a determination about whether a chemical may interact with the endocrine system of an intact animal. Such determinations will require additional screening and testing.

In addition, a nominations program which allows citizens and communities to nominate chemicals for EPA's EDSTP will constitute another criterion for consideration by EPA in the priority setting process.

For information on the possible decisions resulting from the priority setting process, see the accompanying information on "Priority Setting Decisions."

PRIORITY SETTING DECISIONS

The priority setting process will result in one of four possible decisions:

(1) Hold. No further analysis required (at this time).
(2) Set priorities for Tier 1 Screening (T1S).
(3) Sufficient data, or voluntary bypass of T1S, to go to Tier 2 Testing (T2T).
(4) Sufficient data to go to hazard assessment.

The first category is for those chemical substances and mixtures that have a low probability of interacting with the endocrine system or exhibiting endocrine-mediated adverse effects. The Committee identified one class of chemicals – polymers – that, with some exceptions, falls into this category. A polymer is a chemical compound or mixture of compounds composed of many small units bound together to form a larger compound. Because of their molecular size, most polymers are of low concern, and therefore should be placed into a "hold" status pending a review of their components. For information on how these chemicals can be recalled into the priority setting process, see the accompanying information describing the "hold box."

The second category is for those chemicals with insufficient data to proceed to T2T, which therefore will need to be prioritized for T1S. A combination of exposure and effects data will be used to set these priorities.

The third category is for those chemicals for which sufficient data exist to permit them to go directly to T2T, or for which the owner of the chemical has decided to voluntarily bypass T1S and go directly to T2T, according to the specific recommendations found in Chapter Four of the EDSTAC report. As with T1S, it is important to note that prioritizing a chemical for T2T does not mean the chemical is an endocrine disruptor. It means, simply, that sufficient data exist to indicate the chemical substance or mixture has shown the potential to interact with the specific parts of the endocrine system examined in the EDSTP and should therefore be evaluated in T2T in accordance with the priority it receives.

The fourth category is for those chemicals for which existing data provide equivalent information to the T1S and/or T2T batteries. Such data demonstrate that a chemical is an endocrine disruptor for the hormone systems addressed by the EDSTP (i.e., estrogen, androgen, and thyroid). These chemicals will proceed directly to hazard assessment.

TIER 1 SCREENING

Tier 1 Screening (T1S) is defined as the application of assays to determine whether a chemical substance or mixture may interact with the endocrine system for the estrogen, androgen, or thyroid (EAT) hormone systems. It is intended to provide a fast, cost-efficient, and sensitive means of determining which chemicals should be subject to the more comprehensive and specific Tier 2 Testing (T2T). Screening consists of in vitro and in vivo assays designed to screen for activity in EAT hormone systems. However, it is not designed to quantify such activity (i.e., to determine dose-response). The screening process can result in one of two decisions:

(1) No further screening or testing required (at this time).
(2) Further analysis requiring T2T.

T1S is designed to provide sensitivity sufficient to minimize the chance that a chemical substance or mixture that may interact with the endocrine system will pass through T1S undetected (i.e., to minimize false negative results). This, however, is likely to result in an increased number of false positive results (i.e., chemicals which screen positively in Tier 1 screens without ultimately demonstrating adverse effects on the endocrine system). For this reason, a positive result in screening warrants further investigation in T2T.

Chemicals judged to be positive in T1S will proceed to T2T. Chemicals judged to be negative in T1S, are considered, unlikely to interact with the EAT hormone systems, because of the emphasis on sensitivity. These chemicals will not go on to T2T, but instead will be placed in the "hold box." For information on how chemicals can be recalled into the screening and testing process, see the accompanying information describing the hold box.

TIER 2 TESTING

Chemical substances or mixtures enter Tier 2 Testing (T2T) if: (1) existing laboratory, field, or epidemiological data suggest the chemical substance or mixture has shown the potential to interact with the estrogen, androgen, or thyroid hormone systems; (2) Tier 1 Screening (T1S) results are positive; or (3) statutory or regulatory mandates require testing. The Tier 2 battery includes both mammalian and non-mammalian tests designed to evaluate a variety of adverse reproductive and developmental effects.

The purposes of T2T are: to determine whether chemical substances or mixtures may produce changes in endocrine activity that will likely result in adverse effects; to characterize the nature of the effects; and to evaluate dose-response relationships. What constitutes an adverse effect may differ with taxonomic groups and is a matter of scientific judgment that may evolve with new scientific information. The T2T process can result in one of two decisions relating to the hormone systems addressed by the Endocrine Disruptor Screening and Testing Program (i.e., estrogen, androgen, and thyroid):

(1) No evidence of endocrine-mediated adverse effects for estrogen, androgen, or thyroid hormone systems (at this time); and
(2) Evidence of endocrine-mediated adverse effects for estrogen, androgen, and/or thyroid hormone systems in:

- mammals;
- birds;
- fish;
- reptiles;
- amphibians; and/or
- invertebrates.

Positive T2T results may trigger additional testing and/or a hazard assessment.

Chemicals that test negative in T2T are generally considered to possess low or no potential to affect the endocrine system, within the scope of endocrine functions addressed by the program. Such chemicals can, however, be recalled into the testing process, even if it has previously received a negative testing result. For information on the criteria used to determine whether a chemical is reentered into the testing process, see the accompanying “hold box” description.

"HOLD BOX"

At three different points in the EDSTP, chemical substances or mixtures are evaluated and may potentially be placed in what is referred to as the "hold box." The first example of this is illustrated in the priority setting phase, where polymers with a number average molecular weight of greater than 1,000 daltons are placed in a "hold" status, pending screening and testing and, if necessary, exposure assessment of their components. Those polymers that are equal to or less than a number average molecular weight of 1,000 daltons will also be prioritized for and subjected to endocrine disruptor screening and testing.

The second situation where chemicals are placed in a "hold box" takes place in the context of Tier 1 Screening (T1S). If results of a screening battery are deemed negative, the chemical substance or mixture is placed into a "hold box" and no further activity occurs unless certain criteria are met. Specifically, the possibility exists for a chemical substance or mixture to re-enter the screening and testing program if:

(1) existing statutes require periodic review (e.g., FIFRA re-registration);
(2) new statutory requirements mandate review;
(3) new screens for endocrine disruption are incorporated into the strategy and it is determined that these new screens may either generate significant new information or they invalidate prior screens and therefore warrant the re-screening of chemical substances and mixtures that have already been subjected to T1S; and/or
(4) new information on the endocrine disrupting potential of the chemical substance or mixture becomes available which warrants re-screening.

The third situation where chemicals are placed in the "hold box" takes place in the context of Tier 2 Testing (T2T). If results of the T2T battery are deemed negative, the chemical substance or mixture is placed in the "hold box" and no further testing is performed unless certain criteria are met. In addition to (1) through (4) above, a fifth possibility exists for re-entry into the screening and testing program. Specifically a chemical substance or mixture could re-enter the screening and testing program if:

(5) there is a change in the use and expected exposure patterns upon which the selection of tests were made.

A potential outcome of each phase of the screening and testing program, is the development of lists of chemicals. The Committee developed a series of questions EPA should be prepared to address when EDSTP decisions result in the creation of a list of chemicals demonstrating a common decision having been made regarding a chemical's status. The Committee developed these questions as a way to alert EPA to concerns that may arise regarding the results of screening and testing. It will be important for the Agency to clearly communicate about the issues that have been raised to ensure results of the EDSTP are accurately reflected. The questions include:

- What does this list mean?
- For what purpose will the list be used?
- What are the chemicals on the list?
- How was this list derived?
- What are the selection criteria for inclusion on the list?
- What are the limitations and uncertainties of knowledge associated with the list?
- Who compiled the list?
- Are there other ways to get a chemical on the list or considered for inclusion?
- How can a chemical be removed from the list?

b) Screening and Testing Results

Regular EDSTP status reports should be produced and distributed. These documents should include:

- the status of all chemicals and mixtures within the EDSTP;
- a list of all chemicals and mixtures whose status within the EDSTP has changed since the last update; and
- important EDSTP decisions and developments at decisive points in the program, such as calls for nominations of compounds to be considered in priority setting; lists of chemicals that have been prioritized for T1S; lists of chemicals that have been identified for T2T; lists of chemicals that have produced endocrine-mediated adverse effects in T2T and are now subject to hazard assessment; significant scientific advances in the field; the incorporation of new assays into the EDSTP; and expansion of the scope of work (e.g., looking at additional hormones).

c) Nominations Process

As described in Chapter Four, Section IX, of this report, the EDSTAC recommends EPA establish a process that would allow stakeholders, including members of the general public, to nominate chemical substances or mixtures for endocrine disruptor screening and testing. In general, the nominations process is intended to focus on chemical substances or mixtures where exposures are disproportionately experienced by identifiable groups, communities, or ecosystems rather than those where exposures are more broadly experienced by the general population at the regional and/or national levels. The process should provide a mechanism for prioritizing chemicals unlikely to be considered as having a high priority through the core priority setting process.

It is important for EPA to alert the public about the opportunity to nominate chemicals, as well as to provide accurate and up-to-date information about the status of all chemicals considered for prioritization. Members of the public should be encouraged to provide comments during the formal public comment period, which is expected to take place after EPA has publicized its proposed list of chemical substances or mixtures prioritized for screening and testing. An opportunity to nominate chemicals will occur at the start of each phase of the EDSTP.

d) Background Information on the EDSTAC Process

EPA should communicate information to the public about the EDSTAC, including its purpose, goals, and process, as needed. The language contained in Chapter Two of this report could be used by the Agency for this purpose.

2. To Whom Should Information be Communicated?

a) Members of the Public and Other Stakeholders

Throughout the EDSTAC process, an interest in the issue of endocrine disruption and the development of a screening and testing program was evident. This was demonstrated via the public comment sessions held at seven of the nine plenary meetings, where members of the public representing – industry, environmental groups, advocacy organizations, farmers and farm workers, governmental organizations, environmental and health-oriented non-governmental organizations (NGOs), trade unions, disease-impacted groups, environmental justice networks, students, industries that formulate products but do not manufacture the component chemicals (i.e., "downstream" industries), and concerned citizens, among others – were given the opportunity to present their comments to the Committee regarding the deliberations of the EDSTAC and its work groups. A compilation of the statements made by members of the public at each of the EDSTAC meetings can be found in Appendix U. Furthermore, each of these stakeholders was also represented either in one of the work groups or on the Committee itself, further demonstrating the variety of interests contributing to this effort.

It is recommended that EPA proactively communicate with groups, such as those listed above, which have clearly demonstrated an interest in the issue, particularly those organizations and individuals who have requested to receive program information directly from EPA. The database of names and organizations already collected by the EDSTAC could be used as a base of contacts for proactive communication to stakeholders. In fact, much of the data entry has already been done. Other stakeholders to include can be found in the list of organizations that received EPA's September 1997 mailing, as well as The Keystone Center's list of interested parties accumulated over the duration of the EDSTAC process.

b) Specific Audiences

For some stakeholders, EPA will find it necessary to go beyond the generic EDSTP status reports. A tailored set of messages about the program targeted to specific audiences will be

needed. It is clear that the "public" consists of a variety of people and organizations, each with varying levels of knowledge and interest in endocrine disruptor-related issues. In addition, many communities face other challenges such as language barriers and differences in culture or economic viability. Such differences create a need for informational materials to be tailored to such audiences. In particular, EPA should consider this type of communication with environmental justice organizations, "downstream" industries, farm workers, and patient-specific groups. To find out more about communicating with such constituencies, the Committee recommends EPA conduct a follow-up survey, building on the information gathered from the September 1997 survey described in Section I of this chapter.

3. How Should Information be Communicated?

As EPA carries the important new responsibility of screening and testing chemical substances and mixtures for endocrine disruption, it will be necessary to develop a capacity to quickly respond to requests for information, both about specific chemicals and about the EDSTP in general.

a) Electronic Communication

The EDSTAC recommends that EPA create a tracking database with the ability to handle inquiries about the status of specific chemicals and classes of chemicals, as well as summaries for defined sets of chemicals (e.g., organophosphates). The goal for the creation of such a database is that any member of the public should be able to query and quickly determine the status of a chemical or mixture in the EDSTP. Inquiries might come from within the Agency, from the public, or from industry. As a result, it is important that the database be organized so people can submit inquiries in many different ways and with varying levels of expertise. For example, the inquiry might begin with a chemical name or Chemical Abstracts Service (CAS) registry number, a chemical structure, or a stage in the EDSTP process.

The tracking database should be compatible with, and fully integrated into, the Endocrine Disruptor Priority Setting Database (EDPSD), described in Chapter Four. As proposed in Chapter Four, Section X, G, a multi-stakeholder group should be created by the Agency to continue development of the EDPSD as a tool for priority setting purposes. In addition, the Committee recommends that the same group assist in development of the tracking database, in order to promote consistency and ensure it meets the needs of the diverse groups likely to use the database in the future. The database should also be compatible with, and integrated into, those being developed elsewhere in the Agency (e.g., for carcinogens or reproductive toxicants). The EDPSD should not exist in isolation.

In creating this database, several characteristics are desirable if it is to address the needs of a wide range of potential users:

- The database should be useful over the Internet, and a Web site should be established for this purpose. Since it will be integrated with other databases at the Agency, the Web site should be reached through links that begin at several locations (e.g., the main Agency site, a page dedicated to inquiries about toxic substances in general, a page dedicated to searching for

information on endocrine disruptors, and pages dedicated to searching for other effects such as developmental, reproductive, or carcinogenic).

- The database should include the ability to search by specific chemical names, by classes of chemicals, and, where appropriate, by chemical structure. Searching should be by chemical, not by product name.

- The database should include the ability to search for the place of each chemical in the EDSTP process and subsequent regulatory decisions. This includes the ability to obtain a listing of all chemicals that presently are: (i) in HTPS; (ii) undergoing review for priority setting; (iii) in T1S; (iv) in T2T; (v) undergoing hazard assessment; or (vi) have had a regulatory decision made.

- Whenever the location of a chemical in the system is provided to an inquirer, or a listing of chemicals at particular points in the EDSTP is provided, it is essential that this information have appended to it a brief description of what it means for a chemical to be at that location. This description should be consistent with guidance provided elsewhere in this chapter.

- The database should include the ability to obtain the decision results of each step a chemical has completed to date. The designations for these results should be consistent with those detailed elsewhere in the EDSTAC Report. This should include information describing: (i) the result of a chemical's priority setting; (ii) the results of T1S; (iii) the results of T2T.

- The database should not attempt to summarize the rationale for the Agency's decisions discussed in the previous item and based on specific positives/negatives for particular screens/tests. Instead, the database should direct the inquirer to the appropriate documentation, explaining how that documentation can be viewed and/or obtained.

- To facilitate the utility of the database as a research tool, it would be useful if the database contained information on whether the chemical was positive or negative for each individual screening assay and/or test, including the results of HTPS. In stating whether the result of a screen or test was positive or negative, it is important that the database also provide information about the criteria by which a result is considered to be a pass or fail for that assay.

In considering the range of questions users might have in directing inquiries to the database, several kinds of information should be available through the database. These include:

- chemical name and CAS registry number;
- common synonyms (but not product names);
- chemical structure;
- information on the stage in which a chemical currently is found (priority setting; T1S; T2T; HTPS; hazard assessment; "hold box");
- one-sentence descriptions of the purpose and possible outcomes of each of the stages; this description would be provided whenever the inquiry indicates a particular stage has been reached;

- summary of the Agency decision on a chemical at each of the stages through which it has passed (priority setting; T1S; T2T; HTPS; hazard assessment; "hold box");
- summary of the result obtained from each HTPS screen;
- one sentence descriptions of reasonable interpretation(s) of a chemical's having positive or negative results in a particular HTPS screen;
- summary of the result obtained from each T1S assay;
- one sentence descriptions of reasonable interpretation(s) of a chemical's having positive or negative results for a particular T1S assay;
- summary of the result obtained from each T2T test;
- one sentence descriptions of reasonable interpretation(s) of a chemical's having positive or negative results of a particular T2T test.

The availability of a tracking system will be a particularly important tool as it relates to the nominations program. Members of the public should be able to rely on this database to provide timely and accurate information about chemicals that have been prioritized for T1S, either through the nominations process or other means. The availability of such information will be imperative as affected communities, in particular, review the list to determine if chemicals of concern to them have been selected for T1S.

b) Telephone, Fax, Mail, and Other Communication

For those who do not have access to the Internet, the contents of the EPA Web site should be available by other media through EPA staff support. A centralized, automated telephone system should be developed. In addition, regular EDSTP status reports and important program developments should be posted in: the Federal Register; pesticide registration notices; press releases; and Web announcements. In addition, where appropriate, EPA should provide information about the EDSTP through a variety of media, such as general fact sheets, question-and-answer documents, information booklets, EPA newsletters, brochures, pamphlets, trade journals, videotapes, slide presentations, and other publications as appropriate.

EPA should initiate contact with stakeholders, providing them with the address of the Web site and the number of the centralized telephone site. The Agency should maintain proactive communication with these groups until the groups indicate they plan to receive information electronically or are no longer interested.

To be successful, EPA should invest resources into how to effectively manage professional communication efforts.

4. When Should Information be Communicated?

Communication should occur regularly and frequently given the rapid developments in the science of endocrine disruption and the increasing public interest in the issue. There are two kinds of information that EPA should be prepared to communicate at specific points in time.

a) Public Updates About the EDSTP

The COWG discussed the means and mechanisms available for disseminating information to the public regarding the progress and results of the EDSTP. One option EPA has used in other programs is a regular bulletin or newsletter that identifies specific actions, events, and program directions taken by EPA staff. The Committee recommends that EPA explore this option for disseminating information to members of the public for whom e-mail is either not available or is not an effective means of receiving such information.

The Committee recognizes that this type of informing effort needs to be goal-oriented and have some specific parameters in order to provide the best use of Agency funds. Therefore, the following operating conditions should be taken into account in creating an updating bulletin:

- The output should be in the form of a newsletter or bulletin for public review with the purpose of informing the public of the program and its progress.
- The publication should be of a limited length and in a desk top format.
- Publication should start shortly after EPA initiated the program in late 1998 or mid-1999, and continue for a defined period of time.
- The publication should be produced for the duration of the screening phase and into the testing phase, with some predetermined ending time.
- The content of the publication could be chemical-specific, but more likely would direct interested readers to sources where more detailed information could be found, rather than list volumes of scientific technical information.
- The publication should draw heavily on the Web site information, if not duplicate much of what is on the Web site.

The survey conducted by EPA with advice from the COWG indicated that there are members of the public, including individual citizens, organizations, and small businesses, for whom electronic access is not an effective mode of communicating, or is not available. For these constituents, EPA should provide information in an accessible and easy to understand form.

b) Whenever Important EDSTP Developments Warrant Communication

Important developments in the EDSTP of a definitive, non-preliminary nature should be communicated as soon as that information is available, rather than waiting for the generation of regular public updates. Examples might include: calls for nominations of compounds at the outset of each phase of the EDSTP that are to be considered in priority setting; lists of chemicals that have been prioritized for T1S; lists of chemicals that have identified for T2T; lists of chemicals that have been identified as exhibiting endocrine-mediated adverse effects in T2T and are subject to hazard assessment; significant scientific advances in the field; the incorporation of new assays into the EDSTP; expansion of the scope of the EDSTP (e.g., looking at additional hormone systems); and other key decisions or developments within the EDSTP.

C. Adequacy of Resources Devoted to Communication and Outreach

Management of the EDSTP will be a significant new responsibility for EPA, and providing public information on the program will be essential for the full cooperation of affected and interested parties. EPA should allocate sufficient resources with high-level responsibility to manage its communications and outreach strategy.

It is important that all information be available through a small number of centralized sites. It is vital that the public and other interested parties be able to obtain information through such a centralized site rather than having to track the material to a specific office in the Agency.

The Committee identified the following tasks that must be provided resources on a continuing basis:

- creation and maintenance of a centralized tracking system in the form of a database, which may be queried for the status of particular chemicals and for summaries of status across classes of compounds;
- creation and maintenance of a component of a Web site with an appropriate graphical user interface allowing individuals to make these inquiries;
- creation and maintenance of a component of the same Web site allowing individuals to obtain background documents and regular EDSTP status reports;
- creation and maintenance of a centralized, automated telephone system allowing individuals to access the tracking system database and to order specific program documents; and
- assignment of staff to monitor the above four items, and to disseminate materials that are requested through the automated telephone system or other ways. In addition, this staff resource should proactively send regular EDSTP status reports, as well as important program updates, to stakeholders who have requested such.

Management of the EDSTP should continue to be the responsibility of the EPA Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances. Concurrently, coordination across the entire Agency should enable all EPA staff to locate and supply requested information.

IV. Generalized Schedule for Implementation

During the EDSTAC process, the importance of communicating EPA's schedule for implementing the EDSTP became evident. To help inform the public of the estimated schedule for implementation, including opportunities to provide public comment on the EDSTP, a generalized schedule was developed. This schedule, while not precise in dates, provides the reader with a sense of the direction that EPA will be taking as they seek to fully implement the EDSTP. It should also be noted that the schedule was developed assuming adequate resources to carry out each activity as scheduled. Lower levels of funding will cause a stretching of various

activities and the other activities that depend on their completion. Specific resources have not yet been approved for EDSTP implementation.

Several fundamental requirements that must be met as set forth in the FQPA will serve as the basis for EPA's implementation plan. These requirements include:

- Using validated assays, EPA must propose a screening program by August 1998.
- EPA must implement the proposed screening program by August 1999.
- EPA must report to Congress, the progress of the screening and testing program to date by August 2000.

Other key elements of the EDSTP will be implemented according to the attached generalized schedule (Figure 6.1). The schedule describes the key processes and their relationship to each other. The public will have an opportunity to comment on the report once it is made final and released in the FR Notice.

The key elements of the schedule include:

- EDSTAC and SAB/SAP peer review processes;
- High Throughput Pre-Screening feasibility demonstration and utilization;
- Final development, utilization, and maintenance of the EDPSD and completion of the priority setting process;
- Standardization, validation, and utilization of the T1S battery and newly developed Tier 2 Tests; and
- EPA regulatory and administrative processes (e.g., FQPA Orders, TSCA consent agreements and/or rulemaking) related to the EDSTP.

Figure 6.1

Generalized Schedule for Implementation of the Endocrine Disruptor Screening & Testing Program (EDSTP)

V. Compilation of Chapter Six Recommendations

A. Need for Communication

As described in Chapter Two, Section II, the Communications and Outreach Work Group (COWG), and then later the full EDSTAC, recognized the importance of communication about the EDSTP to, among other things, prevent misuse of information. Because the EDSTP applies a tiered approach, results become increasingly definitive as chemicals progress through each step of the screening and testing program. This type of system leaves room for interpretation of results, particularly in the early stages of the EDSTP (i.e., during priority setting or screening), that may or may not be accurate. Therefore, the Committee emphasizes the need for clear and accurate communication to interested stakeholders throughout the development and implementation of the EDSTP. In particular, it is important that EPA clearly communicate about the limitations that must be placed on the interpretation of information and results from the EDSTP, as well as the meaning and implications of its decisions. The recommendations identified in Chapter Six seek to emphasize this point, while providing guidance to EPA as it further develops its communications strategy for the EDSTP.

B. Principles to Guide Implementation of a Communications Strategy

1. The EDSTAC recommends that EPA develop and implement an effective communications and outreach strategy for the EDSTP based on the following set of principles intended to help ensure accurate and open communication to stakeholders:

- Both the process and results of the EDSTP should be open and transparent.
- The results of the EDSTP should be interpreted and communicated within the context set forth in the final EDSTAC Report.
- The limitations and uncertainties of the available data and the results of EDSTP should be articulated clearly when the screening and testing program is discussed.
- As new scientific evidence emerges, the uncertainties and limitations of the data may also change. These changes should be communicated clearly.
- EPA should develop quality assurance processes to assure that any database maintained for the public relative to the EDSTP is accurate and current.

C. Basic Features of a Communications and Outreach Strategy

2. The Committee recommends that EPA base their communications and outreach strategy on the following four questions:

- What should be communicated?

- To whom should information be communicated?
- How should information be communicated?
- When should information be communicated?

Details of the recommendations for each of the four questions are located in Chapter Six, Section III, B. The basic recommendations, however, follow.

3. Under "What should be communicated?," the Committee recommends that EPA be prepared to provide information to interested stakeholders on the EDSTP itself, on screening and testing results, the nominations process, and background information about the EDSTAC process. Suggested language explaining the various components of the EDSTP in less technical terms than is found throughout the report, is included in the chapter.

4. Under "To whom should information be communicated?," the Committee recommends that EPA actively communicate with members of the public and other stakeholders, such as those who have demonstrated interest in the process through their attendance of the public EDSTAC meetings and public comment periods.

5. The Committee recognizes the need for, and recommends EPA develop, tailored information to be relayed through a variety of mechanisms. This would help to ensure that specific audiences – such as environmental justice organizations, "downstream" industries, farm workers, and patient groups – who may not have the ability to access information via traditional means and who have varying levels of knowledge and interest in endocrine disruptor-related issues, have the opportunity to learn about the EDSTP and its results.

6. The Committee recommends that EPA conduct a follow-up to their September 1997 outreach questionnaire in order to find out more information about how best to communicate with certain groups, such as those listed above in recommendation number five.

7. Under "How should information be communicated?," the Committee recommends that EPA develop a tracking system as part of the priority setting database described in Chapter Four. They recommend that, if possible, such a database be incorporated into existing EPA systems to promote efficiency and cost-effectiveness. Several characteristics of a desirable database intended to address the needs of a wide range of potential users have been included. The EDSTAC believes it is important for members of the public to have access to information about the screening and testing program as it progresses, including the ability to query and quickly determine the status of a chemical or mixture in the EDSTP, as well as to access and download relevant EDSTP documents.

8. For those without Internet access, information should be available through a variety of sources, including telephone, fax, mail, Federal Register notices, and other forms of communication, as necessary.

9. Under "When should information be communicated?," the Committee recommends that EPA develop a newsletter or bulletin, as has been done in other EPA programs, that would be made

available on a regular basis. The report should be of a limited length and should be available for a limited duration.

10. The Committee also recommends that information be communicated when warranted by important EDSTP developments, such as a call for nominations, when lists of chemicals have been prioritized for T1S, identified for T2T, or identified as being subjected to hazard assessment after exhibiting endocrine-mediated adverse effects in T2T, as well as regarding other key decisions relating directly to the program.

11. As described in Chapter Six, Section III, C, the Committee strongly recommends that EPA commit adequate resources to the communication aspects of this program. Several tasks requiring such support are identified in the report, such as the creation and maintenance of a tracking database, maintenance of a Web site with an appropriate graphical user interface, creation and maintenance of a centralized, automated telephone system, and assignment of staff to monitor such items.

VI. Literature Cited

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