A USER ASSESSMENT OF THE TOXICOLOGY DATA BANK

August 1982

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AMERICAN MANAGEMENT SYSTEMS, INC.
1777 NORTH KENT STREET
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FOREWORD

The Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB), provides scientific assessments of topics in the biomedical sciences. Reports are based upon comprehensive literature reviews and the scientific opinions of knowledgeable investigators engaged in work in specific areas of biology and medicine.

This technical report was developed for the Specialized Information Services Division, National Library of Medicine, in accordance with NLM Order No. 467-MZ-201015 and is based in part on a report prepared under the terms of Subcontract No. 2881-1 under Definitive Task Order No. DTO-5146-50 of EPA Contract No. 68-01-5146 with American Management Systems, Inc., Arlington, Virginia. The report was prepared and edited by Philip L. Altman, Senior Staff Scientist, and Kenneth D. Fisher, Director, LSRO, FASEB.

The LSRO acknowledges the contributions of the investigators and consultants who assisted with this study. The report reflects the opinions expressed by participants in an ad hoc study group that met at the Federation on April 13, and June 3-4, 1982. The study participants have reviewed a draft of the report and their various viewpoints were incorporated into the final report. The study participants and LSRO accept responsibility for the accuracy of the report; however, the listing of study participants in Section X does not imply that each participant specifically endorses each study conclusion.

The report was reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent Society of FASEB) under the authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures, the report was approved and transmitted to the National Library of Medicine by the Executive Director, FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of each individual member of the FASEB constituent Societies.

September 15, 1982
Date

Kenneth D. Fisher, Ph.D.
Director
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SUMMARY

This report reviews the responsiveness of the Toxicology Data Bank (TDB) in meeting the needs of the user community. It addresses the ability of TDB to meet user needs, TDB effectiveness in data acquisition and processing, the adequacy of TDB procedures, and attributes of TDB management.

Commercial organizations and research institutions, rather than medical schools and hospitals, are the major users of TDB. Scientists are rarely searchers of the database because information specialists and librarians serve as intermediaries between the end-users and the database. For the substances available in TDB, coverage seems to be adequate, but the number of records of specific chemicals in TDB should be increased substantially to meet user needs. The evaluation process to which tertiary data sources for TDB are subjected enhances quality assurance and bolsters user confidence in the data retrieved.

The validity of the data in TDB is high, but the current practice of using tertiary data sources compromises immediacy and availability of new data. The primary literature should be used also as a source for TDB input because the data from the tertiary literature may have been superseded and users want to refer to current primary literature. The Peer Review Committee, which performs a worthy data evaluation function, should be augmented to include a broader representation of users from the toxicology community, who can assist in the selection of substances to be covered in TDB. Reference citations to the source of the data enhance the confidence of the user in the information obtained. A simplified and more flexible reporting procedure would allow the user to decide the quantity of data required for each substance of interest and to vary report formats to support specific needs. Users of TDB should be made aware of reporting options that permit the user to print out a short or condensed report, a modified report, or a fully detailed report with or without references. A regrouping of unit records to produce a somewhat different selection of categories might permit easier searching and retrieval of data and citations.

A simpler and less tedious search procedure, with fewer mnemonics for TDB categories and a compressed synonym format, might better serve user needs. Consideration should be given to improved training on TDB; for example, more sessions might be provided at locations other than the National Library of Medicine. Additional user services, such as an update sheet or newsletter, a news item online, and an online user feedback system, should be made available.

Marketing of TDB has been made more difficult by the absence of a clear picture of who current users are and what services they desire. An expanded marketing, or combined marketing/training,
program should be considered. This program should focus on making prospective users aware of TDB capabilities. TDB is relatively inexpensive in terms of access cost per hour and is generally cost-effective, but costs are apt to rise in future leading to higher consumer charges. When this occurs, perhaps an educational rate for institutions of higher learning might be considered. There is no single readily accessible database or data source that duplicates TDB, but it does not seem to meet the needs of any particular user group totally. Therefore, NLM must find a means of making TDB more attractive and appealing to users of toxicologic data. By making TDB and other toxicology databases accessible through a linking or switching system, without compromising the individual integrity of each database, similar data developed by different groups could be networked for the benefit of the user.

The recommendations outlined in this report with respect to TDB should be considered in terms of practicality, costs of implementation, and possible alternatives by NLM. These recommendations are based on the observations and opinions of the User Assessment Panel members in their work experiences with TDB, and represent a consensus of the group.
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I. INTRODUCTION

The Toxicology Data Bank (TDB), developed by the National Library of Medicine (NLM), is an information resource that provides online access to data of interest to a diverse group of research investigators, reviewers, regulators, and others. This database, containing primarily toxicologic data, is an example of the type of online resource that is being developed by the public and private sectors to fill the information needs of a diverse user community requiring knowledge of toxicologic properties of chemical substances (Decker and Kissman, 1977).

In 1981, the NLM and the Environmental Protection Agency (EPA) agreed that a scientific assessment of online databases by representatives of the user community would be valuable in assisting each agency in its efforts to meet user needs for toxicologic and related data on chemical substances. Under contract with American Management Systems, Inc. (AMS), the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) conducted a user review and evaluation of TDB for NLM, and of the Chemical Information System (CIS) for EPA. Each online data resource was reviewed and evaluated in terms of content, procedures for entry and validation of data, accessibility, data quality assurance, user utility, and other aspects of efficiency and effectiveness. The review, conducted by AMS and LSRO, was based on deliberations of a User Assessment Panel (UAP) selected by LSRO and composed of nationally respected experts in various pertinent disciplines (see Section X, Study Participants).

In selecting the members of the UAP, the LSRO was able to identify scientists and information specialists who were users of TDB and knowledgeable about its utility. The affiliations of the Panel members encompassed private industry, which uses TDB most frequently; the U.S. Government; state government; and the academic community, which uses TDB least of all. The disciplinary expertise of the UAP covered toxicology, chemistry, biochemistry, and information science.

On April 13, 1982, the UAP met during the morning with members of the NLM staff and the EPA staff, who provided background information on TDB and CIS, and responded to questions from the UAP about these data resources. The afternoon session was devoted to a review of documents distributed to the Panel members for in-depth background on TDB (see Section IX, Annotated Bibliography) and CIS. A study plan and schedule were developed, and a general discussion of how Panel members use TDB and CIS completed the one-day session.

The UAP met again on June 3-4, 1982, to review aspects of the TDB documents not discussed on April 13, and to consider specific questions related to the current and future status of TDB,
as well as related questions of a more general nature. The consider-
ration of these questions and the ensuing recommendations
regarding future development of TDB are based on UAP deliberations
and opinions. They are proposed without regard to any analysis of
possible alternatives or cost-benefit considerations.

This report is concerned only with the findings related
to TDB. A similar assessment of the CIS is contained in a
separate report (Life Sciences Research Office, 1982).
II. PURPOSE OF THE STUDY

The purpose of this assessment is to make available to NLM a report on how TDB meets the needs of the user community, and, if appropriate, how it might be more responsive to those needs. To reflect the concerns and opinions of the general scientific community, LSRO established and organized the UAP which was asked to address certain questions. From the deliberations and ensuing suggestions for TDB improvement by the UAP, the LSRO staff has prepared this report covering the following issues:

1) Ability to meet user needs, including considerations of the user audience, the searching audience, data quantity and coverage, and data quality;

2) Effectiveness in data acquisition and processing, including data sources, peer review procedures, provision of references and bibliographies, and reporting flexibility;

3) Adequacy of system procedures, related to searching procedures, training sessions, and supplemental user services; and,

4) System management capabilities, focusing principally on marketing procedures, cost effectiveness, TDB modification, and TDB as a system module.
III. DESCRIPTION OF THE TOXICOLOGY DATA BANK

The Toxicology Data Bank is an online, interactive data retrieval system containing records of chemical, pharmacologic, and toxicologic data, extracted from textbooks, handbooks, and criteria documents. It contains data and information on approximately 3000 substances, with records on more than 600 additional substances in the process of completion. Further information on TDB is available from the National Library of Medicine (see Section IX, Annotated Bibliography).

A. CONTENT

Each chemical substance record in the TDB provides, if available from the source documents selected, the following information:

1) **Toxicity values** for toxic and lethal doses, minimum fatal doses, maximum daily intakes of non-drug substances without toxic effects, threshold limits, and maximum daily doses of drugs without toxic effects;

2) **Textual toxicologic information** on absorption, distribution, metabolism, excretion, poisoning potential, antidote and treatment, pharmacotherapy, therapeutic uses and indexes, warnings and cautions, idiosyncrasies, tolerances and resistances, and mechanisms of action;

3) **Textual environmental information** on environmental and occupational exposure and limits, pollution potentials, fire potentials, explosive limits, radiation limits and potentials, as well as shipment and disposal methods for toxic compounds;

4) **Manufacturing information**, including major uses; methods of manufacturing; names and addresses of manufacturers; consumption patterns; and U.S. production, import, and export figures; and,

5) **Chemical-physical properties data** for boiling, melting, and flash points; color and form; density and specific gravity; vapor pressure; solubility; stability and shelf life; spectral properties; and molecular formula and weight.

B. ADMINISTRATION

As shown in the organizational chart (Figure 1), TDB is managed by the Specialized Information Services (SIS) Division of
SEE FOLLOWING TDB MANAGEMENT SCHEMATIC (Figure 2)

*Other SIS Databases include: RTECS, CHEMLINE, TOXLINE

Figure 1. NLM TOXICOLOGY DATA BANK ORGANIZATION
Figure 2. TDB MANAGEMENT (as of June 1982)
the National Library of Medicine as part of its mandated activities within the Toxicology Information Program. Interagency liaison and advisory services are provided to SIS by the Toxicology Information Subcommittee of the Department of Health and Human Services (DHHS) Committee to Coordinate Environmental and Related Programs, and by the National Academy of Sciences which provides contractually the services of the Toxicology Information Program Committee.

Management of both the in-house project team and the database operational agreement with the Oak Ridge National Laboratory (ORNL) is provided by SIS (Figure 2). A Peer Review Committee (PRC), composed of present and past members of the Toxicology Study Section, Division of Research Grants, NIH, provides technical review and acceptance of all chemical compound data before they are entered into TDB. The PRC consists of 12-14 experts selected by NLM for their interest in TDB and their areas of subject expertise. Proposed TDB records are assigned initially to a specific PRC expert before final review by the entire Committee. In addition to record review, the PRC also assists in compound selection and designation of reference sources. The peer review process and flow of data into the online TDB system are described in Figure 3.
Figure 3. TDB DATA FLOW DIAGRAM (including peer review process)
IV. ABILITY TO MEET USER NEEDS

A. TDB USERS

The NLM mandate from the United States Congress is for the broad application of NLM resources to the advancement of the medical and health-related sciences by collecting, organizing, and making available biomedical information to investigators, educators, and practitioners (Oxman, et al., 1976). As a part of this mission, NLM initiated and developed TDB primarily for physicians, health professionals, and medical investigators.

Assessment: A review of institutional users of TDB indicates that commercial organizations and research institutions are the major users of the database, not medical schools, hospitals, and clinics. The industrial and research chemists and toxicologists who constitute the user majority find that TDB falls short in meeting their specific needs for toxicologic information. Though regulatory agencies use TDB, the Food and Drug Administration is more likely to use TOXLINE and MEDLINE. The EPA and the National Institute of Occupational Safety and Health also use TDB, but have invested in additional databases that are oriented to specific needs.

Recommendation: There must be a sharper focus on the intended users of TDB, and then a greater effort must be made to meet the needs of that particular audience. If TDB is to be a more relevant source of toxicology data, the user population should be more precisely defined, the goals of TDB should be clarified, and if necessary, the database should be restructured to cover more current data on a far greater number of substances.

B. TDB INTERMEDIARIES

Most scientists and those physicians in medical schools and hospitals, who are the end-users of TDB, are seldom the searchers of the database. The vast majority of searchers are information specialists and librarians, usually as intermediaries between the end-users and the data source. The information specialists and librarians have been, are now, and probably will continue to be the major direct users of TDB.

Assessment: The search procedures used by information specialists probably would differ depending on whether the end-users were chemists and toxicologists, or physicians. Searches for the former would most likely be by substance to provide specific facts about the biology, chemistry, and toxicology of the compound or a group of related substances. For the physician, searches would more
likely be by concept to provide information on substances having attributes in common. However, in research settings and in certain poison control situations, often the reverse would apply, thus requiring searches by substance.

There is an evolving need for evaluated, analyzed data in condensed form. Managers and administrators of scientific enterprises or other organizations requiring toxicologic data are becoming frequent end-users of databases such as TDB, as their need for synopses or interim documents required in the decision-making process or the preparation of reports becomes more prevalent. For these purposes, the more readable the document, the better. Thus, textual presentations as output, comparable to mini-monographs, may be appropriate.

**Recommendation:** As the major direct users of TDB, information specialists and librarians should be consulted on a regular basis to determine whether TDB system procedures are meeting their needs. They also can serve as excellent conduits, from the end-users -- be they scientists, physicians, managers, or administrators -- to NLM, by providing feedback on data content, format, quality, and quantity requirements of the end-users, and information on whether TDB is meeting those needs.

C. **DATA QUANTITY**

The TDB contains information on approximately 3000 chemical substances, with records for each substance composed of as many as 60 different data elements, which are grouped into eight categories including chemical, physical, biological, pharmacological, toxicological, and environmental data (National Library of Medicine, 1981). The use of multiple information sources results in repetition of similar data for some substances, and an unnecessary lengthening of records.

**Assessment:** For the substances available in TDB, coverage seems to be adequate, but the UAP concludes that to be a more effective and useful database, TDB should contain many more data records on substances than are presently covered. For each substance, as much information as possible should be available without the repetition now encountered.

Many data records available for some time do not seem to be widely used. On the other hand, data records on many of the substances still undergoing the evaluation process are of interest to a substantial number of users and should become available more rapidly.
Recommendation: Expand TDB to include coverage of far more substances than currently available. There is also a need to streamline the input process to reduce the time required for data record development and entry.

It would be desirable if users were aware that some flexibility in retrieving reports is available. Such flexibility includes the option of printing out a short or condensed record; a modified record without all of the key words or references; or a full record that includes key words, references, and other details. Thus, flexible retrieval allows the user to decide the quantity of data required for each substance of interest and to vary report formats to support specific needs. Further, it would be helpful to the user to have an indication of record length preceding the substance file. Such information could serve as a guide in determining whether the user needs a short, modified, or full report.

D. DATA QUALITY

The bulk of TDB data is derived from tertiary literature sources, such as handbooks, textbooks, and criteria documents (Wykes, 1982). The data from these sources are reviewed by the PRC for the purpose of making evaluated data available for entry in TDB. Accompanying each data item, except for chemical-physical properties, there is a citation to the reference from which the value or information was derived.

Assessment: Data quality should continue to be a top priority for TDB, but timeliness of the data should be given more consideration than it has received in the past. Whereas data quality and timeliness are almost always of vital importance, the degree of completeness of the data is dependent on the user community being served and its particular needs.

Data quality is implied in the use of tertiary sources, which have undergone a process of open peer review in the steps that lead from the primary to the tertiary literature. However, some concern was raised regarding criteria documents, which cannot be subjected to the same level of review as are handbooks, textbooks, and archival compendia. The evaluation process of the PRC enhances quality assurance, and provides the user with confidence inherent in the knowledge that data are from evaluated sources and, in addition, have been reviewed by experts. The inclusion of reference citations for the information items adds another measure of quality assurance.

Recommendation: As conceived and currently organized, most of the data in TDB are derived from tertiary sources because of the emphasis on evaluated data, but in some cases, more complete data could
be derived from primary sources. More emphasis on introducing primary literature would add currentness to the database and provide a balance that is lacking at present. Whether the PRC can handle the added burden of sifting the primary literature, in terms of time and cost, will require careful consideration by the NLM. This aspect should be evaluated in current NLM efforts to upgrade the efficiency of the data-input process. In addition, MEDLINE and TOXLINE, particularly the latter, should be used more frequently and effectively as a source of current references on substances for which primary literature is sought.

Building the database to include coverage of many additional substances is a more important priority than updating the records already in TDB. Nevertheless, data must be revised as soon as possible when new editions of tertiary publications become available. If the user finds that data from the fourth edition of a tertiary source are in TDB but the fifth edition is on the bookshelf, acceptance of the most recent source will be the user's logical choice. Thus, the credibility of the database is compromised. Such a situation reinforces a lack of confidence in the database and leads to underuse, or even non-use, of the data bank. To assure credibility, if not currentness, the last date on which the record was reviewed should precede the item in the record. In addition, all updated records should be tagged to permit recall of updated material only. This would function not only as a quality assurance measure but also as an aid to the user.

An auxiliary function of the PRC in assuring data quality should be to indicate a "best value" when values are inconsistent or extremes in values might be confusing to the user who lacks the expertise to select a "best value." More than an auxiliary function, it should be an essential criterion of peer review.
V. EFFECTIVENESS IN DATA ACQUISITION AND PROCESSING

A. DATA SOURCES

Handbooks, monographs, textbooks, and criteria documents, all of which are tertiary literature sources, have served as input to the TDB (Wykes, 1982). Thus, TDB was designed to be a database containing only published data that were "evaluated" or "peer reviewed."

Assessment: Though the validity of the data in TDB is high, the retrieved information is at least two to five years old. For a multiplicity of regulatory, scientific, and related reasons, toxicology is at the present time a dynamic discipline in which data are being generated at an ever increasing rate. Therefore, the TDB user wants to refer to the primary literature even though the quality of the tertiary literature may be superior. Without data from the current literature, the user is not confident that information retrieved has not been superseded by significant recent findings. As a result, many users seldom rely on TDB alone in conducting an information search. Instead, they use TDB in conjunction with, and as a check on, other sources of data.

Recommendation: The tertiary literature should continue to be used as a source of TDB input, but the primary literature should be used more frequently and on a regular basis. Only original documents, and preferably peer-reviewed articles or reports should be cited whether from the primary or the tertiary literature. Also, review articles from peer-reviewed publications should be considered as data sources. Inclusion of documents such as the NIOSH Registry, which is a compilation of information on substances that cannot be evaluated and which contains references that are not widely available, should be avoided.

More emphasis needs to be placed on building the data file with primary references and current tertiary references than to updating the records only by reviewing new editions of tertiary sources. This is not meant to imply that data from an earlier edition of a handbook should not be replaced by data from a newer edition, but it should be given a lower priority than expanding the files with new information from current primary and tertiary literature.

To provide users with earlier access to information, preliminary data should be put online before they are fully evaluated. Such data could be flagged to indicate their preliminary status, and the flag removed after completion of evaluation.
B. PEER REVIEW PROCEDURES

The Toxicology Information Program Committee (TIPCOM) of the National Academy of Sciences monitored the planning and implementation of TDB. It recommended emphatically that the information provided to database users be evaluated or reviewed. As a consequence, data statements were to be extracted rather than abstracted, evaluated sources such as monographs or handbooks were to be used rather than the primary journal literature, and a consensus-based review mechanism was to be instituted for all data prior to their TDB input (Cosmides, 1982). These functions are performed by the Peer Review Committee (PRC), which consists of 12-14 scientists who have been or are members of the NIH Toxicology Study Section (National Library of Medicine, 1982). The PRC meets on a quarterly basis to review new records selected for possible inclusion in TDB, and to update old records (Futagaki, 1979; Haberman, 1981). The records are prepared in a special peer review format by the Oak Ridge National Laboratory staff before PRC meetings. NLM provides support staff to assist the PRC (Haberman, 1981; Wykes, 1981).

Assessment: The Panel considered the PRC functions to be of value because they increase the utility of TDB by providing the user with peer-reviewed data. Further, these activities contribute to the scope of data included and to quality assurance of the database. However, a redundancy in the information provided is an annoying feature of TDB. For some substances, much of the information is repeated as many as four or five times because it is gleaned from several sources, each of which contains similar data. Also, some concern was noted that most members of the TIPCOM and all of the members of the PRC come from the group constituting the least frequent users of TDB -- the academic community.

Recommendation: The PRC should be augmented to include experts from private industry (the group that uses TDB most frequently) and from state and federal government, who would share, with experts from academic institutions, the responsibility for selection of substances to be covered in TDB. Also, if TDB is to cover toxicology adequately, the scope of the PRC should be expanded by a judicious mix of experts on all of the major categories of toxicology, such as specialists in pharmacology, environmental/occupational exposure, chemical-physical properties of substances, industrial hygiene, poison control, human and veterinary medicine, mutagenicity, carcinogenicity, and teratogenicity. Aside from the permanent members of the PRC, who serve on staggered appointments to assure a constant influx of new blood, ad hoc members might be appointed to serve in an advisory capacity. Such individuals could be expected to serve for a limited time to perform specific tasks, including selection of candidate substances.
Several steps could be taken by the PRC to enhance TDB credibility and usage, and to further quality assurance. The repetition currently present in TDB information items could be eliminated by judicious consensus selections of the best data available. As a check for consistency and accuracy, the PRC should compare the tertiary data selected for TDB inclusion with current primary data.

C. REFERENCES AND BIBLIOGRAPHIES

In each TDB record, reference citations to the source of the data are given for every item of information, except the chemical-physical properties (Wykes, 1982). Data for chemical-physical properties are not referenced because usually they are obtained from standard handbooks, such as The Merck Index (1976) and the Handbook of Chemistry and Physics (Weast, 1981).

Assessment: The provision of citations to the original sources of data in TDB enhances the confidence of the user in the information, and affords an opportunity to consult the article or report from which the data were extracted. This applies to chemical-physical properties as well as the other categories of TDB information.

The references cited precede the information items in TDB. This is somewhat unusual because the accepted convention is to have references follow the value or other information for which they are provided. This is the format the majority of users expect and with which they are most comfortable.

Recommendation: References should be cited for all information items, including accepted physical and chemical properties of a substance. For the convenience of the user and to conform to the most common format, references should be placed after the values or other information to which they apply. References should be numbered within the body of a report. Then a complete list of references in numerical order could be printed out with the data for users who desire such a list. When users do not want a complete bibliography or references, they should be able to retrieve only as many references as needed. Another print-out variation could be the retrieval of references only, without the data.

D. REPORTING FLEXIBILITY

As presently constituted, the data elements in TDB are grouped in eight categories as follows: 1) Descriptive profile, 2) Excerpt terms, 3) Index strings, 4) Values, 5) Pharmacology/toxicology, 6) Environmental/occupational information, 7) Manufacturing data, and 8) Chemical-physical properties (TDB Condensed,
1981). Retrieval of data and printing of reports are formatted according to these unit records.

Assessment: The overwhelming trend among TDB users is to print out a complete record that may contain much information that is not wanted to obtain that which is needed. This is because the other print options are too complex and fragmented to learn and remember. Greater flexibility and simplification of the reporting options could provide TDB users with print-outs that more effectively meet their needs.

Recommendation: Users of TDB should be made aware of the variety of simplified reporting options available, such as printing out a short or condensed report, a modified report, a detailed report including the key words, or only part of a record, if preferred. In addition, the user should be able to have only those desired or all citations to references printed out in full. It would be helpful if field-name abbreviations or acronyms were more complete so users could identify them more readily.

TDB records should be re formatted to provide a more readable document so its value is enhanced as a source of information to the end-user. In its present form, additional instructions and interpretation must be supplied by an intermediary to the end-user to enable the latter to use a TDB record. For example, though the index strings can be useful for searching, they are useless in the final print-out, and if they could be suppressed in the retrieved report, legibility would be markedly improved.

A regrouping of unit records to produce a somewhat different selection of categories might permit easier searching and retrieval of data. Similarly, classification of the data elements within those categories as 1) essential for all records, 2) essential for a given record, or 3) useful but not mandatory, might provide another reporting option. Some data elements, such as name of substance, molecular formula, and Chemical Abstracts Service Registry Number might be labeled "essential" and would be included as required fields in each record print-out, whereas manufacturing information might be designated "useful but not mandatory" and would have to be called up by the user to determine what data were available. Such classification could serve also as a quality control function in that any substance accepted for TDB would be required to have all of the "essential" data elements.
VI. ADEQUACY OF SYSTEM PROCEDURES

A. SEARCHING PROCEDURES

The TDB search capabilities are based on the commands of ELHILL software. The data elements in TDB are grouped in eight categories with all elements, except the name and formula fragments, printable but not all directly searchable. For six of the eight categories of data elements, the user must search the entire category rather than the specific data element, but then has the option of printing either the entire category or a specific data element (National Library of Medicine, 1981).

Assessment: The UAP concluded that the elaborate TDB search procedures are time consuming, do not function to the satisfaction of the users, and too frequently require consulting the "User's Guide." Because of the absence of "user friendliness," it is often easier to go to the original sources from which the data were derived than to use the TDB search system. In part, this is related to the software itself, which was designed originally for bibliographic, rather than descriptive or numeric, data.

Recommendation: Alternate software packages, compatible with ELHILL, are available and should be explored in the course of evaluating methods of enhancing TDB usefulness. A simpler and less tedious search procedure, with fewer mnemonics for TDB categories and a compressed synonym format, might better serve TDB users. Better still, consistency in the commands and search procedures of all NLM databases would be of even greater assistance to the many users who find the variation in NLM information retrieval both time-consuming and complex.

B. TRAINING SESSIONS

The NLM offers a one-week training course designed to provide instruction in the use of all NLM databases. Specialized training in TDB has been available only during the advanced session which is not offered until after the basic session is completed.

Assessment: Many organizations cannot justify the time and cost of sending an employee to NLM for a second five-day advanced course to learn its entire panoply of databases when there is an interest in TDB only. Therefore, many TDB users are self-taught, or rely heavily on the "User's Guide."

Recommendation: The basic training session should include use of TDB. For those who do not require the basic session, separate training sessions for each of NLM's databases, including TDB, might be considered. As an alternative to sending prospective users to NLM for training sessions, organizations would be willing to pay
to have an instructor come to train their personnel and those from the surrounding area. Other options might include training sessions at regional medical libraries, or half-day or even full-day short courses in TDB use that could be offered at national meetings of representative scientific, information, and library associations.

C. SUPPLEMENTAL USER SERVICES

Certain customer services are provided to TDB users such as the "NLM Technical Bulletin" that contains information on the latest changes in the database, and a user response service to answer questions and assist in resolving problems.

Assessment: The "NLM Technical Bulletin" was not considered by the UAP as an adequate source of information about TDB changes and modifications. Also, the changes that are noted must be transferred by the user from the "Bulletin" to the "User's Guide" — a time-consuming process. Frequently, the "Guide" is being used by someone else when changes are noted and should be inserted. The result is that many changes are not included, and the "Guide" rapidly becomes out of date. As long as questions can be relayed by the user to someone knowledgeable at NLM and answers can be obtained promptly, there is no need for a formal TDB hotline. However, it would be convenient if an 800 number were available for users.

Recommendation: One-page sheets, devoted to TDB changes only, should be made available. Other customer services that should be considered are a news item online that not only indicates changes in the database but informs the user promptly of new data added to TDB, and a database information sheet that could be put in the "User's Guide" and would complement the TDB Pocket Card (1981).

A feedback system of online comments from users could keep NLM informed of changes suggested in TDB records for the purpose of better meeting user needs. Also, users could nominate, online, new substances that should be considered for inclusion in TDB. Such comments and suggestions would provide users with a convenient mechanism for communicating with NLM, which could then promptly consider and perhaps implement user suggestions.

The formation of several users' panels from among the various groups of TDB users countrywide could serve as another feedback mechanism if they were truly representative of the different end-users and intermediaries. Such feedback via computer conferencing or meetings could serve to keep NLM abreast of the constantly changing needs of the user community for toxicologic data.
VII. SYSTEM MANAGEMENT CAPABILITIES

A. MARKETING PROCEDURES

A well-conceived marketing program adds to the value of a data resource by making it available to those who require the information it has to offer. Such a program increases awareness of system availability and capability among potential users, increases communication between the organization making the data resource available and the users, increases communication among the users themselves, and identifies the user group in need of the data being offered.

Assessment: The NLM does not market TDB as well as it might because there is no clear picture of who the current users are and what they want. Though TDB was first marketed by NLM in 1978, its user community has been assessed only recently (TDB Task Force, 1982). Also, guidelines on marketing of databases, such as TDB, have not been provided by either TIPCOM or the NLM administration. The competition generated by the free enterprise system seems to motivate the private sector into formulating and using marketing procedures more effectively than does government.

Recommendation: It would be wise for NLM to emulate, within governmental restraints, those procedures used by database suppliers in the private sector whose objective is making a profit. If, for example, a data file is put on a commercial vendor's system, the language is simplified, the file is widely exposed and well publicized, and the file is well marketed. As a result, it is more extensively used than the same file offered by the public sector.

Too often the private sector takes from government that which is widely used, such as MEDLINE, while ignoring that which has a more limited use, such as TDB. Perhaps databases that have been developed together and are complementary, e.g., MEDLINE, TOXLINE, and TDB, should be marketed as a package.

The NLM should explore mechanisms for achieving an expanded marketing, or combined marketing/training, program that would make more prospective users aware of TDB and its capabilities. Such an effort should include better dissemination of online information, more convenient and current documentation for TDB use, and effective periodic newsletters featuring TDB.

Marketing surveys can be misleading as situations change between the time a survey is conducted and the implementation of a service or availability of a product. Therefore, TDB content and use should be reevaluated given the changes that have occurred over the past ten years.
B. COST EFFECTIVENESS

As operating budgets decline, in actuality or as a result of inflation, and online costs increase, decisions will have to be made by various user organizations on which databases are vital and which can be dropped. Thus, rising costs will create a shift in usage to those databases that are, or are perceived to be, the most efficient and cost-effective information sources.

Assessment: The UAP agreed that TDB is relatively inexpensive in terms of access cost per hour and is generally cost-effective. If necessary, databases such as TDB that contain evaluated and summarized information may be able to justify a higher charge per unit of connect time as some of the work has been done for the user already. However, justification for increased charges will require sustained attention to maintenance of quality assurance and persistence in bringing this to the attention of users.

The consequence of increased costs for TDB usage should be weighed against the decreased use of the system, and the subsequent tendency of users to consult more frequently the tertiary source documents directly. Economic pressures eventually may dictate consolidation of related databases, such as TDB and RTECS, despite their obvious differences in software, coverage, and evaluation.

Recommendation: Increased costs for online use of databases will have the greatest impact on institutions of higher learning, with somewhat less impact on industry and government. Therefore, it may be feasible to consider a different scale of charges for universities and colleges, i.e., an educational rate, than the one applied to industry and government.

C. TDB MODIFICATION

There are databases other than TDB containing toxicologic data that have been or are being developed under different mandates. These include the Registry of Toxic Effects of Chemical Substances (RTECS); Chemical Evaluation Search and Retrieval System (CESARS); Chemicals Identified in Human Biological Media (CIHBM); Scientific Parameters in Health and the Environment, Retrieval and Estimation (SPHERE); International Registry of Potentially Toxic Chemicals (IRPTC); Aquatic Toxicity Search System (AQUATOX); and Clinical Toxicity of Commercial Products (CTCP). The Oil and Hazardous Materials Technical Assistance Data System (OHMTADS) is used as a source of toxicologic data of particular interest in handling emergency spills of hazardous substances. However, the UAP members agreed that from their experience, which is consistent with recently collected data on use patterns, the most useful of all
databases that contain some toxicologic information are TOXLINE, MEDLINE, CAS, BIOSIS, EMBASE, and IRL Life Sciences (TDB Task Force, 1982). (See Appendix, Abbreviations and Acronyms.)

Assessment: In terms of the total number of substances covered, TDB lacks certain attributes desired by users that are available in other databases dedicated to toxicology. Also, the UAP perceives TDB as deficient in terms of the number of substances covered when compared to RTECS, and of the level of detail when compared to CESARS which recently became available. As a result of these perceptions of its in-between status, TDB does not seem to meet the needs of any particular user group totally. Therefore, its principal use seems to be as a cross-check or double-check when an in-depth search is performed, or as a guide to sources of additional information or references. It is used as a means of saving time to get at other information, but not as an end source.

Recommendation: It is important that NLM determine the audience for which TDB is intended, and then clearly define what TDB will include as a data file. Such action should eliminate the fuzziness related to the objectives and intended users of TDB.

There is no single readily accessible database or data source that duplicates TDB, but all of the data in TDB are available from other sources, though not on computer. Therefore, NLM must find a means of making TDB more attractive and appealing to users of toxicologic data. One approach might be for TDB to provide neatly-packaged, easy-to-use summary or review level data that are unavailable in such a format from other sources. Another possibility for TDB restructuring was considered by the UAP when it noted that one-third to one-half of a typical TDB record consists of chemical-physical properties, laboratory methods, manufacturing information, and synonyms, whereas the other half to two-thirds is toxicology data. Therefore, it might be feasible to separate the toxicology data from the rest of the information to serve as a core database from which specialized databases, covering areas such as mutagenicity, teratogenicity, and reproduction, could be developed. Thus, a multiplicity of networking mini-systems could be established with TDB at the core.

D. TDB AS A SYSTEM MODULE

There are advantages to having TDB remain a distinct data and information resource of, and easily accessible through, the NLM system. However, if TDB were to become a module of CIS or another interactive searching system outside NLM that links different databases, it could provide users with the added interfacing capability that permits transferring from one system component or database to another.
Assessment: A good example of a database that can be accessed through the NLM system and through CIS is RTECS. Though RTECS is essentially the same within both systems, the software is different, and therefore, it can be manipulated differently. The flexibility that results from having the same database available through two separate systems is beneficial to the user.

In addition to the CIS linking system, a networking system, the Chemical Substances Information Network (CSIN), is being developed for the purpose of enhancing the intragovernmental exchange of data. The Panel is aware that TDB is available currently via CSIN which is being evaluated by a selected initial user group. Toxicology and other databases could become accessible through the CSIN switching technology (distributed database management), without compromising the individual integrity of each database. Thus, similar data developed by different groups could be networked for the benefit of the user.

Recommendation: The NLM may wish to consider the possibility of TDB becoming a module of a linking system, such as CIS, while at the same time remaining a distinct data resource of NLM. As a system module, TDB might be utilized more efficiently, but by a much smaller user group. It is quite possible that TDB may be software-compatible with CIS because the former is a numeric database and the latter is a similarly numeric-data oriented system. The commercial software of some private vendors may also be compatible with TDB, but as part of a commercially available system, the online charges for TDB undoubtedly would be greatly increased. However, this might be balanced by an increased demand for TDB within a much larger user community, as has been the case, for example, since MEDLINE was made available on DIALOG®.

The UAP concluded that ultimately TDB and all other data banks containing toxicologic data should be accessible through a linking system other than MEDLARS, such as CIS, or an interconnected networking system such as CSIN, and through commercial data systems.
VIII. GENERAL CONCLUSIONS

The User Assessment Panel considered several issues that pertain to databases in general. It was agreed that the Federal Government has a role in identifying the need for a database, performing a feasibility study and requirements analysis to confirm the need, and if the need is confirmed, creating a database model (Altman and Fisher, 1981). Unfortunately, as the government attempts to meet the requirements of multiple prospective user groups, the resultant database frequently does not meet any one group's requirements fully, but does meet the requirements of all groups in part. As a result, a database often will not meet the potential indicated in a feasibility study.

As mandates are provided to government agencies for the creation of databases, each agency attempts to make its data banks as complete as possible in fulfillment of its mandate. The UAP concluded that the result is too many small databases with frequent information overlaps and with available services that are not cost-effective. There is a continuing need for a higher level of cooperative effort among agencies that are developing databases containing information on the physical, chemical, and biological properties of chemical substances. A more consistent policy with regard to newly created databases could help to alleviate the problem and develop data banks that could become part of an effective networking system. The U.S. Government has taken some steps recently to foster greater cooperation among its agencies. One such effort is the jointly sponsored study by NLM and EPA of its TDB and CIS databases, respectively, as addressed in this report for NLM on TDB and the similar report on CIS prepared for EPA.

Experience has indicated that the software available for searching an online data file maintained by a private vendor usually interfaces more successfully with the user than the same file available from a government agency. Therefore, it may be logical to have the private sector offer databases created and updated by government agencies even when they are available from the public sector. However, both sectors have a role to play in meeting the needs of users for information resources, products, and services. Whereas government should provide the leadership required for the development and fostering of information services, the private sector should assume responsibility for the management, maintenance, and enhancement of the information resources. As a general guideline, pricing policy for databases created with public funds should not be set to recover development costs but only to recover the costs of accessing the data bank and retrieving the data.

These general conclusions of the UAP are in agreement with a far more detailed set of recommendations of an independent task force assembled and funded by the National Commission on Libraries and Information Science (Public Sector/Private Sector Task Force, 1982).
The recommendations outlined in this report with respect to TDB should be considered in terms of practicality, costs of implementation, and possible alternatives by NLM. These recommendations are based on the observations and opinions of the UAP members in their work experiences with TDB, and represent a consensus of the group.
IX. ANNOTATED BIBLIOGRAPHY


List provides TDB number, Chemical Abstracts Service registry number, and the name of the substance in alphabetical order.


Provides general concepts related to building and maintaining a data bank in terms of establishment of the need for a data bank, identification of developmental procedures, identification of data elements and descriptors, development of data acceptance criteria, acquisition of data, development and refinement of user interactive processes, and identification of performance evaluation procedures.


List provides TDB number, Chemical Abstracts Service registry number, and the name of the substance in CAS registry number order.

Cosmides, G.J. 1982. TIPCOM, history of recommendations re. TDB activities. Memorandum, dated February 1, from Deputy Associate Director of Specialized Information Services, National Library of Medicine to K.D. Fisher, Director, Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD.

Excerpts of reports and recommendations by the Toxicology Information Program Committee regarding TDB from 1973 through 1981, a background statement on TIPCOM and its relationship to the Toxicology Information Program of the National Library of Medicine, and a roster of the current members of TIPCOM.

Description of the potential usefulness of TDB as an information source for the clinical toxicologist and a listing of the data elements for each chemical on record.


Explanation of the priority system that PRC members are to use in grading candidate compounds for data extraction, and a set of code definitions to indicate origin of compounds including samples of how the code is to be applied.


Short statement describing the new TDB feature that permits the user to identify updated or revised records, as well as other modifications and refinements designed to improve the system.


Documentation of PRC No. 16 activities, especially related to revision procedures, and a roster of the PRC members at the time of the meeting held in San Francisco, August 23-24, 1980.

Haberman, C.B. 1981. Peer Review Committee Meeting No. 17. Memorandum, dated February 23, from TDB Peer Review Committee Coordinator.

Highlights of the PRC No. 17 discussions, a list of the PRC members at the time, a letter from TDB-PRC Chairman R.E. Menzer to H.M. Kissman outlining agenda discussion items, and agenda for the meeting of the PRC held at the National Library of Medicine, Bethesda, MD, December 9-11, 1980.

Summary of records reviewed, TOXLINE searches, new literature sources, new compounds, revision of records, and data element changes; attachments include a review of potential literature sources for the TDB, letter from P.-Y. Lu to A.A. Wykes regarding new candidates for TDB records, memorandum on TDB/ORNIL activities discussed in San Diego, memorandum on training (in use of TOXLINE, RTECS, and TDB) for the TDB Peer Review Committee Members, and a roster of PRC No. 18 members at the time of the meeting held in San Diego, March 5-7, 1981.


Short summary of PRC No. 19 Meeting held in St. Louis, MO, June 4-6, 1981; attachments include a memorandum from A.A. Wykes to C.B. Haberman, dated June 25, 1981, on Report on Preferences Expressed by PRC No. 19 members regarding the Identification, Selection, and Prioritization of New Chemicals for the TDB, and the Adoption of New TDB Literature Sources, as well as a list of PRC No. 19 members.


Summary of PRC No. 20 meeting, held at the National Library of Medicine, September 14-16, 1981, and list of PRC members at the time of the meeting.


Review of CIS responsiveness in meeting needs of the user community for an interactive searching system that links different databases.


Alphabetic listing of nearly 10,000 chemicals, drugs, pesticides, and biologically active substances; information provided for each substance covers physical, toxicity, and chemical data, as well as therapeutic category.

Provides information on the TDB unit record (searchable data elements), descriptive (identifying) profile, excerpt terms, index strings, values, pharmacology/toxicology data, environmental information, manufacturing data, chemical-physical properties, substance status, and sample TDB searches.


Short statement on the purposes and functions of the TDB Peer Review Committee, and a list of the current members of the PRC.


Description of TDB at the time of its development projecting online access to chemical, physical, toxicologic, pharmacologic use, and manufacturing data on 4000-5000 selected chemicals including drugs.


Consideration of the practicality of producing pamphlet-like publications (mini-monographs) from individual chemical records of TDB. Sample of TDB Record for Diethylstilbestrol generated by using the NIH computer facility to edit and reformat TDB records.


Review of interactions between the public and private sectors with respect to generation and dissemination of information of all types; report covers historical background, information in the economy and in society, the players and their roles, interactions among the sectors, and current policy statements; "principles" are presented as fundamental guides to policy in the Federal Government with respect to distribution of information products and services; recommendations are proposed for implementing the principles.

Single sheet describing the eight categories of data elements that are fully described in the TDB User's Guide.


Handy condensed pocket version of the TDB User's Guide.


Revised and edited report of January 25, 1982, designed to evaluate and quantify the utility of TDB in satisfying the information demands of the biomedical community; provides information on who is using TDB, how the system is being searched, why it is being used, and how well it meets user needs; problems that limit TDB's usefulness are noted, as well as general comments about TDB usage and suggestions for improving the system.


Classic data book of mathematical tables, tables of inorganic and organic compounds, general chemical tables, tables of general physical constants, and miscellaneous tables of chemical and physical data.

Wykes, A.A. 1981. The ranking of recommended sources of future candidate TDB chemicals by PRC No. 19. Memorandum, dated June 25, to TDB Coordinator, National Library of Medicine, Bethesda, MD.

Ranking by PRC No. 19 of sources of hazardous and high production volume chemicals from which candidate TDB chemicals may be selected.

Wykes, A.A. 1981. Literature sources for the TDB. Memorandum, dated September 10, to PRC No. 20 members, National Library of Medicine, Bethesda, MD.

A list of candidate TDB literature sources for PRC No. 20 consideration.
Wykes, A.A. 1982. Present and proposed procedures/criteria for the selection and elimination of literature sources utilized for TDB data extraction. Memorandum, dated February 3, to TDB Task Force Members, National Library of Medicine, Bethesda, MD.

Summary of the basic criteria for the selection of TDB literature sources and the elimination of literature sources from the TDB Literature Source List, and some proposals for improving the selection and scope of TDB literature sources; attachments include a flow chart of the TDB Literature Source Selection Process, a list of References in Current Use (as of December 1981), and a Literature Source List used to prepare TDB records (as of December 1981).
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APPENDIX

Abbreviations and Acronyms

Abbreviations and acronyms used in this report are defined in the following list. If the name or title of a database or system does not indicate the source, it is shown in parentheses.

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<th>Abbreviation</th>
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<tr>
<td>AMS</td>
<td>American Management Systems</td>
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