



CHEMICAL MANUFACTURERS ASSOCIATION

OCT 21 1996

October 18, 1996

Dear Vinyl Chloride Health Committee Members:

Enclosed you will find additional information from Caffey Norman on CalEPA's Proposition 65 activities that are relevant to vinyl chloride. These materials describe a public workshop scheduled for November 15, 1996 to receive comments on the procedures for prioritizing candidate chemicals for consideration under Proposition 65. The two committees of CalEPA's Science Advisory Board known as the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee serve as the State's qualified experts for rendering an opinion as to whether a chemical is known to the State to cause cancer or developmental and reproductive toxic effects.

The materials previously describe a meeting of the DART Identification Committee scheduled for December 4, 1996 to determine whether the data summary for vinyl chloride clearly demonstrates that vinyl chloride is a developmental/reproductive toxicant; written comments are due no later than November 20, 1996.

If you have any questions on these activities, please call me at 703/741-5639.

Sincerely,

Robert A. Venezia, Dr. P.H.
Manager
Vinyl Chloride Health Committee

Enclosures



**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)**

NOTICE TO INTERESTED PARTIES
October 4, 1996

**Availability of Revised Draft Procedure for Prioritizing Candidate Chemicals for
Consideration Under Proposition 65 by the "State's Qualified Experts", and
60-day Public Comment Period on the Draft Prioritization Procedure**

**November 15, 1996, Public Workshop on
Refinement of the Prioritization Procedure**

**November 15, 1996, Public Forum to Receive Comments on the Draft Prioritized
Candidate Chemicals Under Consideration for Carcinogenicity Evaluation and
Reproductive Toxicity Evaluation and Draft Data Summaries, and
60-day Public Comment Period on Draft Prioritized Chemicals and
Draft Data Summaries**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHLA), as lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), has developed a procedure for prioritizing candidate chemicals for consideration under Proposition 65 by the "State's qualified experts". Two committees of the Science Advisory Board (SAB), known as the Carcinogen Identification Committee, and the Developmental and Reproductive Toxicant (DART) Identification Committee, serve as the State's qualified experts for rendering an opinion as to whether a chemical is known to the State to cause cancer or developmental and reproductive toxic effects.

As part of the development of the prioritization process, comment has been solicited from the public and the two SAB committees, during a workshop (December 1994), public comment periods (Fall 1994, Winter 1994, Spring 1995, Summer 1996), and SAB committee meetings (March 1994; May 1995, July 1996). The October 1996 draft of OEHLA's prioritization proposal, entitled *Procedure for Prioritizing Candidate Chemicals for Consideration Under Proposition 65 by the "State's Qualified Experts"*, reflects comments received thus far and identifies options for further refinement of the procedure. A workshop to present this draft procedure and provide further opportunity for public comment is scheduled to be held on Friday, November 15, 1996 at 400 P Street, Rooms 1160 and 1170, Sacramento, California, from 10:00 a.m. until all business has been conducted or until 5:00 p.m. The members of the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee will be invited to attend.

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This workshop will also serve as a public forum to receive comments on the May 1996 prioritized chemicals for carcinogenicity consideration, and on specific chemicals prioritized on the basis of reproductive toxicity concern. Verbal and written comments submitted during the previous public comment period for chemicals prioritized on the basis of carcinogenicity concern will be considered and need not be resubmitted. Three chemicals from the May 1996 group [5-chloro-*ortho*-toluidine and its hydrochloride (CASRN: 95-79-4), quinoline (CASRN: 91-22-5), and 2,4,5-trimethylaniline and its hydrochloride (CASRN: 137-17-7)] are the subject of a separate request for information, published elsewhere in today's register. These chemicals therefore are not on the agenda for public comment at the November 15, 1996 public forum.

Chemicals prioritized on the basis of carcinogenicity concern are:

CHEMICAL	CASRN
Acetaminophen (paracetamol)	103-90-2
Acetoxime	127-06-0
Acrolein	107-02-8
Benzyl acetate	140-1104
Butyl benzyl phthalate	85-68-7
Carbaryl	63-25-2
Chloramben	133-90-4
Chloroacetaldehyde	107-20-0
Chlorofluoromethane (fluorocarbon 31)	593-70-4
C.I. Disperse Yellow 3	2832-40-8
Clomiphene and its salts	911-45-5
Coumarin	91-64-5
Decabromobiphenyl oxide	1163-19-5
2,6-Dichloro- <i>p</i> -phenylenediamine	609-20-1
Ethyl parathion	56-38-2
Eugenol	97-53-0
Hydralazine and its hydrochloride	86-54-4 and 204-20-1
Hydroquinone	123-31-9
Isophorone	78-59-1
Mercuric chloride	7487-94-7
Naphthalene	91-20-3
Nitrofurantoin	67-20-9
5-Nitro- <i>ortho</i> -toluidine	99-55-8
2-Nitro- <i>p</i> -phenylenediamine	5307-14-2
Ozone	10028-15-6
Pentachloroanisole (pentachloromethoxybenzene)	1825-21-4
Propyl gallate	121-79-9
Semicarbazide hydrochloride	563-41-7
Trifluralin	1582-09-8
Vinyl acetate	108-05-4

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Chemicals prioritized on the basis of reproductive toxicity concern are:

CHEMICAL	CASRN
Acrylamide	79-06-1
Aldrin	309-00-2
1,3-butadiene	106-99-0
Carbamazepine	298-46-4
Carbon tetrachloride	56-23-5
Chlordane	57-74-9
DDT	50-29-3
Ethylene dibromide	106-93-4
Formaldehyde	50-00-0
Heptachlor	76-44-8
Methylene chloride	75-09-2
Progesterone	57-83-0
2,4,5-T butyl ester	93-79-8
Trichloroethylene	79-01-6
Vinyl chloride	75-01-4

CASRN = Chemical Abstracts Service Registration Number

In the interest of assuring that time is provided for the discussion of both subjects (the prioritization procedure and the prioritized chemicals) the November 15, 1996 session will be divided into two segments. During the first part of the session, a brief summary of the October 1996 draft procedure will be presented, followed by the opportunity for comments, questions, and dialogue among the participants. During the second part of the session, which OEHHA anticipates will begin at 1:00 p.m., a brief staff presentation on the prioritized chemicals for carcinogenicity and reproductive toxicity consideration will be presented, followed by the opportunity for comments, questions, and dialogue among the participants. Dependent upon the participants' interest, after the public discussion on the prioritized chemicals, additional time will be provided to further discuss refinement of the prioritization procedure, as needed.

OEHHA is committed to public participation and external scientific peer review in its implementation of Proposition 65, and welcomes public input on the prioritization procedure. The publication of this notice marks the start of a 60-day public comment period on the October 1996 draft prioritization procedure.

This procedure, as well as lists of prioritized chemicals and draft data summaries are available from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the Internet at the following address: <http://www.calepa.ca.gov/net.gov/oehha/>. Other materials available from the Proposition 65 Implementation Office include comments received on these chemicals during an earlier public comment period which closed on July 15, 1996.

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Written comments may be sent by mail or fax to:

Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 942732
Sacramento, CA 94234-7320
FAX (916) 327-1097

Written comments may be delivered in person or by courier to:

Cynthia Oshita
Office of Environmental Health Hazard Assessment
601 North Seventh Street
Sacramento, California

In order to be considered, comments must be postmarked (if sent by mail) or received at
OEHHA (if delivered in person or sent by fax) by 5 p.m. Wednesday, December 4, 1996.

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**DRAFT PRIORITIZED CANDIDATE CHEMICALS UNDER CONSIDERATION
FOR DEVELOPMENTAL/REPRODUCTIVE TOXICITY EVALUATION**

Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

October 4, 1996

Chemicals are prioritized for consideration by the Developmental and Reproductive Toxicant (DART) Identification Committee of OEHHA's Science Advisory Board by the process described in the draft document entitled "Procedure for Prioritizing Candidate Chemicals for Consideration Under Proposition 65 by the State's Qualified Experts". The process involves selecting from agents proposed for evaluation by the DART Identification Committee and evaluating the potential levels of developmental/reproductive toxicity concern through review of information available from secondary sources. Secondary sources consulted include: databases such as Reprotox™, Reprotox®, Shepard's Catalog of Teratogenic Agents and RTECS®; publications by bodies such as USEPA, ATSDR, IPCS; and standard texts such as *Reproductive Hazards Of Industrial Chemicals*, and *Chemically Induced Birth Defects*. Data summaries, which provide an overview of the available data identified, were prepared for each of these chemicals, and each chemical was given a draft level of developmental/reproductive toxicological concern as a result of this initial evaluation. The particular set of agents evaluated below were previously identified as high priority candidates for evaluation through a earlier prioritization process, and so have been used as the initial candidates for evaluation under the present process.

It should be noted that (1) this prioritization process reflects a preliminary, rather than an in-depth review of developmental/reproductive toxicity and exposure data and (2) the process is continuous; e.g., candidate agents continue to be identified, and review of available information appropriate to each step in the process is ongoing for chemicals in the prioritization tracking data base. This process will result in the further prioritization of agents, including production of data summaries on additional chemicals and periodic updates of priorities.

Further consideration of two chemicals, carbamazepine and progesterone, has been postponed pending further investigation of their potential status with regard to listing through an administrative mechanism. If it is determined that these agents are not appropriate candidates for such action, they will resume their status as candidates for consideration by the DART Identification Committee.

Name of Chemical and Level of Developmental/Reproductive Toxicity Concern	Level of Exposure Concern	Page
HIGH Developmental/Reproductive Toxicity Concern		
acrylamide	medium	3
DDT (1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane)	medium	9
MEDIUM-HIGH Developmental/Reproductive Toxicity Concern		
formaldehyde	high	20
trichloroethylene	high	25
chlordane	low	30
ethylene dibromide	low	38
heptachlor	low	42
MEDIUM Developmental/Reproductive Toxicity Concern		
butadiene, 1,3-	medium	46
carbon tetrachloride	medium	49
vinyl chloride	medium	56
aldrin	low	60
LOW Developmental/Reproductive Toxicity Concern		
2,4,5-t butyl ester	low	66
methylene chloride	high	68
Postponed	Status	
carbamazepine ^{a,b}	Clarification of labeling requirement and possible determination of developmental/reproductive toxicity requested from US FDA on 10/4/96	72
progesterone ^{a,b}	Clarification of labeling requirement and possible determination of developmental/reproductive toxicity requested from US FDA on 10/4/96	79

Subject to control by the US Food and Drug Administration. Other things being equal, there is less public health benefit listing under Proposition 65 such chemicals which are already subject to stringent controls compared to chemicals for which no such restrictions exist.

^a Potential listing via authoritative bodies provision (22 CCR § 12306)

^b Potential listing via formally required to be labeled or identified provision (22 CCR § 12902)

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**PROCEDURE FOR PRIORITIZING CANDIDATE CHEMICALS
FOR CONSIDERATION UNDER PROPOSITION 65
BY THE "STATE'S QUALIFIED EXPERTS"**

Reproductive and Cancer Hazard Assessment Section
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
October 1996

Introduction

The Safe Drinking Water and Toxic Enforcement Act (Proposition 65, California Health and Safety Code 25249.5 *et seq.*) requires the Governor to publish lists of chemicals known to cause cancer and reproductive toxicity. One of the mechanisms by which a chemical is placed on this list is a finding by the "state's qualified experts" that a chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity. As lead agency for the implementation of Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) has formed two committees within its Science Advisory Board (SAB) to serve as the state's qualified experts. These committees, which are independent panels of scientists and health professionals, are the Developmental and Reproductive Toxicant (DART) Identification Committee and the Carcinogen Identification Committee (CIC).

The purpose of this document is to describe the procedure used by OEHHA to identify, prioritize, and select candidate chemicals for consideration by the SAB Identification Committees, and to lay out potential process refinements. OEHHA welcomes public participation and public input, and is seeking comment on these issues. In particular, OEHHA asks those submitting comment to include their views on the potential process refinements noted below.

The prioritization procedure is designed to ensure that the efforts of the SAB are focused on chemicals of concern to the state of California, and that these chemicals are selected in an open, objective and predictable manner. Prioritization also ensures that chemicals posing the highest level of carcinogenic, reproductive or developmental hazard concern are addressed first. Key elements of the process include: (1) a database to track chemicals suggested for consideration, (2) development of draft data summaries which contain information on potential human exposure, and assignment by OEHHA of draft priorities based on a preliminary evaluation of the developmental/reproductive or carcinogenic level of concern (high, medium high, medium, or low), (3) public review of draft priorities and data summaries, (4) review of comments received and assignment of final priorities, and (5) selection of high priority chemicals for preparation of comprehensive hazard identification documents, to be used by the Committee in its subsequent deliberations. Opportunity is provided for input and review by state agencies

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and departments, individual SAB Identification Committee members, the Committees as a whole if they so choose, the scientific community, and other interested parties.

Evolution of the Prioritization Process

Prioritization was discussed by the DART Identification Committee at its October 25, 1993 meeting and by the CIC at its March 1, 1994 meeting. A draft version of this document was discussed at a public workshop held on December 14, 1994. Based upon comments received, the prioritization document was revised and presented on May 11, 1995 at the CIC meeting, and on May 12, 1995 at the DART Identification Committee meeting. Comments from the public and the members of the CIC and the DART Identification Committee were considered in the preparation of a revised draft, dated May, 1996. That draft was presented on July 22, 1996 at the CIC meeting. Comments received at that meeting were considered in the preparation of this prioritization process document. This document describes the process, potential refinements to the process, and how the process would work if those refinements were to be incorporated.

Starting Point--The Process as Described in the May 1996 Draft

In the May 1996 draft, the tracking database was organized into tiers. Tier I included all chemicals nominated or otherwise identified. Tier II was to contain all chemicals which appeared to have data sufficient to begin prioritization based on the initial screening. The procedure for selecting chemicals for hazard identification by the appropriate SAB Identification Committee included the following steps:

- Progression of Tier II chemicals to the draft priority list, following the completion of a draft data summary and assignment of a draft priority
- Public comment on the draft data summaries and the draft priority list solicited during a 60-day comment period
- Assignment of final priorities by the Committee at a public meeting, in concurrence with the Director of OEHHHA
- At the same public meeting, Committee selection of chemicals from the final priority list for preparation of synopses
- Public comment on synopses solicited during a 60-day comment period
- Committee review of synopses and selection of chemicals for hazard identification at a public Committee meeting

Potential Refinements Based on Comments from the Carcinogen Identification Committee and the Public

A variety of comments were provided by the Carcinogen Identification Committee and the public at the Committee's July 22, 1996 meeting. In brief, the Committee suggested that its role in general be limited to the final determination as to whether a chemical has been clearly shown to cause cancer. Earlier screening steps, although recognized as necessary, were

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considered by the Committee to be within OEHHA's purview. The Committee also suggested that the process as a whole be expedited, while retaining adequate opportunity for public comment. The Committee expressed interest in developing terminology that would avoid giving unwarranted negative connotations to chemicals found to be of lesser concern. Finally, the Committee indicated that it would benefit from having the public comments on the hazard identification document available for review prior to its consideration of a chemical.

Based on these and other comments received, OEHHA has identified several potential refinements to the process:

OEHHA Selects Candidate Chemicals

Members of the CIC indicated that OEHHA, rather than the Committee, should be responsible for prioritizing candidates for consideration under Proposition 65. In particular, the members of the CIC asked that OEHHA assign final priorities and select chemicals for hazard identification. In response to this comment the process could be refined such that OEHHA will perform all prioritization steps up to and including the selection of chemicals for preparation of hazard identification documents. OEHHA would assign draft priorities, then, following public comment and a public workshop, assign final priorities. SAB members would be free to provide comment as individuals or as a Committee if they so choose. As described more completely below, chemicals selected for preparation of hazard identification documents would be those with a high level of carcinogenic, reproductive, or developmental hazard concern.

Use "Tiered" Evaluation Process

The Committee also expressed interest in expediting the overall process. In response to this comment, OEHHA could refine the process by tailoring the level of analysis employed during the course of assigning final priorities. Under this approach, a "synopsis" step would not be required for every chemical. Instead, when warranted an issue-specific supplemental analysis would be performed as part of the assignment of draft priorities. Preparation of a data summary may provide sufficient information for many chemicals, while for others, additional analysis supplemental to the data summary may be necessary to resolve particular scientific issues prior to the assignment of a final priority. For example, a supplemental analysis may be beneficial by providing a focused evaluation of a key toxicological issue germane to a specific chemical, such as the design of a critical study, apparent inconsistency in results in a given species, or by providing additional chemical-specific information regarding mode of action, or apparent route or species specific toxicity, or with respect to the relationship, if any, of developmental toxicity and maternal toxicity. Public comment is invited as to the criteria for undertaking a supplemental analysis.

Organization of the Database

The tracking database identifies the status of chemicals in the prioritization process. In the May 1996 draft, the tracking database was described as a series of tiers. Tier I included all

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chemicals nominated or otherwise identified. Tier II contained all chemicals which appeared to have data sufficient to begin prioritization based on the initial screening. Chemicals then were selected from Tier II for the preparation of data summaries and the assignment of draft priorities, and prioritized chemicals were placed on a Priority List.

As OEHHA has gained experience in implementing the process, it has learned that from a work flow standpoint the determination of whether adequate data exists (needed to move from Tier I to Tier II) is closely linked to the development of a draft data summary (needed for prioritization). It thus is more efficient to perform both steps at once.

In response, OEHHA is considering changes to the terminology and organization of the tracking database. Under the proposed refinement, the database is organized into three mutually exclusive groups. Category I includes all chemicals nominated or otherwise identified for entry into the tracking database, which have not been assigned a final priority status. Category II includes those chemicals in the tracking database which have been assigned a final priority status other than high. The Candidate List would be composed of chemicals with a final priority status of high level of carcinogenic, reproductive or developmental hazard concern. If data are inadequate, the priority status for the chemical is "inadequate data".

Recognizing the ongoing nature of the prioritization process, assigned priorities may change as new scientifically valid toxicological information showing cancer, reproductive or developmental effects becomes available. In such circumstances, notice would be provided regarding a proposal to revise the prioritization, and opportunity would be provided for public input.

Focus Initial Work on Chemicals with "High" Hazard Level of Concern

As noted above, in the May 1996 process, all prioritized chemicals were placed on a "priority list", from which chemicals were to be selected for further consideration. Public comment was received noting that referring to a chemical as "priority", even if found to have a low level of hazard concern, gave rise to unwarranted negative connotations. The CIC then expressed interest in developing alternative terminology.

In response, OEHHA is considering eliminating the term "priority list". Instead, as noted above, prioritized chemicals with a final high level of carcinogenic, reproductive or developmental hazard concern would be assigned to a Candidate List, from which chemicals would be chosen for the preparation of a hazard identification document. All other final prioritized chemicals would be assigned to Category II. Chemicals with a high level of hazard concern would be brought before their respective Committee. Action would not be anticipated on Category II chemicals until the Candidate List consisting of high priority chemicals is exhausted. At that point, with Committee and public input, OEHHA would refine the existing process in order to determine which of the Category II prioritized chemicals should be brought forward for consideration by the CIC and the DART Identification Committee.

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This approach would ensure that chemicals posing the highest level of hazard concern are addressed first. Taking into account the number of chemicals to be evaluated, OEHHA's goal is to complete the prioritization of roughly 520 candidates for carcinogen consideration and 280 DART candidates within three years.

OEHHA Provide Committee with Public Comments on Hazard Identification Documents

Previously, hazard identification documents were reviewed and considered at public Committee meetings held at or shortly after the close of the 60-day public comment period for those documents. At the July 22 meeting, the CIC emphasized that its members need adequate time to review hazard identification documents and the public comments received on those documents. In response, OEHHA is considering having the 60-day public comment period on a hazard identification document close three to four weeks in advance of a Committee meeting. OEHHA then would organize and index the public comments received and provide the Committee with this information at least two weeks in advance of the meeting at which the candidate chemical is to be considered.

Summary of Process, Incorporating Potential Refinements

To assist in visualizing how the various potential refinements would work, the complete process, incorporating all of the potential refinements, is outlined briefly below and described in more detail in Appendix I. Figure 1 provides a flowchart of the process. [Note: If you downloaded this document from the OEHHA web site, due to formatting problems, Figure 1 is not available electronically. Please contact OEHHA at (916) 445-6900 to receive a hard copy.] If all of the potential refinements were adopted, the complete procedure for selecting chemicals for hazard identification would include the following sequential steps:

- Unbiased random selection of chemicals from Category I for preparation of the draft data summary
- Development of the draft data summary, followed by assignment of a draft priority
- Identification by OEHHA of any chemicals for which there is a key toxicological issue which requires a focused supplemental analysis, beyond a data summary.
- Solicitation of public comment on draft data summaries and draft priorities during a 60-day comment period, and solicitation of additional information on chemicals identified as requiring a focused supplemental analysis. Opportunity for verbal, as well as written comments will be provided by a public workshop held during the 60-day period.
- For those chemicals for which no focused supplemental analysis was found to be needed:
Following review and consideration of public comments received, OEHHA will assign the final prioritized chemicals to Category II or the Candidate List. If public comment identifies a key toxicological issue, such that a supplemental analysis is necessary before a final priority can be assigned, OEHHA will identify the issue and solicit additional information as described in the previous step.
- For those chemicals for which a focused supplemental analysis was needed:

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Solicitation of public comment on the supplemental analysis during a 60-day comment period. Opportunity for verbal as well as written comment will be provided by a public workshop held during the 60-day period. Following review and consideration of public comments received, OEHHA will assign the final prioritized chemicals to Category II or the Candidate List.

- Selection by OEHHA of chemicals from the Candidate List for hazard identification.

Under exceptional circumstances, the process described in this document may be abbreviated to allow OEHHA to respond to specific public health needs. Following consultation with the Committee Chair, the Director of OEHHA may request that a chemical be placed on the agenda of the next scheduled meeting. In all cases, the chemical would be noticed in the California Regulatory Notice Register and minimum notification periods would be followed.

Implementation Considerations

Startup and Transition

The tracking database includes all nominated chemicals. These chemicals have been suggested by state agencies and other sources or obtained from literature searches. Over 520 potential candidate carcinogens have been entered into the tracking database and over 280 chemicals have been identified as potential candidate developmental or reproductive toxicants (DARTs).

Originally, in implementing the prioritization procedure, for carcinogens OEHHA has first considered chemicals previously selected by the Carcinogen Identification Committee and other candidate chemicals with readily available toxicological data. For DARTs, OEHHA proposed to consider the previously identified candidate DARTs prior to considering new candidate DARTs in the following order: 1) all chemicals in the top five ranks of the Donald *et al.* list and all chemicals identified through the Delphi process; 2) chemicals in the remaining ranks of the Donald *et al.* list; 3) all chemicals published in the California Regulatory Notice Register as candidates, chemicals formally nominated by other state agencies, and chemicals identified by the SAP Reproductive Toxicity Subpanel (the predecessor to the current DART Identification Committee).

Now, OEHHA is considering moving to the unbiased random selection process noted above. For DARTs, OEHHA would move to random selection following the completion of evaluation of two groups of chemicals identified by means of the Donald *et al.* and the OEHHA Delphi processes. For carcinogens, OEHHA would move to random selection immediately.

Availability of the Tracking Database

The tracking database will be updated quarterly and will be available upon request for public review.

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Current Status of the Prioritization and Selection of Carcinogens

As noted above, at the July 22, 1996 CIC meeting, the Committee suggested that its role in general be limited to the final determination as to whether a chemical has been clearly shown to cause cancer. The Committee also suggested that the process as a whole be expedited, while retaining adequate opportunity for public comment. In response, as an interim measure OEHHA has implemented some of the refinements noted above for purposes of the prioritization of candidate carcinogens. Specifically, OEHHA has (1) called for data to assist in the preparation of hazard identification documents for three chemicals identified in the May 1996 draft data summaries prepared by OEHHA as posing a high level of carcinogenicity concern, and for which no public comments were provided, and (2) scheduled a public workshop for OEHHA to obtain comment on the remaining May 1996 draft data summaries and draft priorities. These actions are described in more detail in the October 4, 1996 *California Regulatory Notice Register*.

Concluding Remarks

The purpose of this document is to describe and solicit public comment on various potential refinements to the prioritization process. The major elements of the procedure include use of a computer database to track chemicals, prioritization of chemicals based on scientifically valid toxicological data, scientific peer review, and input by interested parties. OEHHA's ongoing goal for prioritization is an approach that is consistent, predictable, open to public input at several important points throughout the process, and which focuses Committee resources on the issues that most merit their consideration. OEHHA seeks public comment on all aspects of this procedure, and in particular on the potential refinements noted above. Public comment may be submitted orally and/or in writing at a public workshop to be held November 15, 1996 at 400 P Street, Rooms 1160 and 1170, Sacramento, California, from 10:00 a.m. until all business has been conducted or until 5:00 p.m., or in writing only to Cynthia Oshita, Office of Environmental Health Hazard Assessment, P.O. Box 942732, Sacramento, California 94234-7320 [FAX (916) 327-1097] by December 4, 1996.

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APPENDIX I

1 THE PRIORITIZATION PROCESS, INCORPORATING POTENTIAL REFINEMENTS

1.1 Introduction

To assist in visualizing how the various potential refinements would work, this Appendix describes the complete process, incorporating all of the potential refinements.

Figure 1 presents a flow chart of the prioritization and listing process, showing how a chemical is tracked, prioritized, may be placed on the Candidate List, and ultimately may reach the Committee for consideration. [Note: If you downloaded this document from the OEHHA web site, due to formatting problems, Figure 1 is not available electronically. Please contact OEHHA at (916) 445-6900 to receive a hard copy.] This flow chart incorporates processes previously described for hazard identification under Proposition 65 (OEHHA, 1993a) and some elements from previous proposals for compiling and prioritizing chemicals for Committee consideration (OEHHA, 1994; 1996). Procedures which have previously been applied for DARTs are described in reports by the California Department of Health Services (CDHS, 1991), OEHHA (1993b), and Donald *et al.* (1992).

The steps of the prioritization process, with potential refinements indicated as appropriate, are described in the following sections.

1.2 Database of Suggested Chemicals for Consideration (Tracking Database)

A chemical may enter the system by a number of mechanisms, including the following: (1) literature searches and reviews of databases by OEHHA, (2) suggestions by members of the SAB Identification Committees, (3) suggestions by other State agencies, (4) suggestions by the general public, and (5) suggestions by the scientific community. The basis for identifying a chemical as a candidate may be, for example, positive cancer or reproductive toxicity bioassays, or some evidence of very high production or use volume, particularly in California.

The five primary sources of potential candidate chemicals are described below:

1. Literature searches and other sources. Sources of potential candidate chemicals include the following:
 - Current scientific literature
 - Chemical Carcinogenicity Research Information System (CCRIS)
 - Database from Gold *et al.* (1984, 1986, 1987, 1990)
 - Survey of Compounds Which Have Been Tested for Carcinogenic Activity (National Cancer Institute)

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- Pesticide registrant data submitted to Cal/EPA
- Publications on DARTs (e.g., Schardein [1993])
- Other databases

OEHHA will conduct periodic reviews of the above sources. OEHHA and the Department of Pesticide Regulation will work together to identify potential candidate chemicals from pesticide registrant data. $\equiv$

2. Suggestions from the SAB Identification Committees. The Identification Committees, as the state's qualified experts, may bring candidates to the attention of OEHHA.
3. Suggestions from other State organizations. A process is being developed to establish an ongoing mechanism for soliciting candidate chemicals from other state organizations. The proposed elements of this process include: (1) a mechanism to regularly request suggestions of candidate chemicals from state organizations and committees and (2) forms requesting summary information on the chemicals.
4. Suggestions from the general public. Input from the public will be solicited through the *California Regulatory Notice Register*. Information supporting the suggestion of a chemical will also be requested, although such information is not specifically required for OEHHA to consider placement of a chemical on the tracking list.
5. Suggestions from the scientific community. Periodically, suggestions from the expert scientific community may be solicited or volunteered.

Suggested chemicals are tracked using a computer database. In unusual cases, for example when a long list of chemicals without supporting data is received, OEHHA may screen the list to determine whether the chemicals should be entered into the database. The information categories for the tracking system will include the source of the suggestion (e.g., literature source, general public); the date the chemical is entered into the database, and other important dates such as assignment to Category II or the Candidate List (if applicable) and subsequent procedural steps; results of reviews by authoritative bodies; brief comments on available epidemiological studies, animal bioassays, and other studies relevant to an assessment of the carcinogenicity or developmental and reproductive toxicity; data on use, occurrence, and production, and other information relevant to an assessment of exposure; other pertinent comments; and key references.

1.2.a Category I

Category I of the tracking database will include all chemicals nominated or otherwise identified, which have not yet been assigned a final priority status. OEHHA will search for information relevant to an assessment of developmental or reproductive toxicity, or

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carcinogenicity for all chemicals in Category I. This information could be in the form of epidemiological studies, animal studies, or other relevant data indicating the potential developmental or reproductive toxicity or carcinogenicity of the chemical. OEHHA will also search for information on the occurrence, use, and level and extent of exposure for all chemicals in Category I.

- **Refinements:** In previous drafts the database was organized into tiers; Tier I included all chemicals in the database. Here, the database is organized into three mutually exclusive categories. Category I includes only those chemicals which have not yet been assigned a final priority status.

Chemicals will be randomly selected from Category I in batches of ten for evaluation of the available toxicological and exposure data, development of a draft data summary, assignment of a draft priority status, and progression into Category II or the Candidate List. An unbiased random method for selecting chemicals for further evaluation is proposed as a means to proceed efficiently through prioritization and avoid any suggestion of bias on the part of OEHHA. Comment is invited regarding how best to accomplish a random selection.

OEHHA will publish in the *California Regulatory Notice Register* on a quarterly basis notice of those chemicals selected from Category I, indicating which appear to have data sufficient to begin prioritization based on the initial screening and which appear to have inadequate data.

The draft priority status will be based on a review and evaluation, in most instances of the secondary literature, resulting in an assignment of a level of developmental or reproductive toxicity or carcinogenicity concern of "high", "medium high", "medium", "low", "no identified concern", or "inadequate data". Chemicals will also be assigned a level of exposure concern of "high", "medium", "low", "no identified concern", or "inadequate data", but this information will not be used in the assignment of priorities.

- **Refinements:** (1) Here, the process whereby a chemical is selected from Category I for initiation of prioritization is specified in greater detail. (2) In previous drafts, chemicals which appeared to have data sufficient to begin prioritization based on an initial screening were placed in Tier II; a listing of all Tier II chemicals was available for release to the public prior to each SAB Identification Committee meeting. Here, OEHHA will publish in the *California Regulatory Notice Register* on a quarterly basis notice of those chemicals selected from Category I, indicating which appear to have data sufficient to begin prioritization based on the initial screening and which appear to have inadequate data.

1.2.b Category II

A chemical progresses from Category I to Category II or the Candidate List following preparation of a draft data summary, assignment of a draft priority, public review and comment,

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review by OEHHA of comments, and assignment of a final priority. Category II includes those chemicals which have been assigned a final priority other than high level of carcinogenic, reproductive or developmental hazard concern. Action would not be anticipated on Category II chemicals until the Candidate List consisting of high priority chemicals is exhausted.

- **Refinements:** In previous drafts the database was organized into tiers; Tier II was defined as the subset of all Tier I chemicals which appeared to have data sufficient to begin prioritization. Here, the database is organized into three mutually exclusive categories; chemicals progress into Category II or the Candidate List once a final priority status has been assigned.

The assignment of a priority to a chemical is based on the level of developmental/reproductive toxicity or carcinogenicity concern. Evidence for prioritization would come from epidemiological or animal toxicity studies or other relevant data indicating the potential carcinogenicity or developmental/reproductive toxicity of the chemical.

Epidemiological studies: The evidence considered will include the study population, exposure situation, tumor type or developmental/reproductive toxicity endpoint, nature of the dose-response curve, possible roles of bias and confounding, and quality of studies. In judging the epidemiological evidence, greater weight will be given to analytical epidemiological studies and lower weight to descriptive studies and case reports. Both positive and negative studies will be considered in assessing the overall level of hazard concern.

Animal studies: The evidence considered will include the number of experiments and species tested, route of administration, frequency and duration of exposure, numbers of test animals, and consideration of dose-response. Both positive and negative studies will be considered in assessing the overall level of hazard concern.

Other relevant data: Evaluation of other relevant data for use in prioritizing candidates will also be made. Such data include information on mechanism of action, chemical structure, metabolism, and genotoxic activity.

A qualitative appraisal of the potential for a chemical to cause cancer or developmental/reproductive toxicity will be made on the basis of a scientific evaluation of the available information. Chemicals will then be assigned a level of concern of "high", "medium high", "medium", "low", "no identified concern", or "inadequate data". This process is not a final hazard evaluation, but rather a preliminary appraisal for the purpose of prioritizing chemicals.

Chemicals will be assigned a high level of hazard concern if this preliminary evaluation indicates the existence of evidence that is likely to demonstrate a strong potential to cause cancer or developmental/reproductive toxicity. Chemicals which appear to have less evidence will be

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assigned lower levels of hazard concern, which reflect OEHHA's preliminary evaluation of the weight of the available information.

For developmental toxicants, chemicals are likely to be assigned a high level of hazard concern if they appear, in animal or human studies, to cause developmental toxicity which is not secondary to concurrent maternal toxicity. In general, the nature and severity of both the developmental effects and any reported maternal toxicity will be taken into account in assigning levels of hazard concern. Chemicals which appear to have less evidence will in general be assigned lower levels of hazard concern, which reflect OEHHA's preliminary evaluation of the weight of the available information.

For male and female reproductive toxicants, chemicals are likely to be assigned a high level of hazard concern if they appear, in animal or human studies, to cause reproductive toxicity which is not secondary to concurrent systemic toxicity. In general, the nature and severity of both the reproductive effects and any reported systemic toxicity will be taken into account in assigning levels of concern. Chemicals which appear to have less evidence will in general be assigned lower levels of hazard concern, which reflect OEHHA's preliminary evaluation of the weight of the available information.

At times, for particularly difficult scientific issues, the OEHHA Director or designee may request assistance from outside experts in assessing the level of carcinogenic or developmental/reproductive toxicity concern.

Although not used in the assignment of priorities, direct or indirect evidence of exposure in California, including information on level and extent of exposure, will be noted and included in the data summary. In general, direct exposure data from monitoring are not likely to be available, as most monitoring programs target only those chemicals that are known hazards. Indirect information may be more widely available. Quantitative information such as amounts produced or used in California will be collected when possible. The tracking system will record use and occurrence information such as whether the chemical is used in California industries, is a byproduct of industries operating in California, is a pesticide used on food crops grown or imported into California, or is a component of consumer products or drugs sold in California. Information on current restrictions on exposure to the chemical will also be noted when readily available. In the absence of information specific to California, evidence of exposure in the U.S. will be assumed to reflect the experience in California. A qualitative evaluation of the level of concern in terms of exposure will be expressed as "high", "medium", "low", "no identified concern", or "inadequate data".

The reporting of priority status will also address evaluations conducted by authoritative bodies. (If an authoritative body formally identifies a chemical as a carcinogen or DART, and the nature of the authoritative body action and the evidence for carcinogenicity or reproductive toxicity meet the criteria outlined in Title 22 Section 12306, of the California Code of Regulations, then the chemical is administratively added to the Proposition 65 list. The United States Environmental Protection Agency, the International Agency for Research on Cancer, the

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National Toxicology Program, the National Institute for Occupational Safety and Health, and the United States Food and Drug Administration have been designated by the state's qualified experts as authoritative bodies under Proposition 65.) Chemicals for which it is anticipated that evaluations will be released within a reasonable time frame (e.g., one to three years) may be assigned a priority but would generally be postponed from further consideration until completion of the review by the authoritative body. Postponement will be noted in the tracking database, and actions by the authoritative body tracked. In addition, chemicals that have been recently reviewed by an authoritative body and found to have minimal or no evidence of carcinogenicity or developmental/reproductive toxicity would likely be categorized as "low" or "no identified concern". Exceptions to these generalizations may occur. For example, if an authoritative body has evaluated a chemical but failed to review all relevant data, or compelling new data have become available since the evaluation, the chemical may be categorized at a higher level of concern.

In the process of reviewing the available data on chemicals in the tracking database, data gaps will likely be identified. To the extent possible, OEHHA will inform other appropriate agencies of this information. For example, if a high exposure chemical is found to be inadequately tested for carcinogenicity, but there is some scientific evidence to suggest carcinogenic potential, OEHHA may recommend this chemical to the NTP for toxicological testing.

- **Refinements:** In previous drafts OEHHA would act to inform other agencies of identified data gaps under the direction of the SAB Identification Committees. Here, OEHHA may initiate action on its own.

Once draft priorities have been assigned, OEHHA will publish a notice in the *California Regulatory Notice Register*, announcing the release of draft priorities and data summaries on these chemicals, the start of a 60-day public comment period, and the date, time and place when a public workshop will be held to provide opportunity for oral as well as written comments.

Occasionally, in the course of assigning draft priorities, OEHHA may identify scientific issues germane to prioritization which could not be adequately addressed in the data summary. In such instances, OEHHA will notice the intent to address specific scientific issues related to individual chemicals at the public workshop. For example, a supplemental analysis may be beneficial by providing a focused evaluation of a key toxicological issue germane to a specific chemical, such as the design of a critical study, apparent inconsistency in results in a given species, or by providing additional chemical-specific information regarding mode of action, or apparent route or species specific toxicity, or with respect to the relationship, if any, of developmental toxicity and maternal toxicity. Public comment is invited as to the criteria for undertaking a supplemental analysis.

Following review and consideration of the comments received, OEHHA will assign final priorities to chemicals and update Category II and the Candidate List. OEHHA will publish

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notice of this action. In some cases, OEHHA may determine that additional analysis and public comment are needed in order to address scientific issues not adequately addressed in the data summary. Once OEHHA has completed the necessary supplemental analysis, this information will be released for public comment and undergo the same comment and review process (i.e., public workshop, 60-day comment period) as that employed for the original data summary.

- **Refinements:** (1) In previous drafts, the SAB Identification Committee in concurrence with the Director of OEHHA assigned final priorities and finalized the priority list at a public meeting, after review and consideration of the comments received. Here, OEHHA holds a public workshop during the course of a 60-day public comment period to solicit comments on the draft data summaries and draft priorities. Following review of public comments, OEHHA would assign the final priorities. (2) In previous drafts, after finalizing the priority list, the Committee selected chemicals from this list for synopsis preparation. Here, OEHHA may determine, following public consideration and comment, that a data summary has provided sufficient information in order to assign a final priority to some chemicals, while for others, additional analysis supplemental to the draft data summary may be necessary to resolve particular scientific issues prior to the assignment of a final priority.

1.3 Candidate List

The Candidate List will consist of those chemicals found by OEHHA to have a final priority of high carcinogenic, developmental or reproductive hazard concern. All other final prioritized chemicals would be assigned to Category II. Chemicals with a high level of hazard concern would be brought before their respective Committee. Action would not be anticipated on Category II chemicals until the Candidate List consisting of high priority chemicals is exhausted. At that point, with Committee and public input, OEHHA would refine the existing process in order to determine which of the Category II prioritized chemicals should be brought forward for consideration by the CIC and the DART Identification Committee.

- **Refinements:** In previous drafts, the SAB Identification Committee selected chemicals for which hazard identification documents were to be prepared from a priority list, which included all prioritized chemicals in the tracking database. Here, in response to Committee comments, OEHHA, rather than the Committee, selects chemicals for which hazard identification documents are to be prepared. In addition, in order to focus Committee resources on issues that most merit their consideration, here the Candidate List will consist only of those chemicals assigned a final priority of high carcinogenic, developmental or reproductive concern, rather than all prioritized chemicals.

1.4 Chemicals Under Consideration for Listing

OEHHA will select chemicals from the Candidate List, and begin the preparation of hazard identification documents for those chemicals. The chemicals selected by OEHHA for the preparation of hazard identification documents and Committee consideration will be published in

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the *California Regulatory Notice Register*, and data concerning carcinogenicity or developmental/reproductive toxicity will be requested. During a public meeting the SAB Identification Committee may suggest, as a goal, the number of chemicals to be considered at their next meeting.

- **Refinements:** The May 1996 draft called for the SAB Identification Committee to review synopses and other documentation on a group of chemicals previously identified from the priority list and, at a public meeting, select chemicals for the preparation of hazard identification documents and consideration at subsequent Committee meetings. Here the selection of chemicals for the preparation of hazard identification documents is performed by OEHHA, rather than the SAB Identification Committee, and the chemicals are chosen from a Candidate List. In addition, here the Committee may suggest, as a goal, the number of chemicals to be considered at their next meeting.

Under exceptional circumstances, the process described in this document may be abbreviated to allow OEHHA to respond to specific public health needs. Following consultation with the Committee Chair, the Director of OEHHA may request that a chemical be placed on the agenda of the next scheduled meeting. In all cases, the chemical would be noticed in the *California Regulatory Notice Register* and minimum notification periods would be followed.

2 FINAL STEPS IN THE CONSIDERATION OF CHEMICALS BY THE STATE'S QUALIFIED EXPERTS

The final two steps of the process under which chemicals are considered by the state's qualified experts, while not part of the prioritization procedure, are described below. As a result of comments received at the July 22, 1996 CIC meeting, OEHHA is considering modifications to the process for the review and response to public comments received on hazard identification documents. This modified process would have as its goal improvement of the Committee's ability to fully consider public comments in its deliberations.

2.1 Development and Publication of a Hazard Identification Document

OEHHA will gather and analyze the available data on the candidate chemicals for consideration by the Committees. Comment from and participation by scientists with the relevant expertise from other state agencies and departments will be solicited. Public input and comment will be solicited by issuing a notice in the *California Regulatory Notice Register* requesting that relevant data on the candidate chemical be submitted to OEHHA within 60 days. The Director of OEHHA may hold a public workshop to provide for exchange of information on a candidate chemical and dialogue with the community.

OEHHA and, if appropriate, scientists having relevant expertise from other state agencies and departments, will develop a hazard identification document utilizing information in the

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published scientific literature, and that received from the public and other sources. Internal review of the predecisional draft document in progress may be conducted by Cal/EPA and other state agencies and departments, as appropriate. When the draft is complete, a notice announcing the public availability of the hazard identification document and commencement of a 60-day public comment period will be placed in the *California Regulatory Notice Register*, and the draft document will be submitted to the members of the relevant SAB Identification Committee. At the close of the 60-day public comment period, OEHHA will organize and index the comments received and provide this information to the Committee at least two weeks prior to the meeting at which the candidate chemical will be considered.

- **Refinements:** In previous drafts, hazard identification documents were reviewed and considered at public Committee meetings held at or near the close of the 60-day public comment period for those documents. Here, in order to provide greater opportunity for the Committee to consider public comments prior to deliberation, the 60-day comment period associated with a hazard identification document will close three to four weeks prior to the Committee meeting at which the candidate chemical is to be considered. In addition, OEHHA will organize and index the public comments received and provide the Committee with this information at least two weeks in advance of the meeting at which the candidate chemical is to be considered.

2.2 SAB Committee Meeting and Decision

The hazard identification document and the public comments received during the 60-day comment period will be considered by the appropriate SAB Committee at a public meeting. The Committee chairperson will facilitate the meeting, during which the public will have further opportunity to comment. At the conclusion of the deliberations, the Committee, as the state's qualified experts, may render an opinion as to the developmental or reproductive toxicity or carcinogenicity of a chemical, as appropriate. The Committee may render an opinion that the chemical has been clearly shown to cause cancer or reproductive toxicity, may fail to reach such a conclusion, or may defer the decision to a later meeting. In those cases where the decision is to defer, the Committee will prescribe an action plan that will discuss further steps to be taken and indicate the timeline for reconsideration of the chemical. For example, the action plan could require reanalysis of data and revision of the hazard identification document, with reconsideration of the chemical at a subsequent meeting. The dates of Committee deliberations on specific chemicals will be recorded in the tracking database. Following Committee deliberation, the draft hazard identification document will be finalized by OEHHA.

2.3 The Proposition 65 List

Chemicals that the SAB Identification Committees find to have been clearly shown, through scientifically valid testing according to generally accepted principals, to cause cancer or reproductive toxicity will be proposed for inclusion on the Proposition 65 list in accordance with

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procedures specified in statute (California Health and Safety Code 25249.5 *et seq.*). The Proposition 65 list is updated at least annually.

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Figure 1
Flowchart for Consideration of Chemicals Under Prop 65

