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

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1 BACKGROUND

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 evaluation by the SAB Identification Committees. The procedure is designed to ensure that the efforts of the SAB are focused on chemicals which pose the greatest hazard to Californians, and that these chemicals are selected in an open, objective and predictable manner. This procedure ensures that chemicals posing the highest level of carcinogenic, reproductive or developmental hazard concern are addressed first and forthwith by the SAB. At appropriate points in the prioritization process, opportunity is provided for input and review by state agencies and departments, individual SAB Identification Committee members, the Committees as a whole if they so choose, the scientific community, and the public. This process has been the subject of extensive review and comment by the public, external scientists, and by the SAB Identification Committees. This refined prioritization process should ensure that chemicals posing the highest degree of hazard are identified promptly and brought to the SAB for their evaluation and finding within an estimated time frame of 9 to 15 months.

2 SUMMARY OF KEY POINTS

This section outlines the key features of the prioritization process.

2.1 OEHHA Selection of Candidate Chemicals

OEHHA will perform all prioritization steps up to and including the selection of chemicals for preparation of hazard identification documents. OEHHA will randomly select chemicals from the tracking database for further evaluation, develop draft data summaries, assign draft priorities, circulate the draft data summaries and priorities for public and SAB committee member review and comment, hold a public workshop, and then, after review of oral and written comments, assign final priorities.

Assigned priorities may change as new scientifically valid toxicological information relevant to potential cancer, reproductive or developmental effects becomes available. In such circumstances, notice will be provided regarding a proposal to revise the prioritization, and opportunity will be provided for public input.

2.2 Use "Tiered" Evaluation Process

To expedite the process and use resources efficiently, the level of analysis employed during the course of assigning final priorities will vary according to the complexity of the toxicological issues to be addressed. Preparation of a data summary will 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. In general, an issue-specific supplemental analysis will be performed, when warranted, only on chemicals which appear to be of higher toxicological concern, i.e., those chemicals assigned a draft priority of "high" or "medium high". Although a supplemental analysis may address several issues, a chemical will undergo, at most, only one supplemental analysis during the course of prioritization.

2.3 Organization of the Tracking Database

Changes to the terminology and organization of the tracking database have been made. The database is now organized into three mutually exclusive groups. Category I includes all chemicals nominated or otherwise identified for entry into the tracking database for which some supporting information is available, but 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. If data are inadequate, the priority status for the chemical is

"inadequate data". The Candidate List is composed of chemicals with a final priority status of high level of carcinogenic, reproductive or developmental hazard concern.

2.4 Initial Work Focused on Chemicals with "High" Hazard Level of Concern and Known or Potential Exposure in California

Prioritized chemicals with a final high level of carcinogenic, reproductive or developmental hazard concern will be assigned to the Candidate List, from which chemicals will be chosen for the preparation of a hazard identification document. All other final prioritized chemicals will be assigned to Category II.

Information on exposure will be taken into account in the selection of chemicals from the Candidate List. Chemicals with the highest level of exposure concern will be selected first from the Candidate List to be brought before their respective Committee. Chemicals on the Candidate List (those with "high" level of hazard concern) for which there are lower exposure concerns in California will, in general, be addressed subsequent to those chemicals determined to have both a high level of hazard concern and a high level of exposure concern.

Action is not anticipated for Category II chemicals until all chemicals identified as posing a high hazard concern have been identified from the tracking database, assigned to the Candidate List, and have been brought before the Committees. At that point, with Committee and public input, OEHHA will 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.

3 SUMMARY OF PROCESS STEPS

The complete procedure for selecting chemicals for hazard identification includes the following sequential steps:

- Random selection of the numerical order for chemicals from Category I to be assigned to groups for preparation of a draft data summary, with notice of each group of chemicals selected published in the *California Regulatory Notice Register* on a regular (e.g. quarterly or biannual) basis.
- Development of a 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 may require a focused supplemental analysis, beyond a data summary. In such cases OEHHA will perform the supplemental analysis prior to assignment of a draft priority.
- 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 oral as well as written comments will be provided by a public workshop held during the 60-day period.

- For those chemicals not identified as needing a focused supplemental analysis:
  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 solicit public comment on the supplemental analysis as described in the following step.
- For those chemicals for which a focused supplemental analysis is determined to be appropriate as a result of scientifically valid comment received during the public comment period:
  OEHHA will conduct the supplemental analysis and then circulate it for public and scientific review during a 60-day comment period. Opportunity for oral 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 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 will be noticed in the *California Regulatory Notice Register* and appropriate notification periods will be followed.

4 DETAILED PROCESS DESCRIPTION

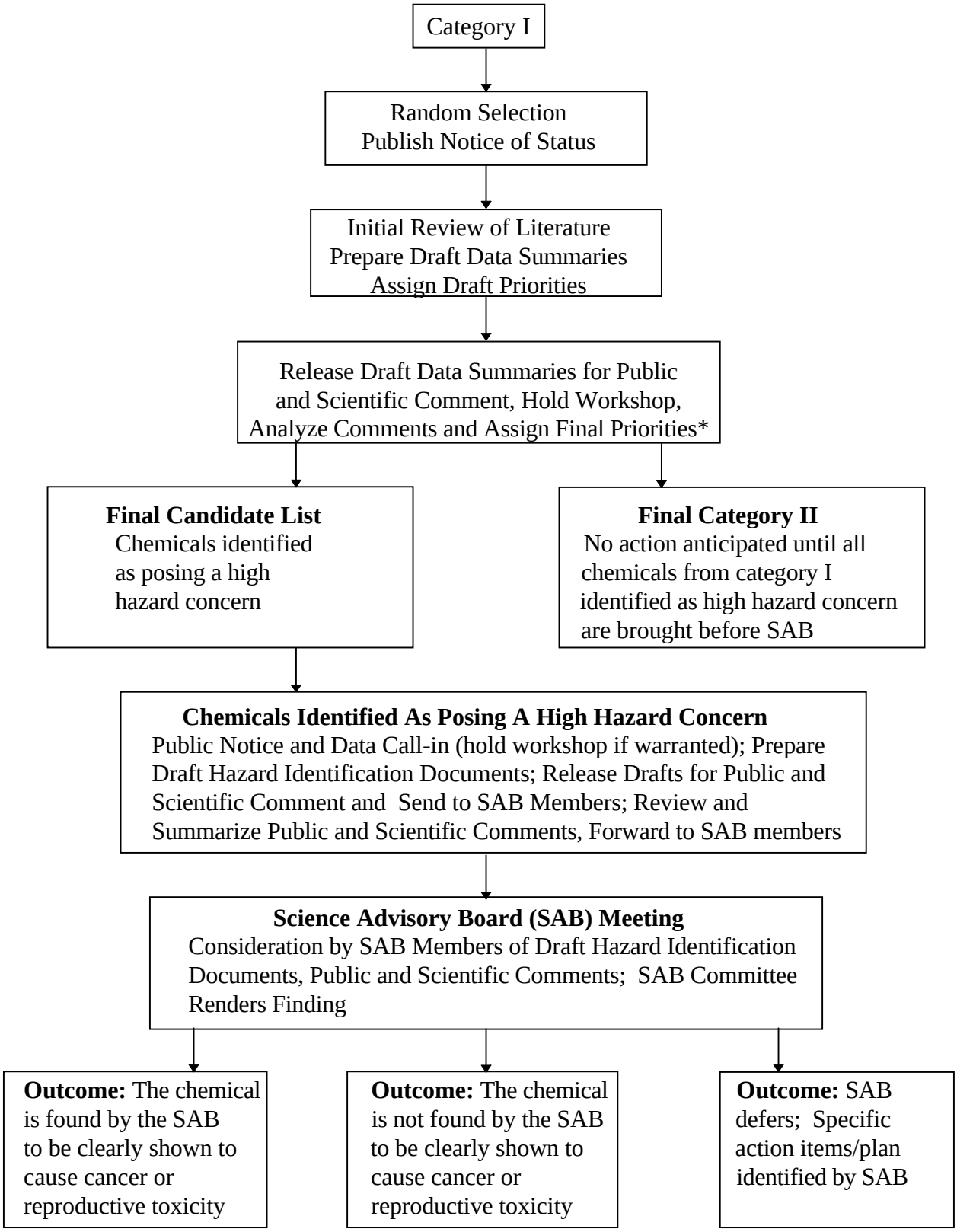
The steps of the prioritization process, summarized above, are described in more detail in the following sections. Figure 1 presents a flow chart of the prioritization and listing process, showing how a chemical is tracked, prioritized, may be placed on the Candidate List, and ultimately may reach the Committee for consideration.

4.1 Database of Suggested Chemicals for Consideration (Tracking Database)

A tracking database has been established to keep account of chemicals entered into the system as they progress through different stages of evaluation. The tracking database, updates of which are released quarterly, includes all identified potential candidate chemicals. These chemicals have been suggested by state agencies and other sources or obtained from literature searches. To date, over 580 potential candidate carcinogens and over 320 potential candidate developmental or reproductive toxicants (DARTs) have been entered into the 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 potential candidate may be, for example, positive cancer or reproductive toxicity bioassays, or some evidence of very high production or use volume, particularly in California, accompanied by some evidence of relevant toxicity (birth defects, reproductive toxicity, or cancer).

Figure 1
Flowchart for Consideration of Chemicals Under Proposition 65



* In some cases, a supplemental analysis may be necessary before assignment of final hazard level (see text for details). A chemical will only undergo one supplemental analysis during the course of prioritization.

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

   OEHHA periodically reviews the above sources. OEHHA and the Department of Pesticide Regulation will work together to identify potential candidate chemicals from pesticide registrant data.

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, OEHHA will use it or other supporting information 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 cases where chemicals are suggested but no supporting data is received, OEHHA will screen the chemicals to determine whether the chemicals should be entered into Category I. 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.

4.2 Category I

Category I of the tracking database will include all chemicals nominated or otherwise identified for which some supporting information is available, but 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 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.

Chemicals will be randomly selected from Category I 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. OEHHA will publish in the *California Regulatory Notice Register* on a quarterly basis notice of those chemicals selected from Category I.

A draft data summary will be prepared based upon a review and evaluation, in most instances of the secondary literature, resulting in an assignment of a draft hazard priority level for 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”. Exposure information will not be used in the assignment of hazard priorities and placement of chemicals on the Candidate List, which is based solely on the level of hazard concern. Rather, exposure information will be considered in determining the order in which chemicals on the Candidate List are selected for the preparation of hazard identification documents. In addition, exposure information will be used as a basis to identify and help fill data gaps for chemicals found to have high potential for exposure, but insufficient or inadequate relevant toxicity data. 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 evidence to suggest carcinogenic potential, OEHHA may recommend the chemical to the National Toxicological Program for further testing.

4.3 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 and external scientific review and comment, 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 is not anticipated

for Category II chemicals until all high priority chemicals have been identified from the tracking database, assigned to the Candidate List, and have been brought before the Committees.

4.3.1 Basis for Assignment of Priorities

The assignment of a hazard priority to a chemical is based on the level of developmental/reproductive toxicity or carcinogenicity concern. Evidence for prioritization will 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, maternal toxicity, 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 hazard 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.

4.3.2 Level of Hazard Concern

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 and biologically plausible potential to cause cancer or developmental/reproductive toxicity. Chemicals which appear to have less evidence will be 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.

4.3.3 Evaluation of Exposure Information

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, although it is recognized that quantity of use does not necessarily correspond directly to actual exposures. 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, production or use 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".

Exposure information will not be used in the assignment of hazard priorities, but will be taken into account in the selection of chemicals from the Candidate List for Committee consideration. Chemicals with the highest level of exposure concern will be selected first from the Candidate List to be brought before their respective Committee. Chemicals on the Candidate List (those with "high" level of hazard concern) for which there are lower exposure concerns in California will, in general, be addressed subsequent to those chemicals determined to have both a high level of hazard concern and a high level of exposure concern.

4.3.4 Authoritative Body Evaluations

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 US Environmental Protection Agency, the International Agency for Research on Cancer, the National Toxicology Program, the National Institute for Occupational Safety and Health, and the US 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 by an authoritative body will be released within a reasonable time (*e.g*., one to three years) may be assigned a priority but will 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 insufficient, minimal or no evidence of carcinogenicity or developmental/reproductive toxicity will 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 hazard concern.

4.3.5 Testing By, or On Behalf of, or for Use By Authoritative Bodies

OEHHA also recognizes that on occasion it may be reasonable to postpone prioritization, for a defined period of time, to allow for the completion of a study undertaken by, on behalf of, or for use by an authoritative body. OEHHA may, at its discretion, choose to postpone prioritization when the study results would allow OEHHA to prioritize a chemical for endpoints for which there otherwise would be insufficient data, or when OEHHA determines that the study is of sufficient significance so as to be relevant to the assignment of a priority to the chemical. Prioritization of postponed chemicals would proceed when the study results become available. Postponement will be noted in the tracking database.

4.3.6 Data Gaps

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 the chemical to the National Toxicology Program for toxicological testing.

4.3.7 Review of Priorities; Supplemental Analysis

Once draft priorities have been assigned, OEHHA will publish a notice in the *California Regulatory Notice Register*, announcing the release of draft priorities and draft 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.

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 notice of this action in the *California Regulatory Notice Register*. In some cases, if a supplemental analysis has not already been performed, 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. Although a supplemental analysis may address several issues, a chemical will undergo, at most, only one supplemental analysis during the course of prioritization.

4.4 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 will be assigned to Category II. Action is not anticipated on Category II chemicals until all high priority chemicals on the Candidate List with known or potential exposure have been brought before the Committees. At that point, with Committee and public input, OEHHA will 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.

4.5 Chemicals Under Consideration for Listing

OEHHA will select chemicals from the Candidate List, publish notice of initiation of hazard identification documents, solicit germane scientific data, studies and analyses, and begin the preparation of hazard identification documents for those chemicals. Information on exposure will be taken into account in the selection of chemicals from the Candidate List. Chemicals with the highest level of exposure concern will be selected first from the Candidate List to be brought before their respective Committee. Thus the end result of the process is a form of triage, in which chemicals with the highest level of hazard concern and with the highest level of exposure concern are selected first and brought forward expeditiously for Committee consideration. Chemicals on

the Candidate List (those with "high" level of hazard concern) for which there are lower exposure concerns in California will, in general, be addressed subsequent to those chemicals determined to have both a high level of hazard concern and a high level of exposure concern.

The chemicals selected by OEHHA for the preparation of hazard identification documents and Committee consideration will be published in the *California Regulatory Notice Register*, and data concerning carcinogenicity or developmental/reproductive toxicity will be requested.

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 will be noticed in the *California Regulatory Notice Register* and appropriate notification periods will be followed.

5 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.

5.1 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 published scientific literature, and that received from the public and other sources. Internal scientific review of the predecisional draft document in progress may be conducted by scientists from 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.

5.2 SAB Committee Meeting and Decision

The hazard identification document and the public comments received during the 60-day comment period are 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.

5.3 The Proposition 65 List

Chemicals that the SAB Identification Committees find to have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer or reproductive toxicity will be proposed for inclusion on the Proposition 65 list in accordance with procedures specified in statute (California Health and Safety Code 25249.5 *et seq*.). The Proposition 65 list is updated at least annually.

6 START-UP

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 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). Using these previous groupings, OEHHA has completed evaluation of one group of candidates for DART evaluation identified by means of the Donald *et al.* and the OEHHA Delphi processes, and a second group is near completion. OEHHA has also completed evaluation for one group of carcinogen candidates.

Now, OEHHA has moved to the random selection process noted above. This random selection approach will be used as a pilot program for eighteen months, after which OEHHA will evaluate its experience under the process and refine the process if warranted.

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