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MEMORANDUM

DATE: June 11, 1996

TO: Hasmukh C. Shah, Ph.D., D.A.B.T.
Chemical Manufacturers Association

FROM: Lynn L. Bergeson *LLB*
Lisa M. Campbell *LMC*

RE: California Proposition 65

The Carcinogen Identification Committee (CIC) of the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), which advises and assists OEHHA in compiling the list of chemicals "known to the state to cause cancer," under Proposition 65 is holding a meeting on July 22, 1996. Included on the agenda for the meeting are the following topics:

- Criteria for determining whether a chemical is known to the state to cause cancer;
- Prioritization and selection of candidate agents; and
- Mechanisms for removing agents from the Proposition 65 list.

OEHHA has provided materials in anticipation of the July 22, 1996, meeting for public comment. Comments are due on July 8, 1996. These materials are of significant interest and include the following draft documents:

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- "Procedure for Prioritizing Candidate Chemicals for Consideration under Proposition 65 by the 'State's Qualified Experts';"
- "Prioritized Candidate Chemicals under Consideration for Carcinogenicity Evaluation," accompanied by summaries of carcinogenicity data for specified chemicals;
- "Mechanisms for Listing Chemicals Under Proposition 65;" and
- "Mechanisms for Removing Chemicals from the Proposition 65 List Based on Findings Made by the 'State's Qualified Experts.'"

Each of these is discussed briefly below.

**Procedure for Prioritizing Candidate Chemicals
for Consideration Under Proposition 65
by the "State's Qualified Experts"**

This draft document describes the procedure that OEHHA uses to compile and prioritize candidate chemicals for consideration by the Science Advisory Board (SAB) Identification Committees -- the CIC and the Developmental and Reproductive Toxicant (DART) Identification Committee. It includes a flowchart of the prioritization and listing process, which shows how a chemical is tracked, prioritized, and ultimately may reach the committee for consideration. The major elements of the procedure include use of a computer database to track chemicals, prioritization of chemicals "based on scientifically valid toxicological and exposure data," scientific peer review, and input by interested parties.

A copy of the flowchart depicting this process is appended as Attachment 1. A brief summary of the process is as follows:

- **Entry:** A chemical may enter the system by a number of mechanisms, including literature searches and reviews of databases by OEHHA and suggestions by

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members of the SAB Identification Committee, other state agencies, the general public, and the scientific community. Suggested chemicals are tracked using a computer database.

- **Tier 1:** Tier 1 of the tracking database includes all chemicals nominated or otherwise identified. OEHHA will search for information relevant to an assessment of developmental or reproductive toxicity, or carcinogenicity, for all chemicals in the tracking database. The availability of such information will be the minimum requirement for moving a chemical out of Tier 1 into the next step of the prioritization process, Tier 2. Chemicals with toxicological data insufficient to begin prioritization will be assigned a priority of "inadequate data" and remain in Tier 1.
- **Tier 2:** Tier 2 of the tracking database will contain all chemicals that appear to have data sufficient to begin prioritization based on the initial screening. OEHHA will review toxicological and exposure data to determine the priority status for a chemical. Priority status levels, based on developmental/reproductive toxicity or carcinogenicity concern, will be assigned. These are: high, medium-high, medium, low, no identified concern, or inadequate data. Candidates will also be assigned an exposure concern level of: high, medium, low, no identified concern, or inadequate data. The draft document states that the process of assigning these levels 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 concern if the preliminary evaluation indicates the existence of evidence that is "likely to demonstrate a strong potential to cause cancer or developmental/reproductive toxicity."

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- For developmental toxicants, chemicals will be assigned a high level of concern "if they appear, in animal studies, to cause developmental toxicity which is not secondary to concurrent maternal toxicity."
- Likewise for male and female reproductive toxicants, chemicals will be assigned a high level of concern if they appear, in animal studies, to "cause reproductive toxicity which is not secondary to concurrent systemic toxicity." With respect to evidence of exposure, the draft document states that because direct exposure data from monitoring are not likely to be available, indirect information will be used. This includes quantitative information, such as amounts produced or used in California -- i.e., whether a chemical is a drug prescribed in California, is used in California industries, is a by-product of industries operating in California, is a pesticide used on food crops grown or imported into California, or is a component of consumer products sold in California.
- **Priority List:** A draft priority list that reports the level of exposure concern and the level of developmental/reproductive toxicity or carcinogenicity concern for all Tier 2 chemicals that have gone through the prioritization process to date is then issued. Along with the draft priority list, draft data summaries are released on these chemicals which have not been postponed -- those that are due to be considered by "an authoritative body." The draft priority list and draft data summaries are made available for public review and comment at least sixty days prior to the meeting of the committee at which they will be discussed. At a public meeting, the committee will

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review the priority list, and assign final priorities at that time in concurrence with OEHHA. At the same meeting, the committee will select chemicals for which synopses will be prepared by OEHHA.

- **Synopses and Selection for Consideration:** Chemicals under committee consideration for listing will have synopses and other documentation released for public comment and committee review at least sixty days prior to the meeting at which they will be discussed. In addition to toxicity and exposure information, these synopsis will briefly describe the regulatory status of the chemical and note the status of restrictions or warnings, if any, for use of the chemical. The draft document states: "[o]ther things being equal, there is less public health benefit derived from listing chemicals under the Proposition which are already subject to stringent controls, than from listing chemicals for which no such restrictions exist." Chemicals selected for consideration will be placed on the agenda of future committee meetings.
- **Hazard Identification Document:** OEHHA will next develop and publish a hazard identification document for a chemical, after gathering and analyzing available data on it for consideration by the committees.
- **Committee Decision:** The hazard identification document and public comments received during the notice period will be considered by the appropriate SAB committee at a public meeting. 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.
- **Proposal for Inclusion:** Chemicals that the SAB Identification Committee found to have been clearly shown through scientifically valid testing

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according to generally accepted principles to cause cancer or reproductive toxicity will be proposed for inclusion on the Proposition 65 list.

**Draft Prioritized Candidate Chemicals
Under Consideration for Carcinogenicity Evaluation**

This document lists chemicals selected for prioritization from Tier 1 of the tracking database by the process described above. Data summaries are available for each of the chemicals on the current priority list.

**Mechanisms For Removing Chemicals From the
Proposition 65 List Based on Findings Made
by the "State's Qualified Experts"**

This document describes procedures for reconsideration of listing decisions based on findings made by the State's qualified experts. The CIC and DART Identification Committees serve as the state's qualified experts for Proposition 65. The CIC or DART Identification Committees may reconsider a previous finding made through the state's qualified experts listing mechanism, if new scientific data or new scientific understanding clearly show that the chemical should not be identified as a carcinogen or reproductive toxicant. Additionally, the public and interested parties may formally petition for reconsideration of a listing decision.

The draft document sets forth a format for petitions for reconsideration. It states that petitions "based primarily on information previously reviewed by the state's qualified experts will, in general, be considered only under exceptional circumstances." A copy of the petition for reconsideration is appended as Attachment 2. A copy of a flowchart depicting the reconsideration process is appended as Attachment 3.

The document describes a "reconsideration tracking database," which tracks candidates for reconsideration. A listed chemical enters the tracking system for reconsideration pursuant to a proposal from OEHHA staff and other state agencies based on literature reviews, reviews of databases and other information,

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proposals from members of the SAB Identification Committees, or formal petitions from the general public and interested parties.

The reconsideration tracking database is structured in a tiered fashion, based on the availability of new and relevant information not previously considered in the finding by the State's qualified experts:

- **Tier 1:** Tier 1 includes all listed chemicals nominated or otherwise identified for reconsideration.
- **Tier 2:** Tier 2 contains all chemicals that appear to have data sufficient to begin prioritization for reconsideration based on the initial screening. The draft document states in this regard that "[p]articular importance will be placed on new and definitive information generated subsequent to the previous finding that substantially questions whether a chemical has been clearly shown to cause cancer or reproductive toxicity."
- **Priority Assignments:** Chemicals with strong scientific evidence supporting reconsideration are assigned a priority of high. Chemicals with moderate, weak, none, or inadequate scientific evidence supporting reconsideration will be assigned priorities of medium, low, no additional new data identified, and inadequate data, respectively. Chemicals with draft priorities of high, medium, or low are placed on the draft priority list for reconsideration. Supporting documentation summarizing the scientific data for reconsideration is made available for public comment.
- **Synopses Assignments:** Priority list chemicals are reviewed at a public committee meeting. During the meeting, the committee chooses chemicals from the priority list for which synopses are to be prepared.

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- **Technical Report Assignments:** Synopses are released for public and committee review at least sixty days prior to the meeting at which they are discussed. At the subsequent meeting, the committee reviews the available synopses and selects chemicals for which technical reports documenting the entire body of evidence relevant to reconsideration of listing will be prepared for discussion at a future committee meeting. A list of chemicals selected for committee reconsideration is published in the *California Regulatory Notice Register*.
- **Technical Report Preparation and Release:** OEHHA and the appropriate scientists with relative expertise from other state agencies and departments prepare the technical reports using information in the published scientific literature and information received from the public and other sources. The draft technical report is then submitted to members of the relevant SAB committee at least sixty days prior to the SAB meeting where it is scheduled to be discussed. At the same time, a notice of public availability of the draft technical report is placed in the *California Regulatory Notice Register*.
- **Committee Decision:** The draft technical report documenting evidence supporting reconsideration of the listing at issue and public comments received during the notice period are considered by the appropriate committee of the SAB at a public meeting. At the conclusion of the deliberations, the committee, as the state's qualified expert, may render an opinion as to the developmental or reproductive toxicity or carcinogenicity of a chemical, as appropriate. Upon evaluation of all information, the committee may decline to act, in which case the chemical would remain on the list, or the committee may revoke its previous finding, in which the chemical will be removed from the list.

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**Mechanisms for Listing Chemicals
Under Proposition 65**

This draft document describes the procedures followed for adding chemicals to the Proposition 65 list under the three statutory mechanisms for doing so. These are:

- The state's qualified experts may render an opinion that a chemical has been clearly shown to cause cancer or reproductive toxicity "through scientifically valid testing according to generally accepted principles."
- Chemicals formally identified as carcinogens or reproductive toxicants by a body considered authoritative under Proposition 65 will be listed.
- Chemicals will be listed if they are required by a state or federal agency to be formally identified or labeled as carcinogens or reproductive toxicants.

A flow chart depicting the listing process for chemicals formally identified as carcinogens or DARTs by Proposition 65 authoritative bodies is appended as Attachment 4.

Of interest to many, due to the controversy surrounding decisions based on it, are the draft document statements concerning the second mechanism for listing -- the authoritative body mechanism. The document states as examples of the types of documents under which listing pursuant to this mechanism have been based, the following: IARC monographs on the evaluation of carcinogenic risk to humans; NIOSH criteria for a recommended standard; NTP annual report; EPA health assessment documents; and FDA *Federal Register* notices.

* * * * *

We hope that this information is useful. If you would like copies of the documents that OEHHA released, which are discussed above, please call 1-800-841-1727. If you have any

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questions or would like further information, please call either one
of us.

Attachments

09ME046_.501 (63)

CMA 114055

FIGURE 1:

**FLOWCHART FOR CONSIDERATION OF
CHEMICALS UNDER PROPOSITION 65**

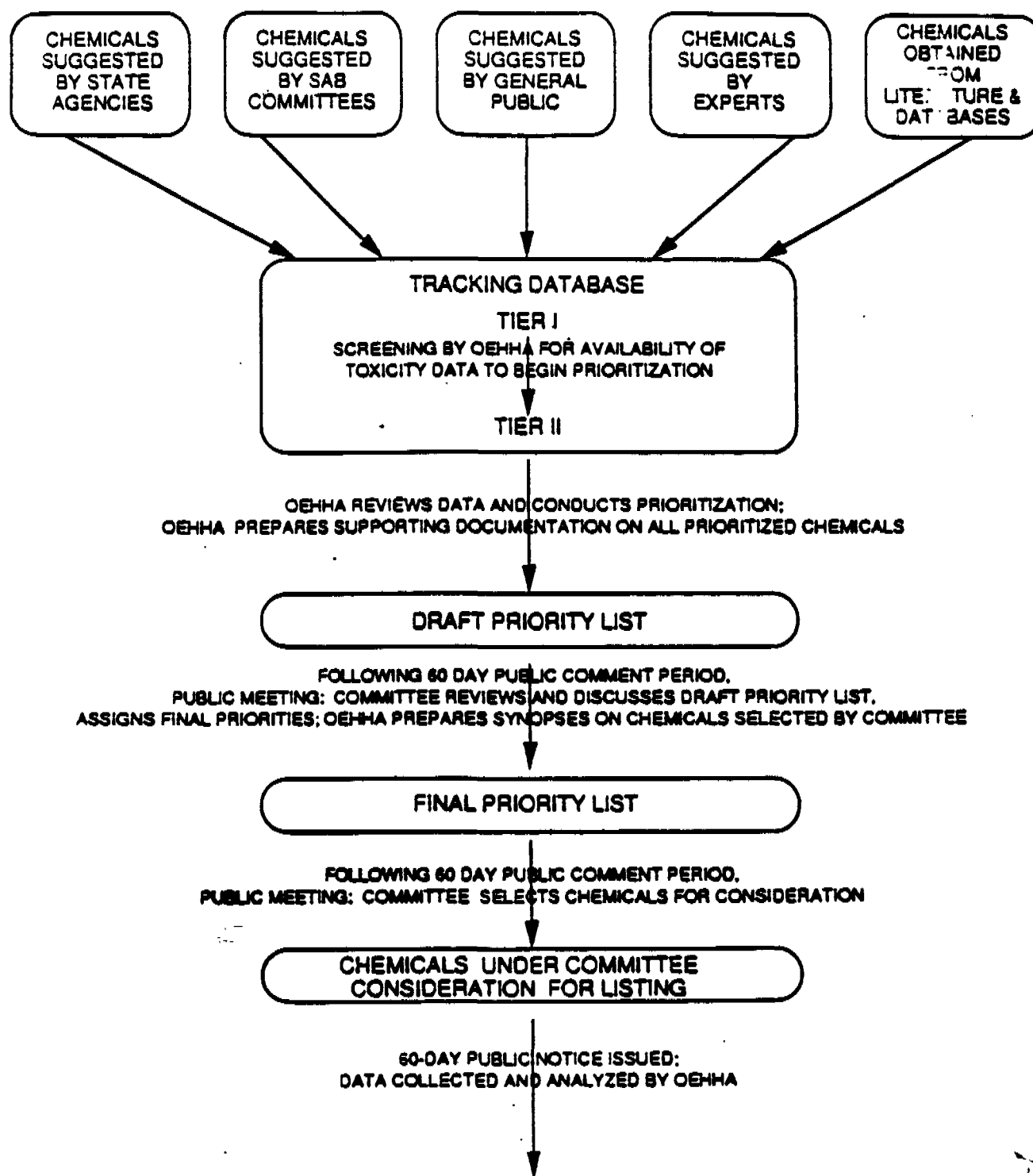
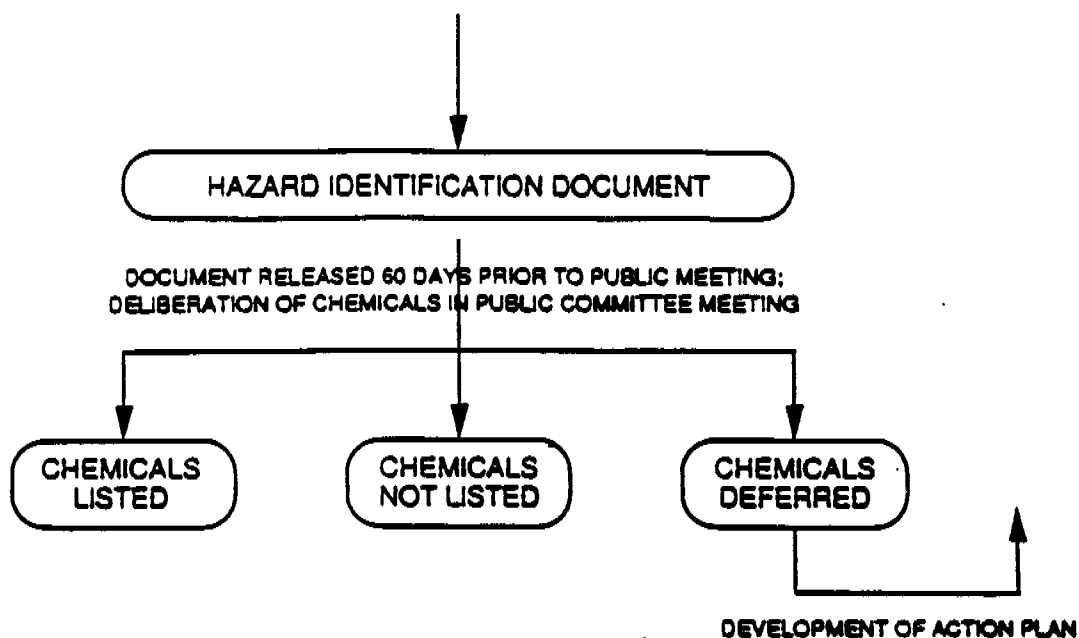


FIGURE 1:

**FLOWCHART FOR CONSIDERATION OF
CHEMICALS UNDER PROPOSITION 65 (CONT'D)**



Attachment III

Petition for Reconsideration of a Proposition 65 Listing Based on a Finding by "The State's Qualified Experts"

In implementing Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) strives always for full, open discussion of all relevant scientific information. In that spirit, OEHHA welcomes discussion of new scientific information that would call into question a previous determination by the state's qualified experts that a chemical has been clearly shown to cause cancer or reproductive toxicity. The following procedures are intended to ensure that sufficient information is provided to allow OEHHA staff and the relevant Science Advisory Board Committee to determine if a particular chemical is a high priority for reconsideration.

Petitions for reconsideration of Proposition 65 findings by the state's qualified experts should be submitted in the format and include the information specified below:

1. Name, address, telephone number and, if applicable, title and affiliation of Petitioner:
2. Name and, if applicable, CAS Number of Chemical:
3. Request for reconsideration of the listing as a Proposition 65:

_____ Carcinogen
_____ Reproductive Toxicant
_____ Developmental Toxicant
_____ Female Reproductive Toxicant
_____ Male Reproductive Toxicant

4. Reason for petitioning for reconsideration (Please summarize briefly):

DRAFT
May 1996

5. Supporting Information:

The information presented in the petition must be presented in a clear and organized manner, with clear identification of new and valid scientific information not previously considered by the state's qualified experts. All supporting data must be presented in a form that permits a full and independent re-analysis. The Petitioner is reminded that the information presented should clearly show that the chemical in question should not be identified as a carcinogen or reproductive toxicant under Proposition 65.

In order to be considered, the petition must clearly indicate new and valid scientific data from toxicologic, epidemiologic, or other relevant studies which were not considered by the state's qualified experts at the time of the previous determination. Petitions based primarily on information previously reviewed by the state's qualified experts will, in general, be considered only under exceptional circumstances. The information submitted in the petition must provide persuasive scientific support for reconsideration in order for the chemical to be entered into Tier II of the reconsideration tracking database. Chemicals in Tier II will be prioritized for reconsideration by the state's qualified experts based upon an evaluation of the overall weight of the scientific evidence.

FIGURE 1: FLOWCHART FOR RECONSIDERATION OF LISTED CHEMICALS UNDER PROPOSITION 65

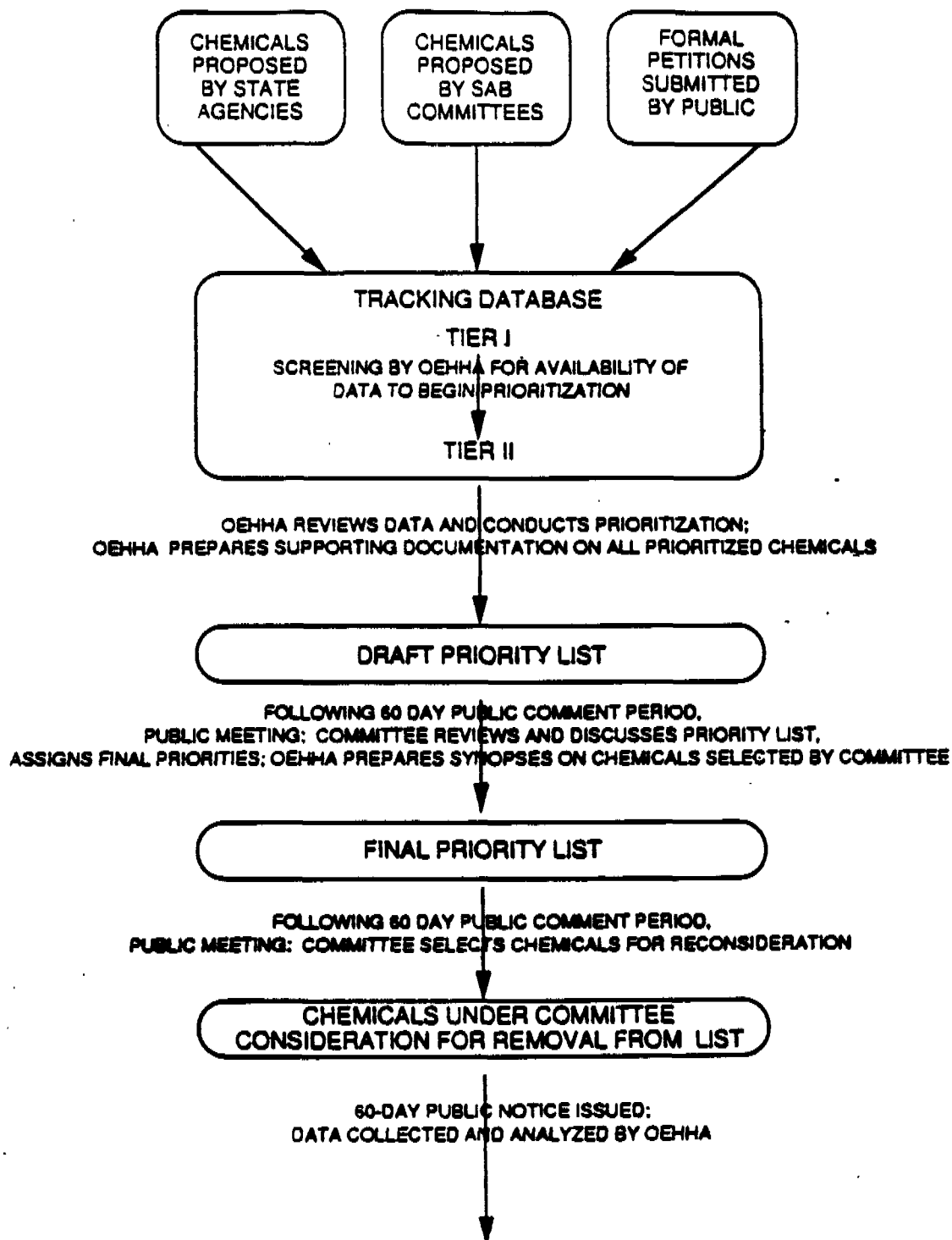


FIGURE 1: FLOWCHART FOR RECONSIDERATION OF LISTED CHEMICALS UNDER PROPOSITION 65 (CONT'D)

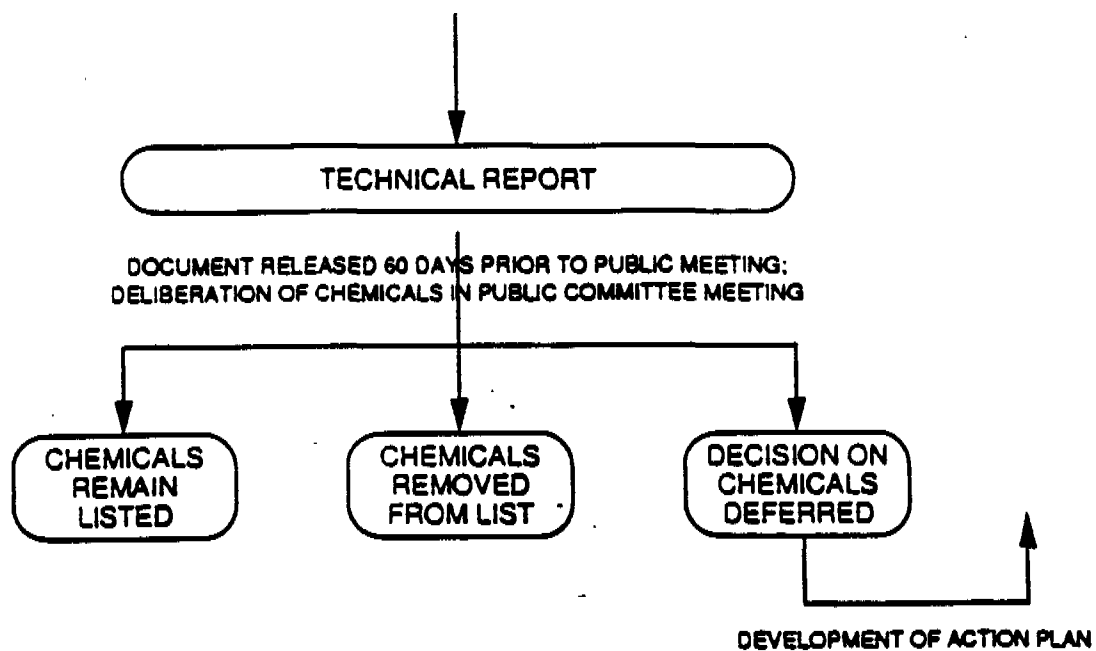
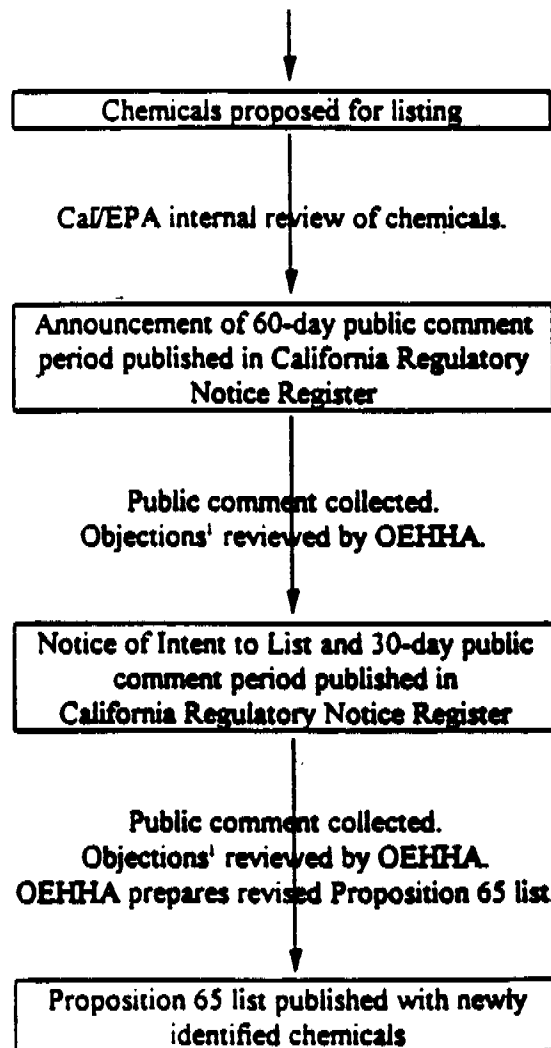


FIGURE 2: LISTING PROCESS FOR CHEMICALS FORMALLY IDENTIFIED AS CARCINOGENS OR DARTs BY PROPOSITION 65 AUTHORITATIVE BODIES

OEHHA monitors publications and databases of the five authoritative bodies (US EPA, IARC, NTP, NIOSH, FDA), reviews data and prepares package on chemicals that meet the listing criteria in Title 22, CCR, Section 12306.



¹ Per Title 22, CCR, Section 12306, "Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection (e) or subsection (g) have been satisfied."