

**SUMMARY OF PUBLIC COMMENTS RECEIVED ON THE
MAY 2004 DRAFT PRIORITIZATION PROCESS**

**Office of Environmental Health Hazard Assessment
September 2004**

No.	COMMENTS AND/OR SUGGESTIONS	PROPOSED CHANGES
1	<p>New process provides less opportunities for public input; eliminates public workshop.</p> <p align="right"><i>Commenters 1 and 5</i></p>	<p>No change proposed. There are still two opportunities for public comments provided during prioritization of chemicals as was provided in 1997 version. Workshops have been poorly attended and yielded few oral comments. [In 1997 – 2 oral commenters; 1999 and 2003 – 4 oral commenters. All but one oral commenter also submitted written comments.]</p>
2	<p>Standards for initial exposure screening of chemicals are not clear; they are too loose and subjective.</p> <p align="right"><i>Commenter 1</i></p>	<p>Clarified further in document (page 6). Examples of initial screening provided.</p>
3	<p>Initially focusing on epidemiological data may exclude many chemicals of serious concern due to the paucity of such data. Suggest that epidemiological studies be interpreted very generally and conservatively in terms of public health.</p> <p align="right"><i>Commenter 3</i></p>	<p>Comment noted and will be transmitted to the Subcommittee to consider when advising OEHHA on the nature of the epidemiology and other screens.</p>
4	<p>Initial toxicity evaluations are not clear; too subjective, possibly arbitrary and represent a less scientific approach than existing process. The references to the consideration of both positive and negative studies as well as genotoxic studies are removed.</p> <p align="right"><i>Commenters 2, 4, and 5</i></p>	<p>Clarified further in document (page 7).</p>
5	<p>Maternal toxicity should be considered in the evaluation of reproductive toxicological effects.</p> <p align="right"><i>Commenters 1 and 4</i></p>	<p>Clarified further in document (page 7). Based upon the U.S. EPA guidelines for reproductive toxicity risk assessment.</p>
6	<p>Mechanistic data used to determine relevance of animal studies to human only when OEHHA finds it compelling.</p> <p align="right"><i>Commenters 1 and 5</i></p>	<p>Clarified further in document (page 7). OEHHA will determine the sufficiency of evidence by scientific review of the data.</p>
7	<p>Committees are not required to consider public comments.</p> <p align="right"><i>Commenter 1</i></p>	<p>Clarified further in document (page 8).</p>
8	<p>Unrestricted discretion provided to the Director to abbreviate or modify process when necessary. OEHHA does not pledge to adhere to revisions in process.</p> <p align="right"><i>Commenters 1 and 5</i></p>	<p>No changes proposed. Director has always had broad discretion. Process is not a regulation and is not subject to the provisions of the Administrative Procedure Act.</p>

9	Recognition (lower priority assignment) should be given to certain categories of chemicals, such as pharmaceuticals, because they are subject to regulation by U.S. Food and Drug Administration and consideration should be given to FDA's findings. <i>Commenter 2</i>	Findings of the U.S. Food and Drug Administration for drugs will be taken into account in the process, as described on page 10.
10	Listing process is hindered because the Committees meet infrequently and consider so few chemicals. Suggest expediting process by eliminating the data call-in step; limiting the hazard identification document to the minimum toxicological information necessary; and streamlining the prioritization process. <i>Commenter 3</i>	No changes proposed. Concerns surround suggestions for improvement in the listing process, which is separate from the prioritization process. OEHHA will take the suggestions under advisement.
11	Process may become cumbersome, time-consuming, and resource-intensive. May be more costly in staff resources and time. <i>Commenter 3 and 5</i>	Proposed revisions to the process are expected to streamline the process and result in higher quality candidates for listing consideration.
12	Process lacks stated goals and benchmarks for how many chemicals will be prioritized over what time period. <i>Commenter 3</i>	No changes proposed. Unable to project a number and timeframe because of the wide variety of chemicals within the tracking database.
13	Removed mechanism for public petitions for abbreviated listing procedure. <i>Commenter 3</i>	Clarified further in document (page 4 and 10).
14	Process does not identify mechanism by which chemicals are entered into the tracking database. <i>Commenter 4</i>	Clarified further in document (page 4).
15	Process implies that committee members may independently suggest chemicals for consideration outside of the prioritization process. <i>Commenter 4</i>	No changes proposed. Committee members are the appointed state's qualified experts and as such OEHHA seeks their advice and opinion in order to carry out the mandates of Proposition 65.
16	Less consistent with the statute's "clearly shown" standard. OEHHA should maintain or increase its standards for level of toxicity evidence. <i>Commenter 5</i>	No changes proposed. Listing process is separate issue from the consideration under prioritization. Document continues to state that the Committees will deliberate on whether the chemical has been clearly shown to cause cancer or reproductive toxicity (page 10.)
17	Inconsistent with the statute's and Committee's identification of authoritative bodies (AB). AB opinions should be considered in the prioritization process. <i>Commenter 5</i>	Clarified further in document (page 7).

18	<p>Revisions to the current process unnecessary. Chemicals with uncomplicated toxicological profiles have already been considered. Those chemicals requiring a more rigorous evaluation remain and should follow the current process not the less thorough approach proposed.</p> <p style="text-align: right;"><i>Commenter 5</i></p>	<p>Carcinogen Identification Committee (CIC) noted deficiencies in the current prioritization process and at its December 2002 meeting asked OEHHA to develop an alternative process to address the deficiencies.</p>
19	<p>Involving the Committees in prioritization decisions contradicts prior Committee decision in July 1996.</p> <p style="text-align: right;"><i>Commenter 5</i></p>	<p>At its December 2002 meeting the CIC asked OEHHA to re-visit the current prioritization process. These revisions are agreed upon and proposed by the subcommittee.</p>

Commenter 1 - Dan Fuchs, Livingston & Mattesich

Commenter 2 - Robert Reinhard

Commenter 3 - Michael Schmitz, California League for Environmental Enforcement Now

Commenter 4 - Scott D. Kumpf, Nutraceutical Corporation

Commenter 5 - Kristin Power, Grocery Manufacturers of America