

**Comments on Proposed Revisions**  
**To the Proposition 65**  
**Prioritization Procedure**

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Submitted by

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Proposition 65 is a law concerning chemicals that have been “clearly shown” to cause cancer or reproductive toxicity. The Proposition 65 Prioritization Procedure, therefore, must respect the legal and scientific guidance in Proposition 65.

The May 2004 proposed revisions to the Prioritization Procedure should not be adopted because they are (i) less scientific, (ii) less open and transparent, (iii) less consistent with the statute’s “clearly shown” standard, (iv) inconsistent with the statute’s and the committees’ identification of authoritative bodies, (v) more costly in staff and committee resources, and (vi) unnecessary. Finally, the proposed revisions contradict prior expert panel input.

#### **I. The Proposed Revisions Are Less Scientific**

The existing Prioritization Procedure, adopted in May of 1997 (“Existing Procedure”), contains 45 lines of appropriate scientific guidance concerning the determinations that govern whether a chemical will be assigned a “high” priority for Committee review.<sup>1</sup> In contrast, the proposed revisions to the procedure released in May 2004 as an “Update” (“Proposed Revisions”) contain a mere 12 lines concerning prioritization determinations. Indeed, the Proposed Revisions merely note that “overall evidence” and “relevant information” will be considered “as appropriate.” A side-by-side comparison is instructive:

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<sup>1</sup> Sections 4.3.1 and 4.3.2 describe the “Basis for Assignment of Priorities” and “Level of Hazard Concern,” respectively. These sections contain 45 lines of text. See Existing Procedure at pp. 8-9.

<b>Existing Procedure (May 1997)</b>	<b>Proposed Revisions (May 2004)</b>
<p>“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.”</p>	<p>“[T]he overall evidence of carcinogenicity or reproductive toxicity of the chemical would be considered, including epidemiologic, animal bioassay, and other relevant information, as appropriate.”</p>
<p>“<i>Epidemiological studies:</i> 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.”</p>	<p>No discussion</p>
<p>“<i>Animal studies:</i> 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.”</p>	<p>No discussion</p>
<p>“<i>Other relevant data:</i> 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.”</p>	<p>“Adverse developmental effects that co-occur with maternal toxicity, and reproductive effects that co-occur with systemic toxicity would be considered evidence of reproductive toxicity unless these toxicities are so severe as to preclude interpretation of the study (U.S. E.P.A. 1991, 1996). In animal data evaluations, effects would be assumed to be relevant to humans, unless OEHHA determines there is compelling evidence to the contrary.”</p>
<p>“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.”</p>	<p>“This preliminary overall evaluation could be based on original research articles, or literature compilations or reviews.”</p>

The Proposed Revisions remove at least three important and valid generally accepted scientific principles from the prioritization procedure. First, the Proposed Revisions make no allowance for changing a prioritization evaluation based upon new information. Considering and responding to new information is a fundamental principle of scientific evaluation that should not be removed from the Prioritization Procedure. Second, the Existing Procedure clearly states several times that “Both positive and negative studies will be considered in assessing the overall level of hazard concern.” This statement has been removed in the Proposed Revisions. Third, scientists agree that genotoxic chemicals generally pose a more significant cancer concern than non-genotoxic chemicals, yet this consideration noted in the Existing Procedure also is removed in the Proposed Revisions.

The Proposed Revisions also specifically de-emphasize two considerations important to any hazard assessment, even a preliminary one, contrary to generally accepted scientific principles. The Proposed Revisions wrongly limit the relevance of maternal toxicity and systemic toxicity to circumstances where those conditions “preclude interpretation of the study.” In contrast, toxicologists generally agree that maternal toxicity and systemic toxicity observed at levels, which are significant, but which do not preclude interpretation of the study, should be weighed in an overall assessment of the level of toxicological concern.

Rather than assess and weigh all the appropriate evidence concerning whether animal data is relevant to humans, OEHHA proposes to only consider mechanistic information when it is “compelling.” Although science sometimes produces

“compelling” data, one more often finds that scientists describe important data in more mild terms. There is no basis to ignore important data that does not rise to the artificially high level of being “compelling.”

## **II. The Proposed Revisions are Less Open and Less Transparent**

The Proposed Revisions are much shorter, much less specific, and provide for less public input. All of these changes undermine the openness and transparency that OEHHA normally describes as an important aspect of its operations. Furthermore, OEHHA does not even pledge to adhere to the Proposed Revisions if they are adopted, instead providing an unrestricted statement that the Director may “modify” the new procedure “when necessary.” In contrast, the Existing Procedure only may be modified in limited circumstances upon a finding that doing so would advance public health.

OEHHA began drafting the Existing Procedure in early 1994 after recognizing that its process was not sufficiently open, predictable and objective. More than three years later, after substantial public input and deliberation, OEHHA adopted the Existing Procedure in May 1997. The Proposed Revisions contain less than half the content of the Existing Procedure (11 double-spaced pages compared with 14 single-spaced pages) and virtually no details concerning how OEHHA will act. The Existing Procedure provides for a workshop on particularly complicated issues that may arise in prioritization, whereas the Proposed Revisions eliminate this opportunity for public input.

A more open and more detailed procedure enhances the final determination by facilitating the exchange of data and analyses. This phenomenon consistently was recognized by OEHHA during the three years of drafting the Existing Procedure, which should be maintained.

### **III. The Proposed Revisions Depart From Proposition 65's "Clearly Shown" Standard for Listing Chemicals**

The core responsibility of the Identification Committees is to express their scientific opinions concerning whether certain chemicals have been "clearly shown" to cause cancer or reproductive toxicity. Proposition 65 provides:

"A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity."

Cal. Health & Safety Code § 25249.8(b).

Neither the purpose of the Identification Committees nor the purpose of Proposition 65 is served by having the Identification Committees review chemicals that do not have a reasonably strong chance of meeting the statute's "clearly shown" standard. Thus, the Existing Procedure states "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." The Proposed Revisions would remove this standard from the procedure and thus should be expected to provide less filtering of the chemicals reviewed by the Identification Committees than the Existing Procedure. The Identification Committees reviewed seven high priority chemicals during the prior four years, but only two of those seven were found to satisfy the clearly shown standard.<sup>2</sup> This low yield rate indicates that OEHHA should maintain or *increase* its standards for

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<sup>2</sup> The Identification Committees reviewed a number of other chemicals during this period through OEHHA's procedure for referring certain chemicals considered by authoritative bodies. See 22 CCR § 12306(i).

the level of toxicological evidence warranting submission to the Committees, not remove the standard entirely.

#### **IV. The Proposed Revisions Wrongly Disregard Authoritative Body Analyses**

Whereas the Existing Procedure provides that OEHHA will address the evaluations of bodies considered authoritative, the Proposed Revisions disregard such evaluations. It makes no sense to identify certain organizations to be “authoritative” for the purpose of identifying carcinogens and reproductive toxicants and to then not even address their evaluations during the prioritization process. The opinions of CERHR, IARC, NIOSH, NTP, USEPA and USFDA are equally “authoritative” whether they conclude that a chemical is a carcinogen or they conclude it is not. These opinions certainly should be addressed as part of the prioritization process. Any other approach would conflict directly with the actions identifying these bodies as authoritative and would waste State resources because the authoritative body’s investment of resources in chemical evaluation would be ignored. Since certain actions by some of the authoritative bodies also can preempt the application of Proposition 65, as recently confirmed by the California Supreme Court, attention to actions by authoritative bodies early in the process conserves resources by avoiding the expenditure of scarce resources on action that would be preempted.

#### **V. Prioritization Revisions Are Not an Effective Use of Resources**

OEHHA deliberated upon the Existing Procedure for over three years. The record of those deliberations is replete with comments that OEHHA should utilize its resources to examine substance, not process. Now that sound procedures are in place for the prioritization of chemicals in a manner consistent with the statute, these comments are

ever more apropos. There simply is no need for OEHHA to revise the existing prioritization process.

The Proposed Revisions provide for a less detailed, less thorough evaluation that does not account for the views of authoritative bodies. It also provides for no reevaluation of prioritization determinations. Thus, chemicals assigned a “high” priority pursuant to the Proposed Revisions would undergo the preparation of a Hazard Identification Document and would be reviewed by a Committee even if further analysis or subsequent information revealed that the chemical did not have a strong and biologically plausible potential to cause cancer or reproductive toxicity. This inevitable submission of high priority chemicals to the Identification Committees, regardless of the information that comes to light after the initial prioritization, will result in a waste of resources by “going through the motions” for chemicals that do not satisfy the statute’s rigorous “clearly shown” standard. Furthermore, this waste of resources would appear to be a frequent risk because the Proposed Revisions specifically defer any review of complicated issues until after prioritization and eliminate the “tiered” evaluation approach of the Existing Procedure.

The Existing Procedure provides that OEHHA will spend less time on the prioritization of chemicals with straightforward toxicological evidence and more time on the chemicals that present more complicated issues: “[T]he 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.” Since this time must be spent in the analysis of a chemical in any event before the chemical is presented to an Identification Committee, it makes sense to devote enough resources during the prioritization stage to confirm that a chemical truly warrants a “high” priority designation. To do otherwise inevitably will result in the analysis after the prioritization demonstrating that some (or many) chemicals do not warrant submission to the Identification Committee, with no prospect for saving staff and Committee time by avoiding that outcome.

#### **VI. The Proposed Revisions Are Unnecessary**

Proposition 65 now regulates over 750 different chemical exposures. This vast list of regulated chemicals is well beyond the number of chemicals envisioned to be covered by the law when it was passed. The original chair of the Scientific Advisory Panel, Dr. Wendell Kilgore, said in December 1987, “I expect that there will probably be approximately 300 compounds eventually on our list.” (SAP Transcript December 11, 1987, page 164). At this stage of Proposition 65 implementation, it should be expected that the high exposure chemicals with uncomplicated toxicological profiles already have been considered. The chemicals that remain for possible evaluation warrant the more rigorous evaluation called for by the Existing Procedure, not the less thorough approach in the Proposed Revisions.

#### **VII. The Proposed Revisions Contradict Prior Expert Panel Input**

The Proposed Revisions contemplate review of draft prioritization decisions by the Carcinogen Identification Committee, with public comment. The Carcinogen Identification Committee unanimously rejected this proposal in 1996. This unexplained, total reversal of approach reveals that the Proposed Revisions do not account properly for

the substantial Committee and public comments that were dedicated to prioritization issues from 1994 through 1996.

The July 1996 meeting agenda for the CIC included that Committee's approval of draft priorities assigned by OEHHA for various chemicals. The Committee unanimously refused to do so. The OEHHA Director asked: "Does the Committee concur with the priorities that have been assigned at this time?" (p. 67). Chairman Mack responded:

"I'm going to rephrase that question. The question really is: Does the Committee want to get into a discussion of the relative merits of individual chemicals in the prioritization process?"

"I, obviously, rephrase it that way because it's a fairly significant decision if we wanted to do that. It would be a substantial commitment of time, particularly since there is going to be no prioritization which makes everybody happy. I would dare say that doesn't just refer to the stakeholder community. It refers even to the Committee.

"These are arbitrary judgments and they're going to be contentious, so it would mean a substantial commitment of time in reviewing data, which is going to have to be reviewed anyway when we get hazard documents."

(Tr. at 67-68).

Dr. Peters, another member of the CIC, immediately concurred:

"It was my understanding that we had been constituted to review the scientific processes that were gone through and to make sure that they made scientific sense, at least to us.

“And that, in pursuit of that, we would be reviewing work done by the State in preparing things for making decisions, but that being involved in specific individual chemicals from the, you know, grassroots up was not a role that I thought was meant for us, nor one that I want.”

(Tr. at 68).

The discussion concluded with a unanimous indication from the Committee that it did not want to be involved in reviewing prioritization determinations, that was OEHHA’s role:

“CHAIRMAN MACK: Anybody else wish to address the issue?

“Are we unanimous then in wishing not to get into individual chemical considerations in the prioritization process? All right. I would not think a motion is required.

“Next question.”

(Tr. at 68-69).

### **VIII. Conclusion**

For the reasons described above, OEHHA should withdraw or take no action on the “Update – May, 2004 Draft” Prioritization Procedure. OEHHA should maintain the May 1997 Prioritization Procedure that was duly adopted after extensive public comment and public hearing.