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DATE
December 11, 2006

TO
Bob Barish
Division of Occupational Safety and Health
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FROM
Barbara Kanegsberg
Surface Quality Resource Center

SUBJECT
Comments and Suggestions to *"Policy and Procedure for the Advisory Committee Process for Permissible Exposure Limit (PEL) Updates to Title 8, Section 5155, Airborne Contaminants"*

Overview and General Comments
We applaud the efforts of DOSH in developing a technology-based, robust, and protective policy and procedure for the advisory committee process for Permissible Exposure Level (PEL). We have reviewed the document (Draft Version #3 on Updates to Title 8, Section 5155, distributed on 12/06); and, based on our experience, we are providing comments that are concerned with assuring that the PEL process is efficient, effective, protective of workers, and supportable.

The PEL-setting process must be comprehensive, transparent, realistic, balanced, and supportable or PEL's may be ignored or overturned. To achieve this, the regulated community must be involved. We are concerned about the position of the FRAC, specifically by wording that would marginalize or eliminate meaningful input by the FRAC. Given time and budgetary constraints, not all data can be generated by public agencies and by academia; we fail to see how the process can proceed effectively without treating industry as a resource and a participant.

Looking at PEL's without considering the consequences to industry will be detrimental to workers because, in our experience, industry will play the numbers game**.** That is, if one chemical has a higher OEL number than another, there is an automatic tendency to use the one with the higher number, even if the supposedly "safer" chemical has a poorly-documented OEL and even if that chemical will be used in such a manner that higher worker exposure will result. In addition, there is a tendency to prefer chemicals with no stated OEL's to those with known OEL's; often a mixture of such chemicals is used. This further complicates the worker exposure

profile and may actually result in increased hazards to workers. Ignoring the input of the regulated community will exacerbate this problem.

While some data may be used from agencies concerned with neighborhood and/or global environmental issues, simply adapting or adopting results from OEHHA or EPA will not result in productive, defensible PEL's. Certainly, the extensive literature resources available through OEHHA should be valuable in PEL development; but they must be reviewed through the perspective of worker safety concerns. Instead, emphasis should be placed on input from those involved directly with worker safety and with practical industrial experience.

California is considered to be a leader in worker safety concerns. The PEL's developed in California are likely to have wide geographical adoption and also might be expected to be open to greater scrutiny by the regulated community.

SQRC is providing comments in support of development of effective, sustainable PEL's. We wish to thank James Unmack for his input and review. For clarity, we have interpolated our comments within the body of the document using the following system:

Suggested rewording is in the Geneva font, in blue.
Rationale is in the Geneva font, in green.

About SQRC
Surface Quality Resource Center is a non-profit (501c3) organization. The SQRC mission includes education and outreach to industry and to communities impacted by industrial activities as well as development of practical, environmentally-preferred industrial processes. (http://www.sqrc.org)

About Barbara Kanegsberg, President SQRC
My comments are based on more than three decades of experience that includes biology, biochemistry, clinical chemistry, and industrial process development. I also have a private consultancy, BFK Solutions LLC, and have been involved in minimizing impact to workers and the environment throughout the U.S. and in other countries. This has allowed me to observe an array of industry practices.

I have had experience working with a wide range of industrial and military applications such as metals, composites, motion picture film, optics, and implantable medical devices. I am a member of the ASTM F04.15.17 committee, concerned with residue on implantable medical devices. I am a proud recipient of a U.S. EPA Stratospheric Ozone protection award. I led the team charged with finding appropriate alternatives to CFCs at Litton Industries (now Northrop Grumman). I am co-editor of and contributor to "Handbook for Critical Cleaning," Kanegsberg and Kanegsberg, CRC Press, 2001. I am also a member of the Joint Services Solvent Substitution Working Group (JS3WG), involved with developing safer, environmentally-sound processes for use throughout the military.

Draft with specific comments:
DRAFT Version #3 distributed on 12/06. [Strikeout & underline changes reflect changes from previous 7/06 Draft #2 version.]

Policy and Procedure for the Advisory Committee Process for Permissible Exposure Limit (PEL) Updates to Title 8, Section 5155, Airborne Contaminants

AUTHORITY: California Labor Code Section 144.6

POLICY:
It is the policy of the Division of Occupational Safety and Health to periodically update the list of Permissible Exposure Limits in Title 8, section 5155, with the assistance of an advisory committee of relevant health experts and the public.

PROCEDURES:
This document provides an outline of the process that will be used by the Division to develop proposals for new or revised Permissible Exposure Limits (PELs). Primarily a ~~two~~ three part advisory committee process is used to assist Division staff in developing rulemaking proposals to add new substances or revise existing substances listed in Section 5155, Airborne Contaminants. A technical expert advisory committee (TEAC) will be used to review the scientific literature and recommend a new or revised ~~airborne concentration or Permissible Exposure Limit~~ PEL to protect the health of employees. The recommended PEL from that technical expert advisory committee will then be considered by a second feasibility and reasonableness advisory committee (FRAC) that will evaluate the technical and economic feasibility issues for each recommended PEL. The selection of substances, composition and procedures of all these advisory committees should adhere to the following three steps to ensure that the resulting rulemaking will be reasonable and effectively protect California employees:

I. Selection of substances for review that includes an initial advisory meeting

II. Technical Expert Advisory Committee

III. Feasibility and Reasonableness Advisory Committee

Note: On occasion the Division ~~may~~ will develop a PEL recommendation using a separate substance-specific advisory committee process where there is a high level of controversy or other factors which necessitate ~~that the Division~~ deviation from the ~~two~~ three part process outlined in this policy and procedure.

I. SELECTION OF SUBSTANCES FOR REVIEW

A. Developing a prioritized list of substances for review.

Prior to the formation of the advisory committee, Division staff will develop a list of existing and new section 5155 airborne contaminant substances to be reviewed for possible inclusion or updating in Table AC-1 of Section 5155. The development of the list of substances to be considered will at a minimum include the following sources:

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

1. New or revised occupational exposure limits (OELs) from nationally recognized professional associations or governmental agencies. The OELs to be considered include Threshold Limit Values (TLVs) of the American Conference of Governmental Industrial Hygienists (ACGIH), workplace environmental exposure limits (WEELs) of the American Industrial Hygiene Association (AIHA), recommended exposure limits of the National Institute of Occupational Safety and Health (NIOSH), and reference exposure levels of the Office of Environmental Health Hazard Assessment (OEHHA).

Suggested addition, 1

OEL's from private, industrial, military, or international agencies may also be considered. Determination of the potential validity of new or revised occupational exposure limits (OEL's) includes transparency of the decision-making process, public availability of reports, quality of the data, and public availability of peer-reviewed supporting data.

Rationale:

Utilizing OELS from nationally recognized organizations may result in an unintended, skewed approach to setting limits. While many national organizations have provided valuable tools for worker protection, the decision-making process, rational, and technical details have not always been available publicly.

In some instances, OEL's are determined by individual companies in a very public, transparent, peer-reviewed manner. Such data should not be ignored, because the OEL may be set by an individual company prior to consideration by any organization or agency.

Suggested action and rewording:

Delete ...and reference exposure levels of the Office of Environmental Health Hazard Assessment (OEHHA).

Add

2. Findings and/or petition decisions from appropriate California, national, or international agencies may be considered. Examples include new or revised environmental/community safety limits or levels from agencies such as the U.S. Environmental Protection Agency (EPA) or reference exposure levels of the Office of Environmental Health Hazard Assessment (OEHHA).

Rationale:

OEL's for chemicals developed by trade groups or governmental agencies involved in workplace exposure limits should be considered separately from

OEL's set by groups concerned with environmental issues. Certainly, it is important that regulations governing employee safety, community health, and environment health be coordinated to avoid conflicts and so that they are enforceable. However, an assessment that involved environmental and community impacts of a given chemical may not be optimal or even appropriate to a seemingly similar analysis to assess worker safety for that same chemical. Therefore, it is suggested that reference levels set by the Office of Environmental Health Hazard Assessment (OEHHA) and by other groups concerned with impact on community health and/or on the environment be treated separately.

Additional relevant resources need to be added to improve and expedite the evaluation process. However, attempting to "rubber-stamp" the findings of OEHHA, a group involved in community safety, and then to attempt to extrapolate those findings to worker safety would be a vastly inferior system to that which is currently present. It would result in a system that would be justifiably open to criticism by both industry and by those involved in worker safety.

2. Form 9 requests and other internal recommendations for consideration from Division, Standards Board and Appeals Board staff.

3. Petition decisions granted by the Cal/OSHA Standards Board and other requests from the public or other governmental agencies such as the Department of Health Services and OEHHA.

B. Division staff will prioritize the list of substances for consideration by the advisory committee based on the following considerations:

1. Evidence of a serious potential hazard not adequately addressed by existing regulations of the Division or other governmental agency.

2. A substantial change in the value of an OEL that could contribute to increased protection of workers if adhered to by employers.

Suggested rewording:

A modification in the OEL could contribute to increased protection of workers, if adhered to by employers.

Rationale:

The OEL should reflect current research findings. Very occasionally, it is found that an increased OEL is appropriate. Such flexibility is important for worker safety in that appropriate options should not be

eliminated based on out of date findings that have been determined to be erroneous.

3. The degree to which exposure to the substance in California is, or may become, widespread and potentially hazardous.

Suggested rewording:
The degree to which exposure to the substance in California is, or may become, widespread *among the workforce* and *exhibits a strong potential for use in a potentially hazardous manner.*

Rationale:
The suggested wording provides a more practical perspective.

4. The seriousness of the hazard presented by the substance. For example a substance with apparent potential for cancer or reproductive effects would generally lead to that substance receiving a higher priority for consideration than a substance where the major hazard potential was mild respiratory irritation.

Suggested rewording:
.... with apparent potential for **acute**, cancer or reproductive effects ....

Suggested additional wording

5. When a new OEL for a given chemical is to be considered, the OEL's for similar chemicals or chemicals with similar properties should be reviewed at the same time. Chemicals with low current usage but with potential future utility may be considered.

Rationale:
Let us assume that Chemical A is under consideration. Industry could also use Chemical B, C, or D. Chemical B might have extensive public toxicity studies along with an historic OEL; chemicals C and D might have only very short term inhalation studies with no OEL. It would be unreasonable and misleading to workers for the advisory committee to set an exceedingly low level for chemical A without setting some proportionally appropriate OEL or guidance for chemicals B, C, or D. This is important in that over the years, we constantly run into the problem of industry adopting inadequately-studied chemicals because inhalation studies have not been performed or are not disclosed (to the public or even to regulatory agencies) by the manufacturer.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

~~Management of the entire PEL updating process~~. It is anticipated that some substances ~~of relatively low priority~~ deemed by the Division to warrant revision but involving little controversy or technical difficulty may be considered by the committee, and possibly included in a proposal to the Standards Board, along with others of higher priority and greater difficulty, in order to manage the workload of the PEL Advisory Committee and Division staff.

C. An initial advisory meeting will be held to review the entire list of substances to be considered.

The list and prioritization of substances developed by Division staff, as noted in section I. B. above, will be discussed at an initial public meeting. This list will include a brief justification for the priority given to each substance as well as an estimate, or estimates, of the number of substances anticipated to be developed for PELs over defined periods of time

~~The Division will develop a tentative list of substances for review based on the criteria detailed above, timeframes planned for completion, and staff resources available. The list developed will then be discussed at an initial meeting.~~ Interested parties as well as prospective members of the TEAC and FRAC will be invited to participate in this meeting. The Division will use this initial meeting to review procedures and priorities, determine if any substances need to be removed or added to the list, and determine if any substances should be sent to a separate substance specific advisory committee process. At this meeting the date and location of the first meeting of the TEAC will be announced.

After this initial meeting, the Division will distribute the minutes and establish the final list of substances for review by the TEAC. The FRAC meetings will begin later when the TEAC has developed a sufficient number of recommendations for the Division to consider and prepare the supporting documentation.

II. ROLE AND SELECTION OF THE TECHNICAL EXPERT ADVISORY COMMITTEE

A. The role of the TEAC

The role of the technical expert advisory committee is to recommend health-based exposure levels for hazardous substances to the Division for development as a possible proposal to the Cal/OSHA Standards Board. The members do this by applying their expertise to the evaluation of scientific evidence regarding the health hazard posed by a substance. In addition, the members, as needed, apply their expertise to defining and refining the process by which scientific evidence is evaluated and recommendations are reached.

Suggested addition:
A normative, standard protocol (or guideline) for evaluating data will be developed by the initial TEAC and by staff. This is an overview document, anticipated to be approximately 20 to 36 pages. The document will be published; it may be updated based on advances in SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

technology or analytical tools. This protocol may involve flow sheets to be followed in subsequent evaluations. The TEAC will follow this guidance document. Where deviations from the guidance document are required, the rationale will be indicated.

Rationale:
The development of a guidance protocol is critical. Certainly, developing a standard protocol takes some up-front design effort (and will probably require some heated discussions. If appropriately-developed, such a protocol will render the evaluation process more even-handed and more transparent, and, in the long run, more rapid. The PEL's so established would also be more defensible.

One example is "Air Toxic Hot Spots Risk Assessment Guidelines, The Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments," August, 2003 (Cal EPA and OEHHA). Flow diagrams such as Figure 1, "Overview of the Air Dispersion Modeling Process" (4-2) are useful in tracking the progress of complex analyses.

A second example from a different but applicable field is ISO 10993-17, a normative standard to evaluate the potential toxicity of leachable residue from medical devices. The standard is basically an enormous decision tree. It provides a framework for developing risk factors for the range of processing materials that are used in manufacturing medical devices; any of the materials might be a source of undesirable residue. Based on our experience, the standard does not hamstring individuals involved in making difficult decisions; it is not a substitute for common sense. Rather, it is proving helpful to device manufacturers who have to evaluate and minimize an array of potential residues in a manner that is protective of patients and supportable to the FDA.

We are by no means suggesting that the ISO standard or any of the OEHHA documents be adopted or even adapted; neither is appropriate for PEL development. We are suggesting that a document using an analogous approach to that developed as ISO 10997-17 or as "Air Toxic Hot Spots ...." will streamline the process of setting PEL's and will make the process more accessible, transparent, and defensible.

We also suggest that the document be kept to a workable size. Exceedingly long documents (hundreds of pages) become difficult to follow. Based on response to ISO 10993-17, we suggest no more than three dozen pages, preferably 20 pages.

B. Selection of technical expert advisory committee members.

The Division will seek technical experts from other state agencies, academic institutions, professional associations, industry and employer associations, unions and other labor organizations, and other interested groups.

1. Areas of expertise. The Division's experience is that the committee functions best when it includes at least two each of the following disciplines:

Toxicology (Ph.D. level preferred)
Epidemiology (Ph.D. level preferred)
Occupational medicine (M.D. level required)
Industrial hygiene (M.S. or M.P.H. level and CIH preferred)

Members may have more than one area of expertise and can be relied upon to fill more than one of the above desired disciplines. For example, an occupational physician may also satisfy the toxicology or epidemiology area if they have sufficient experience in those disciplines as well. Greater weight will be given to a prospective committee-member's demonstrated specific expertise in an area of study or endeavor directly relevant to the PEL development process, such as quantitative risk assessment, than to their particular academic degree.

Suggested rewording:

Toxicology
Epidemiology
Occupational medicine
Industrial Hygiene

Factors to be considered include
expertise in relevant field(s) in:
level and quality of education
pertinent, practical, industry-related experience
publications (peer reviewed preferred)
respect by peers

Rationale:

With all due respect of the effort involved in producing a dissertation or in completing medical school, California may be excluding the best people to evaluate PEL's by the educational restrictions.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

Additional suggested wording:

In matters deemed urgent, professional or contracted staff may be employed to expedite the process. Individuals should be selected based on their technical and practical expertise in worker safety issues.

Rationale:

While OEHHA will be a valuable resource, the expertise is in community and environmental issues. The focus of staff developing the PEL's must be on worker safety.

2. The size of the committees. Generally the committee has functioned effectively with between 5 and 8 regularly attending members. When the numbers get larger than this the time spent on communications and arriving at acceptable meeting times becomes excessive. Generally at least 4 or 5 members would need to be present at a meeting in order to make a recommendation for a PEL. However, the process is rather informal. If there are only 3 attendees at a meeting and they agree that a recommendation can be made, it can be subsequently reviewed by other members and if there are disagreements discussed further at a future meeting. Generally, given the work that goes into arranging meetings, and the staff time that will be taken to prepare for them, a committee meeting would not be canceled for lack of attendance unless fewer than 3 committee members were able to attend.

Suggested rewording:

At least 5 people must attend the TEAC meetings; meetings conducted via teleconference, video conference, or web conference are acceptable alternatives to on-site meetings.

Rationale:

We owe the workers of California no less than full input and consideration of data by the TEAC. Evaluation of toxicological studies is complex; and it is often properly and appropriately contentious. There is no substitute for face-to-face frank, spirited discussions. Simultaneity is essential; evaluation by three people is not adequate. Asking committee members to approve recommendations sent out by mail does not allow adequate input into the process. It would be far too tempting to rubber-stamp the report.

At the same time, this is a volunteer committee. Travel budgets may be limited; and scheduling conflicts may arise. In our experience, it is possible to communicate with several people on the phone and the others around a conference table or office desk.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

3. Process to select members. The Division staff identifies potential candidates through the following types of sources:

a. Recommendations of past committee members.

b. Recommendations of local experts in the field sought who are unable to participate themselves

c. Recommendations of interested parties, including labor, trade and employer organizations, who wish to have their perspectives included in the committee's deliberations but recognize that members serve as impartial experts evaluating scientific studies and not as representatives of particular interests.

Suggested rewording:
In 3c, delete wording "... who wish to have their perspectives included ..... and not as representatives of particular interests."

Instead we suggest the following wording to be placed prior to 3a:
All TEAC members are expected to recognize that members serve as impartial experts evaluating scientific studies and not as representatives or opponents of particular interests.

Rationale:
A general statement regarding bias and professionalism is more respectful of all committee members. In our experience, we have observed opinionated and biased individuals from the academic, private, military, *and* public sectors.

Additional comments:
We are concerned about what be best thought of as analogous to the issue of experience versus term limits, of new blood versus the "old boys club" (of whatever gender). We do not have a complete answer to this problem. However, in point "IIB3b" perhaps local, national, and international experts might be tapped for suggestions as to new members.

Committee members who are selected will be asked to serve a minimum of 2 years. It is anticipated that the committee will meeting every other month and members will be expected to review a significant amount of scientific literature and summary information in preparation for each meeting. Committee members should also declare any conflicts of interest that may affect

their participation and if a conflict does arise for certain substances, the individual will be excused from participation in meetings where there is a conflict. The Division may need to select replacement or alternate members if the selected members are unable to attend or participate regularly.

C. Staff participation and support of the committee.

The Division staff will chair committee meetings and coordinate ~~all~~ technical and logistical support for the committee including performing ~~complete~~ literature reviews, providing copies of key studies, and preparing a summary document of the key scientific recommendations. Board staff will be invited to attend all advisory committee meetings. NIOSH, OEHHA, and OHB/HESIS staff will be invited to provide technical support in preparation for and during all advisory committee meetings.

Prior to each TEAC meeting the Division staff will develop a by-substance summary document that includes disease risk level estimates of relevant acute and chronic health effects such as carcinogenicity and reproductive harm. In developing this by-substance summary document, the Division will research current scientific literature and sources that include government agencies such as NIOSH, OEHHA, the U.S. Environmental Protection Agency (USEPA), and the National Toxicology Program (NTP).

Generally preference will be given in the committee's deliberations to peer reviewed articles published in recognized scientific journals. Consideration may be given to presentations by interested parties and non-published reports where the committee believes they are sufficiently well documented. Relevant documents and briefing summaries will be provided by Division staff to the committee preferably at least six weeks prior to the scheduled meeting. At the meeting staff will brief the committee on these documents. The committee in making a PEL recommendation will strive for a consensus that is both protective of workers and scientifically justified,

Although it is not the primary focus of the TEAC, feasibility considerations can be considered and incorporated into the TEAC's recommendations where staff, committee members or interested parties present relevant facts and opinions. Such facts and opinions can be of value in the subsequent FRAC assessment of feasibility and reasonableness and ultimately to the staff in developing supporting rulemaking documents for the proposed PEL.

Comments regarding paragraphs 2 – 4 (new underlined sections)
We have concerns with the substance-by-substance category document, particularly in that public agency studies and peer-reviewed articles appear to be given equal weight.

Many U.S. EPA and OEHHA analyses have a different emphasis than that needed for worker PEL's in the sense that they are geared to neighborhood and environmental issues. Issues of 24 hour/7 day per week exposures and sensitive populations must be considered.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

Particularly at the Federal level, industry may present data or even data summaries to the agency with the proviso that results not be disclosed to the public. Sometimes there is only voluntary disclosure of toxicological data by industry. The data may not be published; certainly it may not be peer-reviewed. In many cases, findings by public agencies may not be transparent in that the process and documents may not be readily publicly disclosed. Even if a governmental report is published, this publication may not be peer-reviewed. Government agencies do not have the resources to conduct basic research and must often depend on limited information provided by industry. There is value to even limited, unpublished data, particularly when a complete lack of information is the only alternative. However, to equate such results with peer-reviewed data is fallacious and does not well-serve the workers of California and elsewhere.

In paragraph 3, we take issue with the approach used for submission and presentation of non-published results. While some evaluation is necessary, the six week cut-off point is unrealistic. Sometimes, results are not available until shortly before the meeting. For example, we did not have 6 weeks to evaluate this document under consideration.

Also in paragraph 3, where possible, the group submitting relevant data should update the committee; staff should not update the committee. At the very least, an abstract, as submitted by the group doing the research, should be presented directly.

Additional comments regarding 2C:
If substance A is reviewed, it would be prudent to schedule a review of functionally-related substances that might be used as substitutes. This may require extrapolation from historical workplace studies and from other sources that are not published. Because many chemicals, particularly those used in blends, may not have published studies and/or may not have been subject to regulatory scrutiny, the approach used by OEHHA of scrutinizing published data will not yield the necessary information. Additional data and approaches, including expected workplace exposure will need to be considered.

III. ROLE AND SELECTION OF THE FEASIBILITY and REASONABLENESS ADVISORY COMMITTEE

A. The role of the FRAC

The primary role of the Feasibility and Reasonableness Advisory Committee is to provide an opportunity for interested parties to comment informally on feasibility, reasonableness and economic issues related to TEAC recommendations. In this phase of the process comments will be taken in writing, and verbally at a public meeting, with regard to:

1. Technical issues associated with measurements to identify compliance with a TEAC recommended PEL.

2. Technical issues associated with means and methods of control of exposures for compliance with the TEAC recommended PEL.

3. Estimates of the costs associated with achieving and maintaining reliable compliance with the TEAC recommended PELs, and the reasonableness of such costs.

Suggested additional additional FRAC role as IIIA4:

4. Additional technical and worker-safety related consequences of the PEL.

Rationale:

Is it feasible to monitor the workplace at the proposed levels? Will industry simply choose an alternative chemical for which no PEL has been set or for which no inhalation studies have been performed? If so, the TEAC should be informed.

The discussion of the feasibility and reasonableness of costs associated with compliance with the TEAC recommended PEL will be within the context of Labor Code section 144.6:

> 144.6. *In promulgating standards dealing with toxic materials or harmful physical agents, the board shall adopt that standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to a hazard regulated by such standard for the period of his working life. Development of standards under this section shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the reasonableness of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.*

Suggested rewording of above statements:

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

Remove the wording such as “informal” or “informally.” Substitute “advisory” and/or “technical input” and/or “supplemental input.”

Rationale:
We are convinced that the FRAC can serve a valuable role in providing additional input to the TEAC and in providing a form of peer review of the TEAC. A strong, active FRAC will avoid potential allegations that the TEAC might be acting arbitrarily. Ultimately, involving the FRAC will have positive benefits in that the PEL process will be expedited and enforceable, protective rules will be enacted.

We are frankly concerned that the phrase “informal comments” might be construed as being disrespectful. We strongly suggest that the concept and terminology of “informal” comments be removed and that more positive terminology be substituted.

The FRAC will then advise the Division if the recommended health-based PEL is feasible and if not what alternative recommendation would be considered feasible.

In addition to taking and discussing informal comments on the issues noted above, comments on the following topics can also be provided in the FRAC but time will not normally be taken for their discussion in the advisory meeting itself.

Suggested modifications to the previous sentence, delete:
“... but time will not normally be taken for their discussion in the advisory meeting itself.”

Alternative suggested wording:
..... time will be taken for discussion in the advisory meeting itself. If comments provided by the FRAC are judged non-substantive, a brief written rationale will be provided by the TEAC.

Rationale:
The current wording allows the TEAC to largely ignore any substantive input of the FRAC. There is the potential that such statements could be perceived as inherently unresponsive; and this could retard the PEL process. Even more important, potentially important data could be ignored.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

1. Clarity of the supporting documentation for the TEAC recommendation.

2. Comments on the health-basis of the TEAC PEL recommendations

~~2. The complexity of measuring the airborne concentration of the substance at, and reasonably below, the PEL being proposed. A factor in this would be the degree to which the substance is stable and does not have multiple chemical forms which complicate the measurement process~~.

~~3. Information on costs for California workplaces to comply with the TEAC recommended PEL.~~

Note: Interested parties will have the opportunity to present written and verbal comments on all aspects of the PEL proposal during this advisory process and ultimately in the formal rulemaking process.

B. Selection of FRAC ~~feasibility advisory committee~~ members.

Once the TEAC has reached its recommendation for a particular substance or group of substances, Division staff will convene a FRAC that is composed of representatives of affected industry and labor groups along with technical experts and TEAC members. The meeting will ~~be conducted as a traditional advisory committee in order to~~ provide an opportunity for FRAC members and all interested parties to comment and provide information on the technical and economic feasibility and reasonableness of the TEAC's recommendation.

Suggested modification:
The FRAC will be convened during the TEAC process, prior to issuance of recommendations.

Rationale:
The FRAC will add value to the PEL process. Convening the FRAC only AFTER the TEAC recommendation is developed inappropriately reduces the FRAC to an ineffective, marginalized status and deprives the TEAC of a much-needed resource.

C. Staff participation and support of the committee.

The Division with the assistance of Board staff will chair the FRAC and coordinate ~~all~~ technical and logistical support for the committee. The TEAC recommendations for new or revised PELs along with supporting documentation will be posted on the Division's website and provided as handouts at the meeting. The Division will also work to obtain technical and economic data as outlined in section III A. and make it available to the extent reasonably possible, in at least summary form.. ~~A. along with the additional information below. Board staff will be invited to attend all advisory committee meetings.~~ NIOSH, OEHHA, OHB/HESIS and other agency staff

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

will be invited to provide technical support in preparation for and during all advisory committee meetings.

Suggested modification, paragraph 1:
Delete the final sentence.

Substitute:
Related agency staff will be invited to provide relevant technical, advisory support.

Rationale:
The TEAC should have the flexibility of inviting other agencies to participate. It may be pertinent to request input from non-local agencies as well. OEHHA is likely be a valuable resource in terms of studies and literature; but it is crucial that the studies be reviewed from the perspective of worker safety concerns.

~~As needed for the purpose of developing rulemaking documents, Division staff will attempt to obtain the following information and~~

The Division will also attempt to obtain information on the following for briefing at the FRAC:

1. Estimates of the extent of exposure to the substance in California in terms of numbers of employees exposed, numbers of locations where exposures may occur, etc.

2. The types of industries and operations where the substance is used.

~~3. The measures in place or available, to control employee exposures to the hazardous substance~~

~~4. Information on chemical handling practices, including spill prevention and control measures, and their association with particular levels of exposure.~~

~~5. The results of air sampling conducted to assess employee exposures to the hazardous substance, including the numbers and percentages of employees at different levels of exposure.~~

~~6. Air sampling results associated with different operations and exposure control measures.~~

~~7. To the extent it is available, information on incidents of employee injury or illness related to exposure to the hazardous substance.~~

Suggest: Restore 3 to 7. This appears to be potentially valuable information.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

IV. ADDITIONAL ADVISORY COMMITTEE PROCESS ISSUES

A. Public notice and interested party involvement.

At least six weeks prior to all advisory meetings specified by sections I, II, and III, Division staff will send out an agenda, to all committee members and interested parties with the items/substances to be discussed and any supporting documentation that is available. These agendas along with the list of substances, meeting minutes, by-substance summaries and results of the previous meetings will be posted on the Division's 5155 advisory committee website as soon as the documents are available.

The meetings are open to the public and noticed via email, web postings and announced at Cal/OSHA advisory committee and other appropriate public forums. Interested parties are encouraged to attend committee meetings and to participate to the extent that they have factual information to share. In the past some interested parties have requested to make presentations to the committee relevant to the process of recommending a PEL. Such presentations will be allowed to the extent they are respectful of the committee's limited time and voluntary status, and that they are factual and provide references for assertions that can be shared publicly.

Suggested addition to preceding paragraph:

To better obtain technical input from industry, in addition to email and web postings, we suggest that staff will compile a list of relevant trade journals and submit meeting notices to them.

Suggest delete:

> to the extent that they have factual information to share. In the past some interested parties have requested to make presentations to the committee relevant to the process of recommending a PEL. Such presentations will be allowed to the extent they are respectful of the committee's limited time and voluntary status, and that they are factual and provide references for assertions that can be shared publicly.

Rationale:

Many journals have on-line, email, and website presence. Many engineers and chemists do not read government websites; they will peruse the technical journals, either in print or online.

The indicated portion of the paragraph should be eliminated; it could be construed as being demeaning and insulting to the public. In our professional activities, we have encountered challenging, vexing individuals in all walks of life. In our experience, even employees of public agencies, even those with impressive technical backgrounds, are not immune from making the occasional biased, unsupported, irrational statements.

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

Statements about relevance, professionalism, and lack of bias should be general. Perhaps make such a statement one time, early on in the document and not connected to any particular sector.

1. **Identifying and notifying interested parties.** The Division will maintain a list of interested parties for the PEL process and send out e-mail announcements of each meeting at least 6 weeks before it is scheduled to take place. This notice will also announce the substances the committee is scheduled to discuss.

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The Division will also attempt to contact labor, employer, trade, and professional organizations which it believes may have members with an interest in particular substances under consideration. Where for a particular substance no such organization can be identified or effectively contacted the Division will attempt to identify and contact a sample of individual potentially interested parties, usually a manufacturer or user of the particular substance, and inform them of the occurrence of the meeting and enlist their assistance in the process of informing other potentially interested parties of the meeting.

Suggested modification:
Eliminate the word "attempt".

Substitute:
The Division will take reasonable steps to contact .....

Rationale:
Attempt sounds tentative. It would be more supportable to list the outreach approaches that will be used. Perhaps this would be a reasonable point to list articles in magazines, newsletters, ezines, etc.

2. **Web posting of notices and meeting materials.** Recognizing the limitations of e-mail, and the desire of some interested parties to maintain ongoing involvement with the process, the Division will also maintain in its advisory committee web area a list of the substances anticipated to be considered by the advisory committee over its current multi-year process, along with information on the new or revised TLV or other event which led to its consideration. At this web area the Division will also post the notice for the latest upcoming meeting and, to the extent possible, tentative schedules and agendas for future meetings.

As part of the list of substances under consideration noted above, the Division will post recommendations of the committee as they develop along with the date of the meeting at which the recommendation was made and the dates of any other meetings at which the substance was discussed. By-substance documentation of the recommendations, primarily in the form of minutes and reference listings, will also be posted~~, along with minutes of discussion of the particular substance.~~

SQRC Comments and suggested rewording to 5155 Draft (in Geneva font, colorized).

For a variety of reasons the Division is not in a position to post on its website, or copy and mail out upon request, documents that may be referred to in the discussions of the committee. Where a reference used by the committee is publicly available on the Internet and is central to the committee's recommendation the Division will attempt to include a hyperlink to it (or at least an abstract) in the minutes or elsewhere in the PEL web area.

B. ~~Committee consideration of relevant science and feasibility documents.~~

~~Generally preference will be given in the committee's deliberations to peer reviewed articles published in recognized scientific journals. Consideration may be given to presentations by interested parties and non-published reports where the committee believes they are sufficiently well documented. Relevant documents and briefing summaries shall be provided by Division staff to the committee preferably at least 6 weeks prior to the scheduled meeting. At the meeting staff will brief the committee on these documents. The committee in making a PEL recommendation will strive for a consensus that protect California workers exposed to the substance over a working lifetime.~~

~~Cost and feasibility considerations may be incorporated into the committee's recommendations where staff, committee members or interested parties present relevant facts and opinions which can be included in the meeting minutes, or provided in writing. Such facts and opinions can be of value in the subsequent assessment of costs and feasibility for the committee's recommendations. Even if no discussion of cost or feasibility occurs during the committee meeting, the Division will continuously be in the process of gathering such information specific to California should the committee recommendation result in a proposed new or revised PEL.~~

~~C.~~ Supplemental need to consider cost, feasibility or California unique issues

Before, during and after the committee deliberates the Division staff will gather information relevant to cost, feasibility or California unique uses of the substance as it relates to a proposed new or revised PEL. Even if no discussion of cost or feasibility occurs during the FRAC, the Division will continuously be in the process of gathering such information specific to California should the committee recommendation result in a proposed new or revised PEL.