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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:

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

~~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.

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.

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.

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.

Committee members who are selected will be asked to serve a minimum of 2 years. It is anticipated that the committee will meet 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.

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.

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.

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.

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.

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

~~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.~~

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.

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.

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.

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.~~

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.