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 a three-step advisory committee process seeking the input of relevant health experts, feasibility experts, interested parties, 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) for airborne contaminants. Primarily a 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 health expert advisory committee (HEAC) will be used to review the scientific literature and, where it deems there is sufficient scientific evidence, recommend a new or revised PEL to protect the health of employees. The recommended PEL from the HEAC will then be considered by a feasibility advisory committee (FAC) that will evaluate technical and economic feasibility issues for each PEL recommended by the HEAC.

The selection of substances, and the composition and procedures of these advisory committees will generally adhere to the following three steps to ensure that the resulting rulemaking will be technically and economically feasible and will effectively protect California employees:

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

II. Health Expert Advisory Committee (HEAC)

III. Feasibility Advisory Committee (FAC)

Note: On occasion, the Division may develop a proposed PEL using a separate substance-specific advisory committee process when this appears warranted due to unusually widespread interest or controversy. Interested parties and experts will be invited to participate if and when such a substance-specific advisory process is utilized.

Underlying the process described in this Policy & Procedure is a commitment by the Division to transparency and active facilitation of participation by interested parties. The specific means that will be used to accomplish these goals are additionally described in section IV of this document.

I. SELECTION OF SUBSTANCES FOR REVIEW

A. Developing a prioritized list of substances for review.

Prior to the formation of the HEAC and FAC, 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 and internationally recognized professional associations and governmental agencies. Examples of OELs that will 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), along with OELs derived from reference exposure levels and Proposition 65 listings of the Office of Environmental Health Hazard Assessment (OEHHA) and the U.S. Environmental Protection Agency.

2. Cal/OSHA "Form 9" requests and other internal recommendations for new or revised standards from Division, Standards Board and Appeals Board staff.

3. Petition decisions granted by the Cal/OSHA Standards Board; and

4. 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 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 a substance is in widespread use in California or to which there are other indications of pervasive and potentially hazardous worker exposure to the substance.

4. The seriousness of the the nature of the health hazard presented by the substance. For example, substances with apparent potential for cancer, reproductive, developmental, or sensitizing effects would generally receive a higher priority for consideration than substances where the major hazard potential is mild respiratory irritation.

5. The potential for exposure in California (#3) in combination with the degree of hazard (#4). For example, a limited exposure to a highly toxic substance may be just as significant as widespread exposure to a less toxic substance.

Note: The Division will generally work to move substances through the process and on to the Standards Board in the approximate order of their priority established through the initial meeting process. However, this general order of work will not preclude lower priority substances from being processed simultaneously with higher priority substances.

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 will be discussed at an initial advisory meeting. This list will include a brief justification for the priority given to each substance which may include the following types of information:

1. A brief description of the human health effects of the substance, including the type of effect (*e.g.*, carcinogenicity, sensitization, irritation) and a qualitative assessment of the seriousness of the hazard.

2. The availability of occupational exposure limits for the substance, or other regulatory levels such as reference exposure levels.

3. 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.

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

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

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

7. 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.

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

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

10. A qualitative summary of the seriousness of the health hazard in combination with the potential for exposure in California.

Interested parties as well as prospective members of the HEAC and FAC will be invited to participate in this meeting. The Division will use this initial meeting to:

1. Review procedures and substance priorities,
2. Receive comments on whether any substances should be removed or added to the list, or have its priority on the list revised,
3. Receive comments on whether any substances should be sent to a separate substance-specific advisory committee process. and
4. Set the date and location of the first meeting of the HEAC.

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

II. ROLE AND SELECTION OF THE HEALTH EXPERT ADVISORY COMMITTEE

A. The role of the HEAC

The role of the Health Expert Advisory Committee is to consider the need and scientific basis for recommending to the Division new or revised health-based exposure levels for airborne contaminants. In

evaluating the scientific literature HEAC will use a "weight-of-evidence" approach rather than attempt to evaluate all existing scientific evidence relevant to a particular substance.

Where the committee finds there is sufficient scientific evidence, its role is to recommend new or revised PELs for airborne contaminants that, consistent with Labor Code 144.6, will most adequately assure that no employee will suffer material impairment of health or functional capacity even with regular occupational exposure to the substances for the period of a working life.

The HEAC will consider all aspects of Permissible Exposure Limits, including time-weighted average exposure limits (TWAs), short-term exposure limits (STELs), ceiling limits, skin notations, and special footnote provisions for additional information. The HEAC will also inform the Division when it believes that a comprehensive standard for a carcinogen or reproductive hazard is warranted, but will not work on developing such a standard.

At its initial meeting, the HEAC will review and determine the process it will use to make its assessments, reach decisions, and document their rationale. Generally this will involve the HEAC reviewing the process used in the preceding round of meetings, deciding whether to use that or another process, and detailing the administrative mechanics of implementing the process with the assistance of Division staff. At this meeting, the HEAC will also decide upon the format of a decision template to facilitate transparent reporting of the results of the committee's deliberations. The decision template will summarize in a consistent format the scientific evidence evaluated by the committee for each substance, the committee's assessment of the conclusions and validity of such evidence, and the study or studies upon which the committee's recommended PEL, if any, is based. The decision template and other documentation including minutes, will strive to illuminate the levels of risk associated with different levels of exposure, including the current PEL and any PEL revision recommended by HEAC.

B. Selection of HEAC members.

For membership on the HEAC, the Division will seek experts from other state agencies, academic institutions, professional associations, and other interested groups. HEAC members will be expected to disclose fully any organization they represent or affiliations they have which might be a source of bias. However, they will also be expected to serve on the committee to the best of their ability as neutral technical experts.

1. Areas of expertise. The Division's experience is that the committee functions best when it includes at least two members from 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 bring to the committee more than one area of expertise and may 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 committee. For the committee to function effectively, the Division will attempt to appoint and maintain eight regularly attending members and four alternate members.

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

a. Recommendations of past committee members.

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

c. Recommendations from relevant professional associations.

d. Applications and recommendations from interested parties and the public.

Expectations of HEAC members and alternates. 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. Where a committee member, for whatever reason, is unable to reliably participate in committee meetings, the Division will select an alternate member to serve as a replacement or appoint a new member if no alternate is available. To facilitate maximum HEAC member attendance, the Division will consider multi-location meeting tools such as video conferencing.

HEAC decision process. The HEAC is convened as an expert advisory group to provide technical assistance in reviewing relevant information from the health sciences with respect to possible PEL revisions. Its purpose is to make recommendations so that the Division can make the best informed decision it reasonably can. In light of this, the Division believes it is most appropriate that the HEAC operate primarily on a consensus-based decision-making model. In those instances where consensus cannot be achieved, the minutes will clearly reflect the different points of view of the members and the evidence behind those points of view.

C. Staff participation and support of the committee.

Division staff will chair committee meetings and coordinate technical and logistical support for the committee including performing literature reviews, providing copies of key studies, and preparing a summary document of the key scientific findings and recommendations of the HEAC. Standards Board staff will be invited to attend all advisory committee meetings. OHB/HESIS staff will be invited to provide technical support in preparation for and during all advisory committee meetings, and to coordinate technical input from other agencies, such as OEHHA or NIOSH.

Prior to each HEAC meeting Division staff will develop a by-substance summary document that includes brief summaries of disease risk level estimates of relevant acute and chronic health effects such as carcinogenicity and reproductive harm, available occupational exposure limits from other agencies, and risk-based estimates for occupational exposure limits, if appropriate. In developing this by-substance summary document, the Division will research current scientific literature and secondary sources that include government agencies such as NIOSH, OEHHA, the U.S. Environmental Protection Agency (USEPA),the National Toxicology Program (NTP) and other sources, such as ACGIH. Recommendations and studies of private industry, the military, and international organizations may also be used as reference sources. The HEAC will discuss with Division staff on an ongoing basis the most efficient and productive approaches to generating these documents.

Generally preference will be given in the committee's deliberations to peer-reviewed articles published in recognized scientific journals. Other studies, such as industry-sponsored studies or other unpublished reports, will be considered if they are relevant, sufficiently well documented, and submitted in a timely fashion.

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 Division 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.

Decision Template. Division staff will work with the HEAC to complete a decision template to be produced for each substance evaluated. It is anticipated that the template will consist of a tabular summary of the scientific evidence evaluated for each substance, and a narrative describing how the evidence was weighed by the committee, and upon which study or studies the recommended PEL, if any, for the substance is based. The decision template, along with by-substance minutes of committee deliberations, will constitute the documentary product to be produced for each substance reviewed.

Time frames and production expectations. Based upon past Division experience working with an expert advisory committee for PELs meeting six times per year, it is anticipated that the HEAC will be able to review between 12 and 20 substances per year. This expectation will be affected by such factors as the technical difficulty or controversy surrounding the particular substances under review, as well as the capability of Division staff to provide the bulk of relevant references to the committee early in its deliberations on each substance.

III. ROLE AND SELECTION OF THE FEASIBILITY ADVISORY COMMITTEE

A. The role of the FAC

The Feasibility Advisory Committee provides an opportunity for interested parties to comment in an informal process prior to formal rulemaking on technical and economic feasibility of HEAC-recommended PELs**.** The primary function of the FAC is to determine whether, and if so how, a PEL proposed by HEAC should be modified based on feasibility issues. In this phase of the process, comments will be taken in writing prior to the FAC meeting and verbally at public meetings, with regard to:

1. Technical issues associated with making measurements to identify compliance.

2. Technical issues associated with means and methods of control of exposures for compliance.

3. Estimates of the costs associated with achieving and maintaining reliable compliance and the reasonableness of imposing such costs.

The discussion of technical and economic feasibility issues associated with compliance with the HEAC-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.

Note: The primary function of the HEAC is to arrive at proposed PELs by considering health impacts alone, and the primary function of the FAC is to help the Division determine whether a PEL proposed by HEAC should be modified based on feasibility issues. To keep this process on track, the Division will ensure that the meetings are chaired in a manner that focuses discussion on the mission of the particular committee and generally avoids digression into areas that are outside the scope of the committee. However, the Division recognizes that limited discussion of feasibility issues during the HEAC process and of health issues during the FAC process may be needed to facilitate adequate perspective, and will allow such discussion as needed to accomplish the overall objectives of both committees.

B. Selection of FAC members.

Once the HEAC has reached its recommendation for a particular substance or group of substances, Division staff will convene a FAC with representatives invited from affected industry and labor groups and individuals with expertise in relevant technical areas such as ventilation engineering, industrial hygiene chemistry, engineering economics. HEAC members may choose to participate as FAC members. The meeting will provide an opportunity for members and all interested parties to comment and provide information on the technical and economic feasibility of HEAC recommendations.

FAC decision process. The FAC is convened to advise the Division with respect to technical and economic feasibility so that the Division can make the best informed decision it reasonably can. In light of this, the Division believes it is most appropriate to strive for consensus recommendations from the FAC. In those instances where consensus cannot be achieved, the minutes will clearly reflect the different points of view and the evidence behind those points of view.

C. Staff participation and support of the committee.

The Division with the assistance of Board staff will chair the FAC and coordinate technical and logistical support for the committee. The HEAC 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. NIOSH, OEHHA, OHB/HESIS and other agency staff will be invited to provide technical support in preparation for and during all FAC meetings.

To open the discussion of each substance at the FAC meeting, the Division will present a summary of information produced from previous discussions on the substance under consideration.

Time frames and production expectations. The goal for the FAC is that it process HEAC recommendations at about the same pace as they are generated. The Division will pursue the goal of holding FAC meetings for HEAC recommendations not later than six months after they are generated, consistent with the time required for Division staff to develop the information needed for each substance for the FAC process to be effective.

IV. ADDITIONAL ADVISORY COMMITTEE PROCEDURES

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 briefings at Cal/OSHA Advisory Committee meetings 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, are factual, and provide supporting references 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.

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Through interested parties, the Internet, and other available sources, the Division will work to identify and contact labor, employer, trade, and professional organizations that it believes may have members with an interest in particular substances under consideration. When dealing with a particular substance for which no such organization can be readily identified or effectively contacted, the Division will work with more general organizations, e.g., the California Labor Federation or the California Chamber of Commerce, to attempt to find directly affected organizations.

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 HEAC 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 HEAC and FAC meetings 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 HEAC and FAC 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. A by-substance

documentation of the recommendations, primarily in the form of minutes and the decision template will also be posted.

For a variety of reasons, including copyright and logistical limitations, the Division is not in a position to post on its website, or copy and mail out upon request, all 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. Rulemaking documents. In developing the draft Initial Statement of Reasons for submission to the Standards Board for each proposed PEL amendment, the Division will develop and provide:

1. The occupational exposure level, if any, associated with the original inclusion of the substance on the HEAC agenda such as the ACGIH TLV, AIHA WEEL, or the NIOSH REL, or the limit derived from the OEHHA, U.S. EPA or other sources. In addition to the original source OEL, the document will detail other occupational exposure limits from nationally or internationally recognized organizations that may be of interest to the Board and the interested public.

2. The health based exposure limit recommended by the HEAC and a summary of the basis for the recommendation.

3. Findings of the FAC with regard to the HEAC recommendation and, where the FAC modifies the HEAC recommendation, the basis in terms of technical and economic feasibility for the FAC recommendation.

4. The basis for the Division's draft proposed PEL for each substance where it differs from the FAC or HEAC recommendation and, if deemed necessary in the face of recognized controversy or substantial uncertainty, elaboration on why the Division chose the FAC recommendation, the HEAC recommendation, or another level.