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Juliann Sum, Chief

April 27, 2015

OSHA Docket Office
Docket No. OSHA-2012-0023
U. S. Department of Labor, Room N-2625
200 Constitution Avenue, N.W.
Washington, DC 20210

Dear Occupational Safety and Health Administration:

California Labor Code Section 144.6 requires that California standards for toxic materials, to the extent feasible, assure that no employee suffer material impairment of health. To that end, the Cal/OSHA program over the years has made more or less consistent efforts to review and update its listing of Permissible Exposure Limit values. Between 2000 and 2014, the California OSHA program has adopted new or lowered PELs for approximately 115 chemicals and has also adopted a comprehensive standard covering another chemical (diacetyl) and its analogs.

These far-reaching changes to PELs were accomplished via interaction between voluntary committees of experts and stakeholders, Cal/OSHA headquarters staff (Cal/OSHA) and the independent California Occupational Safety and Health Standards Board. Stakeholders provided input at both the public meetings of several iterations of advisory committees initiated by Cal/OSHA and later at public hearings conducted by the Occupational Safety and Health Standards Board after concrete proposed changes to PELs were formalized and submitted to the Board by Cal/OSHA. Formal proposals from Cal/OSHA to the Occupational Safety and Health Standards Board were made only after thorough review of existing published scientific studies on health endpoints had been completed, and only after feasibility issues were evaluated. Especially in earlier years, many of the PELs adopted by Occupational Safety and Health Standards Board relied in part on independent evaluations of the documentation supporting ACGIH TLVs as well as presentations and additional documentation provided by interested parties (such as chemical producers). In contrast to the 1980s or 1990s, in recent years, the form and function of these several advisory committees on permissible chemical airborne concentrations has evolved to rely less exclusively on ACGIH TLV documentation as starting and ending point for recommendations. Recent PEL recommendations proposed to the Occupational Safety and Health Standards Board tend to incorporate more quantitative analysis and broader use of toxicological models than was the case previously.

This experience may be relevant to several of the questions federal OSHA has asked in its Request for Information on Chemical Management and Permissible Exposure Limits, Docket No. OSHA 2012 – 0023.

Question IV.A.1: OSHA seeks input on the risk assessment process described above. When is a model-based analysis necessary or appropriate to determine significance of risk and to select a new or revised PEL? When should simpler approaches be employed? Are there specific approaches OSHA should consider using when a model-based analysis is not required? To the extent possible, please provide detailed explanation and examples of situations when a model-based risk analysis is or is not necessary to determine significance of risk and to develop a new standard.

In recent years Cal/OSHA has increasingly utilized risk assessment models where there is sufficient evidence to develop numerical PELs values. Cal/OSHA does not develop the models itself, but has relied on the risk

assessments done by organizations that have a well-developed risk assessment process, including scientific peer review. The US EPA IRIS database, which is developed through risk assessment modeling, is one example of a resource Cal/OSHA's advisory committees have utilized as a basis for recommending PELs for adoption to Cal/OSHA and the Occupational Safety and Health Standards Board. California EPA Office of Environmental Health Hazard Assessment (OEHHA) acute and chronic reference levels [<http://www.oehha.ca.gov/air/Allrels.html>], after adjustment for occupational exposure, are another source of risk assessment based data upon which Cal/OSHA has relied. The OEHHA reference levels are adopted only after approval from a formal scientific review panel.

Pursuant to the California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Prop (proposition) 65"), OEHHA also researches and creates a list of chemicals known to the state to cause cancer or reproductive toxicity. Decisions to add chemicals to this list, and the risk assessment models employed to make those decisions are also peer reviewed. Cal/OSHA has relied upon the Prop 65 list to both identify chemicals to review and to help develop PELs.

Cal/OSHA developed its comprehensive standard on diacetyl and other butter flavorings relying partially on the CFD-PBPK model for diacetyl developed by NIOSH scientists John Morris and Ann Hubbs. The Occupational Safety and Health Standards Board adopted this regulation in 2010 (<http://www.dir.ca.gov/oshsb/Diacetyl.html>).

Currently the Division is evaluating an OEHHA updated PBPK model relating airborne lead exposure to worker blood lead exposure. The PBPK model was commissioned by the California Department of Health, and is being studied by the Division for possible consideration by a public advisory committee working on revising the PEL for lead. The PBPK model allows air concentrations of lead to be related to discrete health effects.

Question IV.A.2: If there is no OSHA PEL for a particular substance used in your facility, does your company/firm develop and/or use internal occupational exposure limits (OELs)? If so, what is the basis and process for establishing the OEL? Do you use an authoritative source, or do you conduct a risk assessment? If so, what sources and risk assessment approaches are applied? What criteria do facilities/firms consider when deciding which authoritative source to use? For example, is rigorous scientific peer review of the OEL an important factor? Is transparency of how the OEL was developed important?

Cal/OSHA relies on the OELs and risk assessments performed by other organizations to inform and guide our PEL adoption process. The National Toxicology Program (NTP), International Agency for Research on Cancer (IARC), ACGIH and the Prop 65 list are among authoritative sources Cal/OSHA has relied upon. All of these sources have rigorous scientific peer review procedures. The recommendations of these organizations are developed via transparent mechanisms. In its PEL review process, Cal/OSHA favors consideration of those risk assessments made pursuant to explicit and consistent guidelines with limitations of the assessment clearly stated and with the assessment's results and conclusions independently reviewed. Many of the PELs adopted by Occupational Safety and Health Standards Board relied in part on independent evaluations of the documentation supporting ACGIH TLVs as well as presentations and additional documentation provided by interested parties (such as chemical producers). Recommendations of Cal/OSHA's advisory committees were made on the basis of consensus.

Question IV.A.3: OSHA is considering greater reliance on peer-reviewed toxicological evaluations by other Federal agencies, such as NIOSH, EPA, ATSDR, NIEHS and NTP for hazard identification and dose-response analysis in the observed range. What advantages and disadvantages would result from this approach and could it be used in support of the PEL update process?

Given our agency mandate to protect worker health, it is not appropriate to waste time by waiting for perfect human epidemiology or recapitulating scientifically sound risk assessments made by reputable organizations. Therefore Cal/OSHA supports reliance on the peer-reviewed work of other Federal agencies. Cal/OSHA also supports reliance on the peer-reviewed work of other reputable organizations that are not Federal agencies, such as, but not necessarily limited to, IARC and California's OEHHA. The only disadvantage to this approach might be the possibility of misunderstanding the assumptions incorporated into such analyses. For example, it is sometimes necessary to make adjustments of a dose response relationship for the general population to an estimate fitting OSHA's target population, workers.

Question IV.A.4: OSHA is considering using the Point of Departure (POD) (e.g., BMD, LOAEL, NOAEL), commonly employed by other authoritative organizations for carrying out non-cancer risk assessments as a suitable descriptor of the Low End Toxicity Exposure (LETE) level that represents a significant risk of harm. Is this an appropriate application of the POD by OSHA? Are there other exposure values that OSHA should consider for its LETE?

Cal/OSHA has at one time or another utilized all the types of POD mentioned as basis for new PELs. Cal/OSHA believes that when sufficient data exists, these methods should be utilized. Health conservative assumptions and corrective factors often need to be applied before the appropriate POD can be chosen.

Question IV.A.5: Several methodologies have been utilized to adjust critical study exposures to a worker equivalent under representative occupational exposure conditions including standard ventilation rates, allometric scaling, and toxicokinetic modeling. What are reasonable and acceptable methods to determine worker equivalent exposure concentrations, especially from studies in animals or other experimental systems?

Cal/OSHA has developed PELs by calculating worker equivalent occupational exposures from 24 hour a day environmental estimates to the standard working week of 40 hours. Only carefully evaluated models should be used to determine worker equivalent exposure concentrations. Whatever methodologies are chosen, they must be explicitly transparent and carefully designed to provide health protective results. For example, the healthy worker effect should not be over-estimated when reproductive and developmental effects are the health endpoint being considered. Recent epigenetic findings illustrate that in some cases effects of chemical exposures that are not mutagenic can still be passed on to future generations. Caution must also be taken to avoid over-reliance on models where data may be insufficient or lacking in transparency, as is sometimes the case with proprietary industry data.

Question IV.A.6: OSHA is considering a Margin of Exposure approach that compares the LETE with the Lowest Technologically Feasible Exposure (LTFE) as a decision tool for low dose extrapolation. Is this a reasonable means of determining if further low dose extrapolation methods are needed to meet agency significant risk findings? What other approaches should be considered?

This approach should only be utilized with care that the method is defining truly low risk. There needs to be a clear standard protocol, supported by example, which identifies the uncertainty of the extrapolation and default values.

Question IV.A.7: Can the uncertainty factor methodology for extrapolating below the observed range for non-cancer effects be successfully adapted by OSHA to streamline its risk assessment process for the purpose of setting updated PELs? Why or why not? Are there advantages and disadvantages to applying extrapolation factor distributions rather than single uncertainty factor values? Please explain your reasoning.

Cal/OSHA has utilized uncertainty factors in this fashion in adopting new PELs for ethyl benzene and many other chemicals. Examples of how Cal/OSHA has used uncertainty factors are found for specific chemicals on Cal/OSHA's

advisory committee web page [http://www.dir.ca.gov/dosh/DoshReg/5155Meetings_2009.htm .] Uncertainty factor methodology is a valid approach when there is sufficient quantity and quality of data. In the absence of such data policy defined default values consistent with scientific consensus should be utilized.

Question IV.A.8: Are QSAR, read-across, and trend analysis acceptable methods for developing risk assessments for a category of chemicals with similar structural alerts (chemical groupings known to be associated with a particular type of toxic effect, e.g., mutagenicity) or other toxicologically-relevant physicochemical attributes? Why or why not? Are there other suitable approaches?

QSAR should be utilized, but cautiously because the method is difficult to use properly. QSAR works when there exists a strong database of related chemicals, such as for the association of aromatic amines with bladder cancer and the association of isocyanates with respiratory irritation. QSAR is less likely for novel compound assessments where what “similar” means is less defined. Cal/OSHA relied upon scientifically informed chemical structure analysis from NIOSH to extend the scope of its flavoring regulation beyond diacetyl to partially include other artificial butter flavoring, including diacetyl trimer, acetoin, 2,3 pentanedione, 2,3 hexanedione], and 2,3 heptanedione even though animal toxicological and human epidemiologic data had not yet been developed for these substances. Federal OSHA should also consider the utility of the EPA Chemotype Program and European efforts such as REACH and QSAR table software.

Question IV.A.9: How should OSHA utilize the new molecular-based toxicity data, high throughput and computer-based computational approaches being generated on many workplace chemicals and the updated NRC risk-based decision making framework to inform future Agency risk assessments?

These methods work most reliably when strong positive results are the outcome. Such results flag the presence of a health hazard. However, negative results may not always be good indicators that no health effects exist. At this stage of the field, this methodology may help in hazard identification, but its use in dose response estimation is less well validated.

Question IV.B.1: OSHA described how it obtains information necessary to conduct its industry profiles. Are there additional or better sources of information on the industries where exposures are likely, the numbers of workers and current exposure levels that OSHA could use?

In our most recent PEL prioritization process, Cal/OSHA was able to estimate California usage of chemicals from a few local Hazardous Materials Business Plan summary reports that were available electronically from CUPAs. As of 2013 California law mandates that all local Hazardous Materials Business Plans must be available electronically. This should make California chemical usage data much more available and accurate for future PEL review projects. See <http://cers.calepa.ca.gov/business> . It would seem to be a reasonable to research such HMBP data in other states for similar information on a national basis. Another tool Cal/OSHA utilized in prioritizing chemicals for PEL development is the US EPA Toxics Release Inventory *Explorer*. While not an explicit record of chemical exposure, TRI *Explorer* data is at least suggestive of the exposure potential of high usage chemicals.

Question IV.B.7: How can exposure information in REACH be incorporated into OSHA's technological feasibility analysis?

Cal/OSHA supports the use of REACH data, to the extent it becomes publicly available, to help establish the range of possible exposures for particular processes, and also for information on the efficacy and costs of possible process controls. REACH data should not be the sole source relied upon. Together with information from use of models (as

discussed in this section of the RFI) and whatever limited sampling data is available, valid analyses can be performed utilizing REACH data.

Question IV.B.8: To what extent and in what circumstances should OSHA argue that feasibility for a regulatory alternative can be established by proving the feasibility of reducing the highest exposures to the level proposed by that regulatory alternative?

Question IV.B.9: To what extent and in what circumstances can OSHA argue that feasibility for a regulatory alternative can be established by the enforcement of a lower PEL [e.g., the 1989 PEL (See Appendix B)] by an individual state or states?

Question IV.B.10: What are the appropriate criteria that OSHA should use to assess whether control strategies implemented in a process from one industry are applicable to a process from another industry (e.g., similarity of chemicals, type, extent and duration of exposures, similar uses)?

Question IV.B.11: Regardless of the industries involved, are there criteria that OSHA should use to show that control strategies implemented in a process from one operation are applicable to a process from another operation? Please explain.

Establishing appropriately protective health based exposure limits must supersede technical and financial feasibility. It might not be technically or financially feasible to protect workers from a particular chemical via engineering controls, but this does not mean workers should experience chemical exposures that cause serious health consequences. Missing from the discussion on feasibility is the concept that the limits of acceptable health risk should trump realities of chemical usage in which neither feasible engineering controls nor administrative controls are sufficient to protect exposed workers in all circumstances or for all processes. Determination of feasibility must be linked to risk assessment. When unacceptable risk remains after feasible controls have been implemented, respiratory protection must be mandated.

For example in adopting its food flavoring (diacetyl) regulation 8CCR 5197, Cal/OSHA determined that where enclosing processes was not feasible and/or employee exposure exceeded the Reliable Quantitation Limit of the specified analytical method, respiratory protection was required. The health risk [potential permanent lung damage (bronchiolitis obliterans)] was too severe even at exceedingly low levels to not address with respiratory protection. The main industry association FEMA, Flavoring Extract Manufacturing Association, supported this approach during rulemaking. It should be noted that during the rulemaking process, NIOSH was able to demonstrate through development of prototype feasible engineering controls that exposures to diacetyl could be substantially reduced or eliminated for many of the processes in the flavor manufacturing. Yet some processes in the industry still require the use of respiratory protection. Since adoption of the food flavoring regulation, no additional cases of bronchiolitis obliterans have been reported to the California Department of Public Health.

Question IV.B.12: How should OSHA take into consideration the size of a business of facility when determining technological feasibility?

It is the nature of the chemical processes utilized and not the size of the employer entity involved that is relevant to the technological feasibility of operating within the bounds of a PEL. It may be that smaller employers are more likely than larger employers to use technology less successfully to limit chemical emissions, but this is an economic factor related to the structure of an industry, not a technical feasibility-related factor.

Question IV.C.1: Should OSHA consider greater use of process oriented regulations, such as regulations on abrasive blasting, welding, or degreasing, as an approach to health standards? Should such an approach be combined with a control banding approach?

Yes, process oriented regulations provide employers with important guidance on which types of work produce the greatest risk.

Question IV.C.2: Should OSHA consider issuing substance-specific standards in segments as the analysis of a particular process or industry is completed rather than waiting until every process and industry using a substance has been thoroughly analyzed?

It may occasionally be practical to issue standards that address only some of the ways in which a substance is utilized or handled. Cal/OSHA did so in 2008, adopting a Construction Safety Order regulation, "Control of Employee Exposures from Dust-Generating Operations Conducted on Concrete or Masonry Materials."

http://www.dir.ca.gov/Title8/1530_1.html

Question IV.C.3: To what extent and in what circumstances can OSHA argue that feasibility for a regulatory alternative can be established by the enforcement of a lower PEL (e. g., the 1989 PEL) by an individual state or states?

The Division believes that the PELs adopted by Cal/OSHA that are lower than federal OSHA PELs certainly do demonstrate economic and technical feasibility for these regulatory chemical exposure levels. This argument is available to federal OSHA in all circumstances. The argument becomes stronger the longer that a California PEL has been in existence without variance filings or efforts to repeal the lower PEL.

Question IV.C.4: Should OSHA consider providing ranges of costs for industries in situations where even the upper range of the costs would obviously not provide a threat to the existence of competitive structure of an industry?

Question IV.C.5: What peer-reviewed economics literature should OSHA consult when determining whether the competitive structure of an industry would be altered? Are there any instances where an OSHA standard did threaten the existence or competitive structure of an industry? What were they and what is the evidence that an OSHA standard was the origin of the difficulties?

The foundational principle and starting point for OSHA must be protecting workers from the health endpoints of concern. While OSHA should make some attempt to predict economic impacts of a PEL on industry structure, it should not mistakenly overly fetishize what are essentially exercises in divination. [Predictions

The most famous example of predications of industry disaster should a PEL be passed is the case of vinyl chloride. It turned out that industry was able to install engineering controls to control most of the hazard. The fact of the matter is that when the societal need for a particular chemical remains, and there is no substitute for its use, market forces will ensure that important sectors of the affected industry will evolve to provide the necessary protection to the workforce while continuing to use the chemical of concern—often at considerable savings, as was the case in the vinyl chloride example. One thing OSHA can do to ameliorate economic impact of a new PEL is to phase in requirements over a longer period of time, permitting respiratory protection in lieu of engineering controls in some industries for a longer period than the initial effective date of a new PEL. Extending effective dates for engineering control may provide sufficient time for businesses to capitalize the needed improvements. Sometimes more stringent exposure limits drive innovation and technology. This is the process unfolding now in Europe in regard to Hexavalent Chrome plating

operations; new technology is emerging in response to stringent REACH regulations that will take effect in 2017. New electroplating methods are being developed that fully enclose the process; see <http://www.ahc-surface.com/en/surface-treatment/processes/selga-coat%C2%AE-chrome.html> .

Question IV.C.6: Should OSHA consider and encourage substitution and elimination of substances that cause significant risk in workplaces even if such substitution or elimination will eliminate or alter the competitive structure of the industry or industries that produce the hazardous substance?

Yes. California has adopted PELs for several substances whose strong toxicity had resulted in recommendations for substitution by other competent authorities. The California Department of Public Health's Hazard Evaluation System and Information Service (HESIS) issued a Hazard Alert in 2003 recommending substitution for 1-bromopropane due to its neurotoxicity. Substitutes are available for many of the uses of 1-bromopropane, a fact that was relevant to the adoption of a PEL of 5 ppm in 2009. IN 2014, Cal/OSHA adopted a PEL of 1ppm for N-Methylpyrrolidone (NMP), another chemical identified by HESIS as a candidate for substitution, in this case due to its toxic reproductive effects. HESIS has continued to research the use of solvent free substitutes for NMP. The goal of such efforts is precisely reduce societal use of such chemicals, which is consistent with California's Green Chemistry Initiative (Safer Consumer Products law <https://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/>).

Question IV.C.10: What factors should OSHA consider in determining whether a chemical should be part of an overall PELs update or subject to substance-specific rulemaking? Should OSHA consider some application groups for a given chemical as subject to a PELs update rulemaking if some other application groups present feasibility issues that make them inadvisable candidates for a PELs rulemaking?

Substance specific rulemaking should be considered only for those substances with severe effects for which interventions like requiring medical surveillance, specific training and reporting are likely to lead to large reductions in ill workers.

Question V.A.2. How might the information on the properties and toxicity of chemicals generated by CompTox, ToxCast, and/or Tox21 be utilized by employers to identify chemical hazards and protect workers from these hazards? OSHA is also interested to hear from commenters who may currently make use of these data in their worker protection programs.

A limitation to Tox21 data is that the results may not be metabolically competent because cell culture media are utilized to test the chemicals rather than observation of the complex interaction of full body systems in a living animal. Often there can be metabolic potentiation of a chemical by a body system or organ that would not be apparent in a test of a cell based system. While such systems may be useful tools, the obtained results should be judiciously evaluated as incomplete or perhaps falsely negative or positive. Discovery of a clear positive link to a known toxic mechanism via these methods is far more important to take seriously than negative findings resulting from application of these methods.

Question V.A.3: Are QSAR, read-across, and trend analysis useful and acceptable methods for developing hazard information utilizing multiple data sets for a specific group of chemicals?

Yes, these tools can be useful but may not be definitive, as mentioned in our answer to Question IV(A)(8)

Question V.A.8: Should OSHA pursue efforts to obtain data from ECHA that companies are required to provide under REACH?

Yes. Once obtained, as much as possible this information should be made available on a public website.

Question V.B.1: To what extent do you currently consider elimination and substitution for controlling exposures to chemical hazards?

Elimination and substitution were important considerations in Cal/OSHA's adoption of PELs for 1-Bromopropane and N-Methyl-Pyrrolidone. See our answer to Question 1V-6.

Question V.B.2: What approaches would most effectively encourage businesses to consider substitution and adopt safer substitutes?

The California Department of Public Health HESIS program has conducted field tests of the effectiveness of chemical substitutes with contractors. HESIS has had conversations with top management of big box construction supply vendors about carrying substitutes on retail outlet shelves. HESIS has also worked with such vendors to promote point-of-sale educational materials about the availability of effective substitutes for such chemicals as 1-bromopropane, n-hexane, and NMP. Educational efforts to encourage substitutions for PBDE flame retardants would also seem to be a potentially fertile area for OSHA.

Question V.B.5: How could OSHA leverage existing data resources to provide necessary substitution information to businesses?

OSHA should utilize and popularize existing chemical data bases from other states and countries, for example, the California Green Chemistry Initiative. Part of this resource is the comprehensive listing of the California Department of Toxic Substance Control's California Toxics Information Clearinghouse [<http://www.dtsc.ca.gov/scp/tic.cfm> and <http://www.dtsc.ca.gov/SCP/RegInfo.cfm>].

V.B.13.: How might OSHA use voluntary guidance approaches to assist businesses (particularly small businesses) with implementing the principles of hazard banding in their chemical safety plans? Could the GHS chemical classifications be the starting point for a useful voluntary hazard banding scheme? What types of information, tools, or other resources could OSHA provide that would be most effective to assist businesses, unions, and other safety and health stakeholders with operationalizing hazard banding principles in the workplace?

Federal OSHA could provide educational materials as guidance to employers for choosing appropriate control measures for chemicals without OSHA PELs. Part of such guidance could be an expansion of the current annotated PEL tables federal OSHA has on its website [<https://www.osha.gov/dsg/annotatedpels/index.html>] that list some OSHA PELs and the differing (usually lower) limits for these chemicals of ACGIH, Cal/OSHA and NIOSH. This table could be expanded to include chemicals for which federal OSHA does not yet have a PEL but for which these organizations do. While it is true the hyperlinks to the full chemical lists of these organizations are included on the OSHA web page, it would be more useful to publish the complete list of suggested limits in table form, searchable by chemical name. The recommended exposure limits of other organizations or of countries could be added as additional columns.

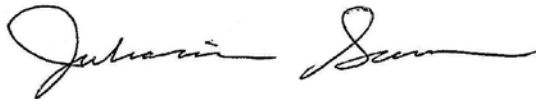
Question V.B.14.: Should OSHA consider greater use of specification standards or guidance as an approach to developing health standards? If so, for what kinds of operations are specification approaches best suited?

No.

Question V.B.15: OSHA requests comment on whether and how task-based exposure control approaches might be effectively used as a regulatory strategy for health standards.

Task-based exposure control approaches are already utilized in some OSHA standards, such as the lead and asbestos standards. Task-based exposure control approaches are most suited for chemical exposures with well-documented significant health endpoints which also have well-documented effective industrial controls available in the marketplace. As mentioned earlier, Cal/OSHA's construction regulation "Control of Employee Exposures from Dust-Generating Operations Conducted on Concrete or Masonry Materials" requires the use of mechanical exhaust ventilation or wet methods to reduce silica exposures from tasks that create dust from concrete and masonry materials. A similar regulation addressing silica hazards could be developed for the general industry sector that manufactures granite countertops. This too is an industry in which the effectiveness of mechanical exhaust ventilation and/or wet methods has been well-documented via numerous Cal/OSHA, OSHA and NIOSH investigations. For example, in one intervention by Cal/OSHA Consultation, a ten-employee granite countertop fabricator was able to reduce task-based silica exposures to as little as 1/20th of pre-intervention levels as high as 11 times the silica PEL. This reduction was accomplished through converting from conventional cutting tools to those that utilize water. The cost was \$50,000, mostly for construction of a water catchment system. The new tools were significantly lighter and easier to use, increasing productivity, and the \$1000 per month cost to repair the dry cutting tools was eliminated. Additionally, the shop was now free of visible dust clouds that previously had made it embarrassing to show the workplace to potential customers.

Sincerely,

A handwritten signature in black ink, appearing to read "Juliann Sum". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Juliann Sum, Chief, Cal/OSHA