

Minutes of Diacetyl/Flavoring Advisory Meeting 3 21 07

Attendees:

<u>NAME</u>	<u>AFFILIATION</u>
Aho, Janet	Mane, Inc.
Barbeau, Aisha	Little Mendelson, PC
Borman, Heather	SCIF
Broyles, Juli	GMA/FPA
D'Amato, Bob	American Safety Institute
Edens, Amanda	Federal OSHA
Falasco, Mike	Wine Institute
Fisher, Marti	CA Chamber of Commerce
Gloriani, Charlene	DOSH Compliance
Gold, D.	Cal/OSHA
Hallagan, John	FEMA
Hogan, Mary Ellen	Holme Roberts&Owen,LLP
Hormigosa, Loren	Federal OSHA
Howard, Kelly	Cal/OSHA
Hrabchak, Rhonda	American Fruits&Flavors
Kochie, Mary	Cal/OSHA
Krasny, Leslie	KH Law
Martin, Amy	DOSH Staff Counsel
Mashayekhi, Azita	Teamsters
Materna, Barbara	Occ Health, CA DHS
McCarrel, Daniel J	Ventura Foods
Neale, Thomas	Chubb
Nowell, Jackie	UFCW
Pearce, Susan	Mckenna, Long&Aldredge
Prudhomme, Janice	Occ Health, CA DHS
Pulliam, Michael	Drinker, Biddle &Reath
Rabinowitz, Bobbie	Worksafe
Rachman, Nancy	GMA/FPA
Reed, Larry	NIOSH
Riley, Peter	DOSH Compliance Mgr.
Roberts, Jennifer	health scientist ChemRisk
Saechao, Kaochoy	UCLA Occ. Env. Medicine
Schrieberg, Fran	Worksafe
Scott, Mark	T.Hasegawa USA
Silveira, Caroline	GMA/FPA
Smith, Jeremy	CA Labor Federation
Sylvester, Steve	Sara Lee
Thompson, Kevin	Cal-OSHA Reporter
Treanor, Elizabeth	Phylmar Group
Verduin, Pat	GMA/FPA

SUMMARY OF MAJOR DISCUSSION ITEMS AND AGREEMENTS

In regard to subsection (a) and (b) of the draft standard, there was substantial agreement that the list of covered flavoring constituents should include both diacetyl and acetoin; many but not all participants thought acetaldehyde should be included; many thought benzaldehyde could be omitted from the list. There was agreement that the scope of the standard would not extend to mixing of foods themselves, but would be restricted to the adding of flavoring constituents to foods or food products. There was general agreement that the standard should not be based around a PEL, but instead must include performance assessment and documentation requirements of the employer, such as a report or form. A guide or form could be an assessment guide, some suggested, that would be part of an appendix. Potential interferences during sampling in high humidity were discussed. Subsection (c) on engineering controls was discussed in terms of traditional engineering controls now being adopted by some flavoring companies and controls being developed by NIOSH. There was substantial agreement on respiratory protection requirements as expressed by the current wording of subsection (d) in the draft. There was discussion on adding a medical removal section to the standard. The current wording of the medical surveillance section (e) was criticized for not being HIPPA compliant; the medical surveillance section of the formaldehyde regulation was suggested as a model. There was no opposition to adding appendices to the standard that would provide a standard respiratory symptom questionnaire, medical information to physicians, a form to standardize the communication between physicians and employers and a sampling and analysis guide for exposure assessments. The meaning of the labeling requirements of subsection (f) was discussed as was the proper length of time necessary to keep signs and symptoms surveys.

OPENING OF THE MEETING

Len Welsh gave a review of the purpose of the meeting. He summarized the history of Cal/OSHA Consultation's efforts in the Flavoring Industry Safety and Health Emphasis Program (FISHEP) which included active collaborative efforts with the National Institute of Occupational Safety and Health (NIOSH) and the California Department of Health Services Occupational Health Branch (DHS OHB). Federal OSHA had remained silent so far in regard to flavoring issues, Len Welsh said. The health problem at the root of this activity is fixed obstructive lung disease. In comparison to the episodic airway obstruction common in such diseases as asthma, fixed obstructive lung disease can ultimately lead to *bronchiolitis obliterans* which can be permanent and lead to death. Len Welsh emphasized that the draft standard that had been distributed was just that, a draft to focus discussion at the meeting. He had already noticed errors in the draft; he expected the draft proposal to evolve with discussion.

Finally, Len Welsh noted that this meeting was part of a phase of pre-official rulemaking. The public nature of this discussion works, he said, to generate a good product that can more easily pass through the formal rulemaking process. Those who may disagree with the product of an advisory committee have ample opportunity to make their views known

to the Cal/OSHA Occupational Standards Board (the Board) during the formal rulemaking phase.

MINUTES OF THE FEBRUARY 18, 2007 MEETING

There were no comments or corrections on the draft minutes from the previous meeting of the advisory committee.

SUMMARY OF RECENT FISHEP ACTIVITY

Kelly Howard gave a summary of the status of the work of FISHEP. There was not a lot new to report since the last meeting, he said. FISHEP was nearing the very final stages of determining the baseline concentrations of the priority ingredients in use at the 26 participating flavor manufacturing plants. Two companies are well on their way to installing engineering controls, he said, and several have received NIOSH reports to guide the process. Two other companies are in the planning stages for installing engineering controls. The companies that have begun the installation process have faced some feasibility issues concerned with EPA approval of scrubbing devices. Essentially there are two issues: directing the exhaust of ventilation controls away from the workplace and scrubbing the exhaust with charcoal filters. Eventually, NIOSH suggestions on engineering and work practice controls will be distributed to all the California flavor manufacturers.

Kelly Howard summarized some recent FISHEP sampling data at several plants that will be utilized as baseline exposure metrics to compare to exposure results to be measured after engineering and work practice controls have been initiated.

John Halligan asked if the monitoring results specified the nature of the operations being monitored.

Kelly Howard answered affirmatively and promised to provide a summary table of these results for the minutes of the meeting. This table is reproduced on the next page. (Note: Table may take several seconds to appear in electronic version of this document.)

Diacetyl Exposures Corresponding to Quantities of Diacetyl Used

Quantity of Diacetyl	Exposures (PPM)
	0.56 PPM STEL (weight-out of pure diacetyl)
1.4 Kg diacetyl chilled to 38 F, used to make up a 1000 kg batch of flavored powder. Liquid flavor mixed up, then added to the powder	3.80 PPM STEL (pour into powder) 1.12 PPM STEL (packaging finish dry blend containing 0. diacetyl) 0.60 PPM 8-Hr TWA (weigh-out, pour, packaging)
	2.5-4.4 PPM STEL (pour pure diacetyl)
0.65 Kg used to make up a 161 Kg key, which was then used to make up a 5467 kg batch of flavor	0.28-0.45 PPM 8-Hr TWA <0.49 PPM (60 minute average while transferring/pouring 0.4% diacetyl) <0.042 PPM 8-Hr. TWA (packaging liquid containing 0.0 diacetyl)
12 lbs	8.7 PPM STEL (pour pure diacetyl) 0.89 PPM 8-Hr TWA
2.9 lbs used to make up an 8 lb key	<0.91 PPM STEL (poured pure diacetyl) 0.49 PPM 8-Hr TWA
2.2 lbs used to make up a 101 lb key	2.1-7.2 STEL (poured pure diacetyl) 0.13-0.55 PPM 8-Hr TWA

Kelly Howard then discussed some recent NIOSH lab tests that indicated that both the NIOSH and Federal OSHA validated sampling methods for diacetyl greatly underestimated exposures at and above 80% relative humidity. In most cases this did not invalidate FISHEP sampling results as these results were obtained at 40% to 60% relative humidity--although the past Monday some monitoring had been done at 78% or 79% relative humidity.

Len Welsh clarified for the attendees that high relative humidity was therefore a potential interference during diacetyl monitoring.

John Hallagan noted that he believed the NIOSH Mary Glister HHE had demonstrated some effects of relative humidity on the solubility of diacetyl and therefore sampling effects would seem to be logically related.

Mary Ellen Hogan asked how relative humidity came up as an issue in sampling.

Larry Reed responded that NIOSH found some anomalies in the data.

Len Welsh asked if the issue of concern was only ambient humidity or that humidity due to industrial processes. Kelly Howard replied that both were factors.

SUMMARY OF RECENT DHS ACTIVITY

Dr. Janice Prudhomme next gave an update on the efforts of the DHS in FISHEP. She stated that she has been assisting Barbara Materna, the chief of the DHS OHB in this work. About 750 employees had been identified in the flavoring industry. Of these, medical information on about 400 employees had been received by DHS, including spirometry data. Dr. Thomas Kim, a Center for Disease Control Epidemic Intelligence Service officer assigned to the DHS, is managing this large influx of medical data. One thing DHS is doing is ensuring that the flavor companies are providing spirometry of adequate quality. Technical assistance towards this goal is being provided via the assistance of NIOSH consultant Dr. Paul Enwright, a national expert on spirometry. NIOSH is also assisting in developing a suitable standardized medical questionnaire in Spanish and English for use in all flavoring plants.

Another goal is to try to address and tease out recommendations for different moderate abnormalities that have not reached the stage of frank *bronchiolitis obliterans*. Janice Prudhomme stated that four current workers with moderate abnormalities on pulmonary function tests have been identified, as have another 18 workers with mild abnormalities, for a total of 22 workers identified through medical surveillance so far. She noted that the NIOSH protocol for pulmonary function tests is to utilize a bronchodilator challenge as a check on any apparent lung function abnormalities. These workers will receive an additional test to see if their lung function abnormalities are reversible or are fixed (non-reversible) obstructions.

Fran Schreiber asked if the symptoms of these 22 workers appeared to be fixed obstructive disease related to flavoring exposure and if these individuals had been removed from that exposure.

Janice Prudhomme answered that some were fixed obstructive symptoms, but that at this point of time these individuals were at a stage of really mild disease—which just means they are now on a spectrum of disease. It doesn't mean they have flavor-related disease or not, but it does mean that there is a continuing need to monitor the medical condition of these individuals for signs of disease progression. But yes, some individuals have been removed from exposure.

Len Welsh clarified that “moderate” in this context means pretty broken, so that's why we are trying to follow employees at the “mild” stage.

Fran Schreiber asked if all 22 individuals were being removed. Janice Prudhomme answered that Cal/OSHA Consultation is getting the names so they can do individualized work assessments so a relationship between disease and exposure can be seen and where

appropriate workers can be removed from the exposure. But two individuals have been removed from exposure.

Fran Schrieberg opined that this issue is related to medical removal protection which should be in the standard but is not in the draft standard. Janice Prudhomme said that DHS OHB also thought medical removal being missing from the draft standard is a problem.

Pat Verduin stated that there was not yet clarity about fixed obstructive lung disease; we don't know if it is flavor-related. 22 cases out of 400 is about 5%, a common rate you might find in a normal population for many types of disease. We don't know the root cause of fixed obstructive lung disease even though it is associated with exposures to flavors. But treatment of employees is key.

Janice Prudhomme clarified that fixed obstructive lung disease is rather rare in the general population. However, the 5% figure is for those found to have mild to moderately abnormal screening spirometry, not fixed obstructive lung disease; this rate is similar to what is found in the general population.

Fran Schrieberg reminded the group that an additional 8 flavoring employees had been diagnosed with severe fixed obstructive lung disease. Len Welsh acknowledged that these 8 cases do indicate a problem.

Janice Prudhomme added that also former workers need to be looked at. Why did they leave employment? Due to sickness? For example, she noted one case, a 31-year old former male worker with severe disease. We are now saying "severe fixed obstructive lung disease" since it is often not clear it is bronchiolitis obliterans [without doing invasive tests that would not change the course of treatment]. This case was going through Workers Comp as a denied claim, but the worker is now believed to have severe lung disease related to his diacetyl/flavorings exposure. Janice Prudhomme stated that a letter could be sent to flavor employers to ask them to review rosters of leaving employees and to report those workers leaving for health reasons.

Juli Broyles asked, when Workers Comp denied this claim, since it is such a new disease, maybe they didn't know?

Len Welsh commented that the disconnection of the Workers Comp system from the occupational safety and health program is a constant problem. The point is we want the 26 flavor companies to be more on top of the medical issues and to identify workers who have left, especially those who may have had workers comp cases that were possible flavor-related lung disease. We started by asking for companies to query their workers about symptoms every six months. Now we have the idea about employers checking in monthly about symptoms; we sent a letter to the flavor companies asking them to do this.

Bob D'Amato asked if the employers were reporting to Len Welsh. Welsh responded that the employers have been asked to voluntarily keep a log which will be reviewed by the Division's FISHEP consultants when they visit the plant.

Bob D'Amato then asked about outreach to physicians. Barbara Materna and Janice Prudhomme detailed the types of efforts made, such as via letter by the DHS OHB to reach physicians and plans to provide information and materials to the May California meeting of the American Thoracic Society. Information was also sent via email to American Thoracic Society members, though not all busy physicians may read it. A presentation to physicians is being planned for the Western Occupational Medical Conference in November. A joint article by DHS OHB, Cal/OSHA and NIOSH for the Center for Disease Control's *Morbidity and Mortality Weekly Report* is soon to be published. *MMWR* articles are published in the *Journal of the American Medical Association*, which reaches many physicians across the country.

Len asked if we should contact the California Medical Association as it might be useful to have them publicize information about this disease. Barbara Materna said this could be considered.

NIOSH REPORT

Larry Reed next delivered a PowerPoint presentation on the engineering controls being developed and evaluated by a team of NIOSH researchers for the conditions found in the flavor manufacturing industry. [This presentation is available via email from the Division upon request.] Larry Reed said the final findings of the researchers would eventually be posted on the NIOSH web site.

INITIAL DISCUSSION OF DRAFT STANDARD

Len Welsh next introduced discussion on the draft standard. Let's see if we can learn from the flavoring manufacture experience the application to food manufacture, Len Welsh suggested. The draft standard is a guide so we can see its problems; hopefully next time we'll get a draft out well ahead of the meeting.

Most important is the scope, Welsh said. The draft is industry neutral. First thinking is that it is not important where the diacetyl is used. There is enough information to suggest the problem is not limited to diacetyl; other flavoring ingredients may be key too. The NIOSH approach is to treat diacetyl as a marker. Subsection (a)(2) of the draft is about diacetyl alone. Subsections (a)(1),(3) and (4) focuses on things generally, on flavorings that may have diacetyl. There is a need for discussion of whether we need to look beyond diacetyl. Acetaldehyde, acetoin and benzylaldehyde are well-known irritants.

In the draft, he said, if any one of (a)(1), (2), (3), or (4) apply, then the whole standard does. Subsection (a)(1) is primarily directed towards flavor manufacture even though it is not stated. The subsection also covers some downstream applications, even though classified as food manufacture.

DISCUSSION SUBSECTION (a)(1)

Rhonda Hrabchak said such downstream mixers are rare but it does happen.

Len Welsh indicated that such situations are instances of a flavoring mixture being mixed with another flavoring mixture, and these should be covered because these are the type of operations causing problems in California.

Fran Schreiber said, so (a)(1) excludes scratch bakeries?

Len Welsh agreed, saying, right, (a)(1) is mixing flavors, not flavors with food.

Mark Scott said food manufacturers do often mix flavors. Len Welsh said the intent was to address flavor mixing wherever it occurs since there appears to be a hazard.

Pat Verduin said there are not really many food manufacturers mixing flavors, at least not among her members.

Mark Scott said soda syrup mixing may be more like food manufacture than flavor compounding.

Len Welsh asked, OK, at what point does a flavor become food?

John Hallagan compared the problem to popcorn, that is, the flavoring is not part of a food system.

Len Welsh said this is good, we are moving towards developing more specific terminology.

Mary Ellen Hogan asked, so mixing flavors with food is covered?

Len Welsh answered that probably not; he doesn't envision examples like soda syrup that are food ingredients, not flavors, being captured by the standard.

Fran Schreiber asked if popcorn was covered in (a)(1). Len Welsh replied, no. He said we are trying to capture all flavors with one of the four subsections. Dan McCarrel said (a)(1) suggests mixing flavor into food is included. Len Welsh said that is not the intention.

Pat Verduin suggested the wording should say "creation of a flavoring blend" as opposed to including mixing flavor into food.

Dan McCarrel said, I think you'd capture foods.

John Hallagan said that the FDA defines flavor as non-nutritive. Len Welsh said that could be helpful.

DISCUSSION SUBSECTION (a)(2)

Len Welsh moved on to (a) (2), which just refers to diacetyl, stating that the 5% was arbitrary. I'm agnostic on the percentage and the temperature.

Fran Schreiber asked if the concentration meant to refer to concentration by weight. Len Welsh replied, yes. Fran Schreiber said we also should worry about total quantity, not just the percentage. Len Welsh agreed we need a handle on quantity.

Pat Verduin said she absolutely disagreed. She agreed that high concentrations should be covered by stated she did not agree that low concentrations, no matter how often used, posed a concern. John Hallagan pointed out that diacetyl was not at 100% concentration in food manufacturing. Len Welsh replied that the concentration, the quantity and the temperature all appear to be key and should be addressed.

Fran Schreiber asked if we are setting a matrix with these concepts. Len Welsh replied, yes.

John Hallagan said the "spray" term should be replaced by the term "spray dry."

Kelly Howard spoke about exposures when adding liquid diacetyl to powders. He said that FISHEP was noticing that when liquid was added to powder, higher exposures were measured than when liquids were added to liquids. Pat Verduin stated that if the intent was to "capture the iceberg," then (a)(2)(C) goes too far in not limiting it to powder to powder instead of any form to powder. Mark Scott stated that these concerns were addressed in flavor manufacturing by (a)(1) and that this discussion was opening up food producers again. He asked if that was the intention. Len Welsh agreed that (a)(2) was targeted at food manufacturers, not flavor manufacturers.

DISCUSSION SUBSECTION (a)(3)

Len Welsh then shifted the discussion to (a)(3) which kicks in the standard when there exists a peer reviewed study that shows a particular process can lead to fixed obstructive lung disease and to (a)(4) which kicks in the standard at a place of employment when an employee is diagnosed with fixed obstructive lung disease. Len Welsh speculated that the draft standard could include a way for a place of employment to test out of the standard. There should be test out procedures based on exposure or diagnosis or an opt-out provision if studies are later determined to be erroneous.

John Hallagan agreed in regard to these two subsections it is important for the converse to apply, that is, if there is nothing to show a problem then it is OK and a place of employment is not covered.

Larry Reed pointed out that, as currently written, (a)(3) would not include NIOSH Health Hazard Evaluations (HHEs), which are not peer reviewed. Len Welsh stated HHEs

should be included, as in his mind they were legitimate. So more needed to be done with the draft standard's wording, Len Welsh said.

Juli Broyles commented that since all the information pointed to diacetyl, the other chemicals should not be included. Acetaldehyde has its own PEL in any case.

Barbara Materna replied that acetoin is lacking in toxicology studies but it is also a ketone and very similar to diacetyl. Len Welsh added that acetoin is rarely found without the presence of diacetyl. John Hallagan added that one can make a strong scientific argument that acetoin is the #2 concern. Benzaldehyde is less of an irritant than acetaldehyde which has a PEL. Dr. Kaochoy Saechao noted that the article by Kay Kreiss of NIOSH documents three cases of obstructive lung disease caused by exposure to acetoin alone. Mark Scott agreed that benzaldehyde is different from diacetyl and acetoin which arguably are similar.

Len Welsh asked the representatives of Labor where the line on benzaldehyde should be drawn. Jackie Nowell said the same conversation had been held around the filing of the petition.

John Hallagan thought that diacetyl and acetoin should definitely be included in the standard. Since acetaldehyde has its own PEL, it was covered in that way. Benzaldehyde is the least likely to cause a problem.

Len Welsh said that while there was not much pointing to acetaldehyde, its PEL had not been developed with *bronchiolitis obliterans* as a consideration.

Barbara Materna noted that the Lockey abstract mentioned in Kay Kreiss' article documented five cases of *bronchiolitis obliterans*, one of which was associated with exposure to acetaldehyde.

John Hallagan said he had spoken to Dr. Lockey, and the link to acetaldehyde was more tenuous. The individual could remember one occasion in which he had been exposed to what he believed was acetaldehyde. The exposure to acetaldehyde could not be independently verified, and the link to acetaldehyde was based upon the individual's recollection alone.

Barbara Materna countered that the latest fixed obstructive lung disease diagnosis that Dr. Prudhomme had described was associated with a report of a severe acetaldehyde exposure. However, she acknowledged, diacetyl could have been there, too.

John Hallagan said it was well known that acetaldehyde was an acute irritant causing the kind of immediate reaction you don't forget, as in the Lockey report.

Len Welsh said that for the flavor industry there may be an argument for acetaldehyde inclusion, but it may be tough to capture this chemical for the food manufacturing

industry. He noted that in order to demonstrate necessity for California rule making it is necessary to show scientific backing.

Jackie Nowell commented that if only diacetyl were to be regulated, this would open up the door to substitution of other substances that could be hazardous.

John Hallagan agreed that this is the problem with substitution. That's why FEMA focuses on process control.

Len Welsh summarized that what he got from the discussion was that there was support for including acetoin and maybe acetaldehyde, but probably not for benzaldehyde.

FURTHER DISCUSSION OF SUBSECTION (a)

Barbara Materna said that the standard, as written, would not include other chemicals unless there is evidence of disease under subsections (a)(3) and (a)(4).

Dan McCarrel noted, in regard to (a)(3), that there is a problem in comparing processes from one manufacturer to another or from one study to other locations..

Mark Scott thought (a)(3) could be covered under (a)(2) and advocated dropping (a)(3).

Steve Smith clarified that (a)(3) covers related industries while (a)(4) was meant to address situations with one sick employee at that one plant.

Len Welsh acknowledged that it might be problematic to get a process defined precisely enough to compare from plant to plant. But, he said, the model for (a)(3) is the microwave popcorn industry; these plants were similar enough for there to be a common problem. Thus, (a)(3) catches what (a)(1) and (a)(2) may miss. [Knowing what we know] how could we let a popcorn manufacturer start up in California without being covered by this standard? Regarding (a)(3), it will be a matter of precision of wording.

Mark Scott said the popcorn industry had been using exceedingly high levels of diacetyl.

Jackie Nowell stated we were talking about the ways workers are exposed. This isn't about popcorn. I'm saying it doesn't matter that everyone has a different process.

Len Welsh argued that there is enough commonality among downstream industries that they should be covered.

Azita Mashayekhi said that if covering popcorn was the concern, then couldn't (a)(2) be rewritten to cover popcorn explicitly?

Len Welsh suggested that what commenters are really asking for is if you have done controls is there a way out of being covered by the standard. Can you show by screening overtime, if your use of diacetyl is very low, that the regulation is no longer triggered.

Peter Scholz suggested getting rid of the specific example [of popcorn]; we can be broader, he said.

Rhonda Hrabchak suggested that maybe the problem we are having is semantic. The use of the word “process” may be throwing people off. The problem is to identify specific processes that are problematic.

Len agreed. For the most part I’m hearing that the concepts of the draft are valid, he said, and that the paradigm is good.

Jackie Nowell said there was only ½ hour before lunch and some folks may have to leave. She suggested a subgroup tackle the next steps. Len Welsh said he’d like to shoot for the beginning of official rulemaking within 3 to 5 months, with the next meeting of this informal advisory committee in 6 to 8 weeks. May 18, 2007 was selected for the next meeting. John Hallagan, Juli Broyles, Fran Schrieberg, Jackie Nowell, Azita Mashayekhi, Jeremy Smith and Barbara Materna said they would be interested in being part of a working subgroup to meet via telephone conference call. Len Welsh said the subgroup should work towards further refining the scope of the draft standard.

AFTER LUNCH: SHOWING COMPLIANCE WITH THE STANDARD

The meeting was adjourned for lunch. After lunch, Fran Schrieberg suggested that for a company to get out of the standard’s coverage, the company should have to have documented proof of the reasons, such as feasibility, or the lowest level of exposure had been achieved. Len Welsh suggested that such documentation should include justification and descriptions of the engineering controls, the administrative controls and the exposure assessment tools utilized.

Fran suggested that without a PEL, an enforceable order needs to require the employer to document that they have implemented controls down to the lowest levels feasible. For example, they should have an engineering report to document that they did it as required. Len Welsh wondered if such a documentation record of in-house was really enforceable.

Rhonda Hrabchak suggested making an appendix to guide the feasibility assessment, like the flow chart in confined space, with a form to fill out.

Fran Schrieberg said she was thinking the report should be by an engineer.

Pat Verduin asked what FISHEP was doing to assess the remediative efforts of flavor manufacturers. Kelly Howard said FISHEP reviewed to see if basic engineering procedures and principles were being applied. Fran Schrieberg asked how this was possible without a PEL to guide the assessment. Azita Mashayekhi asked how you would know the controls work. Len Welsh said subsection (b) requires assessment of engineering control effectiveness; you want more than an exposure record, you want an

engineering assessment. Juli Broyles said most companies have someone on staff capable of making that judgment.

Len Welsh liked Rhonda Hrabchak's idea of a form. The employer would state on the form why this is the best we can do. Or, on any report saying what was done, have an exposure assessment to show the effectiveness. Len Welsh addressed Fran Schrieberg, saying, what you want is a written report regarding what was done, an effectiveness assessment, and a statement about how the employer came to the conclusion that this was all that could be done.

Barbara Materna said, like a lead compliance plan maybe.

Marti Fisher asked how any engineer could assess effectiveness if NIOSH is still pondering that very question.

Len Welsh replied that Kelly Howard and FISHEP have also struggled on how to first get controls built and then to assess their effectiveness. Kelly works with contractors during the process so some sort of evaluation of engineering control effectiveness can be done. On the form should be the essential doable things.

Fran Schrieberg said the guidance appendix should be a non-mandatory one. We don't know what effective measures are, so I'm proposing we have the employer document how they reached the conclusion that the measures they put in place are effective.

Azita Mashayekhi reiterated that it would still be a good idea to have the guidance.

Juli Broyles agreed that in order to make assessments more uniform a best practices guide would be useful.

Len Welsh summarized the discussion as covering either a form or report with certain elements. He said there is value to requiring documentation of engineering control effectiveness. A form might be good; we need to figure out what would be key elements of that. We could always add information on what should go on the form at a later time; we don't need a regulatory change for that. So we should require documentation of effectiveness whether it is a form or a report.

CALL FOR DOCUMENTATION REQUIREMENT W/O PEL

Pat Verduin asked if this documentation requirement would be guidance or mandatory.

Len Welsh said it should be mandatory. It ought to be easy enough for an employer, given their investment, to state the evidence of why they think it will work. It is not unreasonable to expect employers to have to write up a rationale.

Pat Verduin said her concern would be with the breadth of industries to be covered, such as wine and bread making. What will be required for each? I need to think about scope.

Len Welsh said the model here is without a PEL; therefore enforceable guidance is acceptable.

Rhonda Hrabchak stated that any exposure requires assessments or comparisons, not just theory.

Azita Mashayekhi asked if NIOSH had a Recommended Exposure Limit (REL).

Larry Reed said a REL has been discussed at NIOSH but that more animal or human data are needed to establish a dose response relationship for a quantitative risk assessment. My sense is we are not there yet, although progress is being made, he said.

Barbara Materna agreed that there is not yet enough information to establish exposure limits. She noted that PELs are usually needed to trigger respiratory protection requirements, for example, appropriate respirator selection.

Len Welsh said the message we are trying to send is that a PEL doesn't make sense.

John Hallagan said that National Jewish Hospital's work has shown some success with engineering controls but even so respirators are still recommended for handling diacetyl neat (100%) and for significant diacetyl concentrations of 10 to 20% and up.

Len Welsh stated that if you are able to measure it [diacetyl] FEMA recommends respirator use. John Hallagan said, yes, but for the time being only.

Nancy Rachman said that preliminarily the GMA/FPA was finding levels are very variable, but are found at all only with mixing processes.

John Halligan said that what Fran is saying is that she doesn't want full shift respirator use, and I agree.

Len Welsh asked, when are you going to say that engineering controls are enough—out of an abundance of caution.

Rhonda Hrabchak agreed on a protocol of .02 ppm. If we get non-detect then we shouldn't mandate engineering controls. If we can keep exposures below the non-detect level.

Mark Scott suggested the only case for no respirator requirement should be when the operation is completely enclosed. Pat Verduin said requiring non-detect levels to rule out respirator use would put a lot of people in respirators.

Len Welsh asked if anyone wanted to argue for a PEL and if so what that level would be.

Fran Schrieberg said a PEL is needed if the language on controls is not good enough.

Mary Ellen Hogan said that in effect you are setting non-detect as the PEL.

Len Welsh disagreed, pointing out that if an employer was doing all they could to limit exposures with feasible measures, then they wouldn't be in violation even if the levels were detectable.

Mary Ellen Hogan said that then you had to move to lowest feasible exposure achieved via engineering controls.

DISCUSSION OF ANALYTICAL/SAMPLING APPENDIX

Barbara Materna said that since such low concentrations would have to be measured the standard needs to be very detailed about sampling and analytical method for full shift and short term monitoring, limits of detection, etc. This detail could be provided by an appendix.

Len asked if Barbara could work with Kelly Howard and others towards drafting such an appendix. She agreed.

Len Welsh had to leave the meeting at this point. Before relinquishing the chair to Steve Smith to lead discussion on medical removal, Len Welsh mentioned that medical removal benefits had been omitted from the draft and needed to be added. He mentioned the medical removal benefits in the lead standard as a possible model. Mark Scott asked if reassignment of a removed worker would be appropriate. Len Welsh answered affirmatively, and then left the meeting.

MEDICAL SURVEILLANCE DISCUSSION

Steve Smith asked for any initial statements on the medical surveillance section of the draft.

Fran Schrieberg said there should also be an appendix with a health questionnaire detailing the signs and symptoms associated with exposure to flavorings. She said the section was conceptually in the right direction but she would need to see the details of the technical appendices to decide. The section was missing a requirement for an exit exam and also perhaps the section should require a disease registry as well for people leaving employment. The registry could be at DHS as is done for blood lead.

Mark Scott asked how to reach workers who simply fail to show up.

Steve Smith replied that most of these standards just require making the offer of the exit evaluation. He said a disease registry requirement for the DHS couldn't be in this regulation without legislative mandate.

Janice Prudhomme said that so far people had the disease when they left and an exit evaluation would have picked it up. Maybe there should be an appendix for guidance for exiting workers.

John Hallagan added that while non-flavor related *bronchiolitis obliterans* sometimes demonstrated progression of the disease after removal from exposure, there does not appear to be progression in the flavor-related disease. John Hallagan went on to say that the section would benefit from guidance on the handling of medical records. Clarity on HIPPA issues was needed. Sometimes workers don't want doctors to report information to their employers.

Rhonda Hrabchak stated that section (e)(3)(E) was not possible as the employer would not have medical information from previous employers.

Amanda Edens said the term "medical opinion" should be utilized, not "evaluation."

Fran Schreiber said the DOSH Legal Unit should assess this section for HIPPA compliance.

Mary Kochie thought the section should refer to Licensed Health Care Professionals (LHCP) rather than physicians only.

DISCUSSION OF MEDICAL REMOVAL

The discussion then turned to the issue of medical removal. Fran Schrieberg said she would like to see something like the medial removal requirements of the lead standard.

Pat Verduin asked what would trigger removal protection.

Fran Schrieberg said the physician's opinion.

Pat Verduin asked if that meant a diagnosis of fixed obstructive lung disease.

Dr. Kaochoy Saechao said by then it would be too late to prevent morbidity.

Peter Scholz pointed out that in the lead standard, removal is triggered by blood lead monitoring and is reversible. This situation is different because the disease is irreversible.

Steve Smith said that hopefully the medical surveillance would catch it before the disease became irreversible.

Elizabeth Treanor asked if the removal would be based on a physician's opinion that there was fixed lung disease.

Fran Schrieberg stated, no, its based just on the physician's opinion that the removal is necessary.

Janice Prudhomme suggested using the formaldehyde regulation as a model for medical removal. She could see situations in which a worker would be temporarily pulled out from exposure but later that worker might be permitted to go back if further medical review showed the employee was not on a path towards fixed obstructive lung disease. But if the worker is on that path, then the medical removal path is dictated. It does seem that some times when caught at an early enough stage there may be some reversibility. We need to use a system of diagnostic tests before turning to the Workers Comp system.

Janice Prudhomme said appendices were needed: a respiratory questionnaire, a form for medical providers and an appendix with medical information for physicians to tell them what to look for.

Rhonda Hrabchak pointed out that in the draft standard there was no definition of what is meant by “in areas adjacent.” Everyone agreed with this need.

Mike Horowitz said it meant adjacent to areas where there was a risk of exposure.

Fran Schrieberg said so say that.

Pat Verduin said she would have to see the appendices before making up her mind about them.

Janice Prudhomme attempted to clarify how a medical survey questionnaire would work. The questionnaire could help identify if more tests were needed to tease out if the employee’s symptoms were fixed or not. It would protect employee’s privacy if, say, the condition turned out to be pre-existing asthma.

MATERIAL SAFETY DATA SHEET DISCUSSION

Fran Schrieberg asked for a discussion about Material Safety Data Sheets (MSDS).

Nancy Rachman said that food makers don’t have information on the percentage of diacetyl in ingredients. Steve Smith agreed this is often proprietary information. Nancy Rachman said if the MSDS requirement is to be based on percentage, then flavor manufacturers should be required by the standard to include the percentage.

John Hallagan stated that FEMA wouldn’t object if the regulation required flavor manufacturers to state the percentage of diacetyl on the MSDS.

Steve Smith said the regulation could not require this for suppliers from other countries or to flavors coming into California via interstate commerce.

DISCUSSION OF LABELING REQUIREMENTS OF SUBSECTION (f)(2)

Next there was a discussion on labeling requirements.

Mark Scott wanted to clarify that in (f)(2) the label is only for internal use in the producing plant, not for out-going product items.

Pat Verduin said that this section on labeling diacetyl mixtures required labeling for any percentage of diacetyl, not just 100%. This puts too much burden on users to label materials coming into their plants.

Steve Smith said this requirement is consistent with the requirements of the hazard communication regulation.

Tom Mitchell added that the hazard communication regulation exempts FDA approved substances from labeling.

Mike Horowitz asked, in light of that maybe we don't need the additional labeling requirements of (f)(2).

John Hallagan clarified FDA flavor labeling requirements were restricted to barrel or bin size containers and for the retail food container that is sold in the store.

Steve Smith noted there is no health hazard warning required by the FDA.

Azita Mashayekhi stated it was possible to use signage instead of labeling. She said (f)(2) should be expanded to clarify what and where labeling would be required.

Dan McCarrel said he thought that the "respiratory hazard" warning required in (f)(2) would be sufficient given all the other training components.

Steve Smith said the record keeping section of the draft standard was pretty standard.

Mary Kochie thought the signs and symptoms report should be part of the exposure record and kept for a longer period than the 3 years specified in (g). Such records should be kept for the full 30 years required by section 3204.

The advisory meeting then adjourned until the next meeting scheduled for May 18, 2007.