

## DRAFT MEETING SUMMARY

### First Advisory Meeting on Diacetyl and Chemicals in the Flavor Manufacturing Industry in California

September 28, 2006  
Elihu Harris State Building  
1515 Clay Street  
Oakland, California

#### Attendees

Jim Abel	Mane, Inc.
Janet Aho	Mane, Inc.
Michael Boyle	Bimbo Bakeries
Juli Broyles	California Chamber of Commerce
Michael DiBartolomeis	California Dept. of Health Services (DHS)
Nachman Brautbar	Medical Consultant
Barbara Cohrsen	Cohrsen Environmental
Dorothy Dougherty	Federal OSHA, Washington DC
Mandy Edens	Federal OSHA, Washington DC
David Egilman	Medical consultant
Judi Freyman	Organization Resources Counselors
John Froines	UCLA School of Public Health
John Hallagan	Flavor and Extract Manufacturers Association (FEMA)
Robert Harrison.	DHS and UCSF
Loren Hormigosa	Federal OSHA, San Francisco
Kay Kreiss	NIOSH, Morgantown, WV
Dan Leacox	Greenberg Traurig law firm
Christopher Lee	Federal OSHA, San Francisco
Connie Leyva	President UFCW Local 1428 and California Labor Federation
Frances Low	Principal Consultant, Senate Labor & Industrial Relations Committee
Barbara Materna	DHS Occupational Health Branch
Ralph Metzger	Toxic Torts
Thomas Neale	Chubb Loss Control
B. James Pantone	DiMarco, Araujo, Montevideo law firm
Janice Prudhomme	DHS, Cal/OSHA Medical Unit
Julia Quint	DHS, HESIS
Bobbie Rabinowitz	WorkSafe
Larry Reed	NIOSH
Libby Sanchez	Law Offices of Barry Broad (Teamsters)
Jason Schmelzer	California Manufacturers and Technology Association
Fran Schreiber	WorkSafe
Mark Scott	T. Hasegwa USA
Kevin Thompson	Cal/OSHA Reporter
Valeria Velazquez	Labor Occupational Health Program, U.C. Berkeley
Angie Wei	California Labor Federation
Jon Wellwood	Gold Coast Flavors
Stacy West	Mutual Flavors

## Cal/OSHA Participants

Len Welsh, Acting Chief, DOSH (meeting chair)  
Steve Smith, Supervising Industrial Hygienist, DOSH  
Tom Mitchell, Cal/OSHA Standards Board  
Amalia Neidhardt, DOSH Research & Standards  
Mike Horowitz, DOSH Research & Standards  
Bob Barish, DOSH Research & Standards  
Kelly Howard, Cal/OSHA Consultation Service  
Mary Kochie, DOSH Medical Unit  
Gilbert Martinez, Cal/OSHA Consultation Service  
Peter Scholz, Cal/OSHA Consultation Service  
Charlene Gloriani, DOSH High Hazard Enforcement Unit  
Gene Murphy, DOSH High Hazard Enforcement Unit

## Meeting Summary Outline

Summary of major discussion items  
Overview of flavor-related activities to date in California  
Discussion of California activities and the overall problem  
Cal/OSHA Consultation Service field activities and findings to date  
Cases of serious lung disease reported to Cal/OSHA in the flavor manufacturing industry  
Department of Health Services activities  
Discussion of morning topics  
NIOSH activities  
Discussion of NIOSH activities  
Discussion of possible regulatory responses  
Meeting wrap up

## Summary of Major Discussion Items

The meeting consisted of two distinct parts: review and discussion of the multi-agency effort to address the problem of respiratory disease risk in flavor manufacturing and use (**pages 2 – 13 in this meeting summary**), and then discussion of regulatory alternatives (**pages 13-18**).

The review of activities consisted of presentations on Cal/OSHA's field activities, including information on reported cases of bronchiolitis obliterans in California, activities of the California Department of Health Services, and NIOSH. Key points included:

- Short term exposures to diacetyl and other flavoring substances of concern may be an important factor in risk for respiratory disease. Such exposures can occur during cleaning of mixing vessels and pumps, with the result that "closed systems" for mixing may not always be the complete answer for exposure control.
- Identifying flavor-related respiratory illness in its early phases through medical screening can be difficult, but is critically important because in operations with high levels of exposure to hazardous substances it has been seen in some cases to develop very rapidly (within 6 months). Therefore frequent and highly competent pulmonary function testing and physician evaluation is critically important, particularly where exposures have been found to be highest as in ingredient mixing operations.

Key points of agreement in the discussion of regulatory action included:

The need to continue research to better characterize the nature & extent of the problem, including development of a “matrix” to help identify and list operations of particular concern at downstream user locations of flavoring substances (ie. food manufacturing locations).

The need for informational outreach to all companies where employees might be exposed to hazardous flavoring substances, as well as to the medical community.

It is not too early to put out basic information to the food manufacturing industry on hazards and possible methods for risk reduction.

Consideration should be given to early development of a regulation requiring at least employee training and information at all locations where diacetyl use may pose a hazard while the problem is studied further. A labor representative supported employee training and information as an interim step while a more comprehensive regulation is developed.

There should be additional discussion of a more detailed regulation requiring medical surveillance and exposure controls, though there was not agreement among labor and employer representatives on how broadly such a regulation should apply. Discussion centered around whether it might reasonably apply to all locations where diacetyl (particularly other than naturally occurring) is handled and used, or if there needs to be a triggering limit based on quantities and nature of use.

There needs to be a focus on assuring that Material Safety Data Sheets for potentially hazardous flavoring substances provide sufficient information on the hazards posed and appropriate exposure control measures.

### **Meeting Summary**

Len Welsh welcomed attendees and started with a review of the history of recent cases of respiratory illness at California flavor manufacturing locations. He said that the first case was reported to the Division by a pulmonologist in Southern California in August 2004. An enforcement inspection was conducted in response which resulted in a number of citations and a special order which included requirements for hazard evaluation, hazard control, and medical surveillance. He said that both the citations and the special order are on appeal, but that the employer has, to a still unknown extent, worked on hazard evaluation and medical screening of employees with the consulting group from National Jewish Medical Research Center in Denver identified by the Flavor and Extract Manufacturers Association (FEMA).

### **Overview of flavor-related activities to date in California**

Len Welsh said that throughout 2005 discussions were held with staff of the Occupational Health Branch of the Department of Health Services, NIOSH, FEMA, and National Jewish Medical Research Center on how the problem could be addressed effectively in California and what arrangements would need to be made to work cooperatively on the problem with California flavor manufacturing companies, recognizing their concerns such as effectiveness and expense of recommended control measures, and protection of trade secrets and confidential information. In April 2006 a second case of illness was reported to the Division and an enforcement inspection was opened at the location. At almost the same time, the Division met with representatives of 13 flavor manufacturing locations in California arranged by FEMA. Particularly with the report of the second case, this meeting amounted to the kick-off of the Division’s program to evaluate California flavor manufacturing locations under the High Hazard Program model of mandatory consultations. This special emphasis program has been named “FISHEP” for Flavor Industry Safety and Health Evaluation Program.

Under FISHEP the Cal/OSHA Consultation Service coordinator for the program, Kelly Howard in southern California (where most of the sites are located), has contacted approximately 30 locations and has been coordinating on-site consultations by industrial hygienists including measuring levels of exposure to potentially hazardous substances where practical. At those locations which have retained the assistance of private consultants, the Consultation Service is still conducting on-site assessments and is reviewing the consultants’

results and recommendations to determine if additional assistance is needed. It is planned that by the end of 2006 all of the locations will be visited and most of the Consultation Service on-site activities completed, although it is anticipated that there will be continued involvement as locations implement recommendations for exposure controls.

Another required component of participation in FISHEP is medical screening of employees exposed to potential respiratory hazards. This screening consists most notably of pulmonary function testing and a medical history. NIOSH and the Department of Health Services are coordinating this effort and providing assistance to employers in obtaining the necessary services and assuring that they are consistent with recognized professional medical standards.

Len Welsh noted that the FISHEP program of mandatory consultations is different than the usual assistance provided by the Cal/OSHA Consultation Service. For example, results of industrial hygiene and medical screening obtained by flavor manufacturers from outside vendors is required to be provided to the Division and will be available to the public, with appropriate protection of trade secrets and confidential medical information.

### **Discussion of California activities and the overall problem**

Len Welsh noted that the meeting was called in part in response to a petition to the Cal/OSHA Standards Board filed by the United Food and Commercial Workers (UFCW) and the California Labor Federation. The petition, similar to one filed with federal OSHA by UFCW and the International Brotherhood of Teamsters, requests an emergency regulation for a Permissible Exposure Limit (PEL) for diacetyl, an ingredient in butter and other flavorings, and development of a permanent comprehensive regulation for hazardous flavoring substances. He noted that the petition requested development of a regulation that would address potentially hazardous exposures not only in the flavor manufacturing industry which is the focus of Cal/OSHA's efforts at the moment, but more generally at all users and handlers of flavoring substances where hazardous exposures could be occurring.

Angie Wei asked what had prompted the Division to initiate the flavor industry program. Len Welsh responded that in light of the illnesses found in some microwave popcorn plants that were associated by NIOSH with butter flavoring, he felt after the report of the first illness that, if one was possible, a cooperative effort with California flavor manufacturers was likely to be more productive than enforcement alone, particularly given the greater uncertainty that existed in early 2005, and the desire to do something quickly.

Angie Wei asked how the FISHEP process differed from a regular Cal/OSHA consultation. Len Welsh said that the "usual" consultation provided by the Cal/OSHA Consultation Service is at the request of the employer, and even if done in response to notification of a high experience modification in the High Hazard program is generally done on a confidential basis without release of documents. In contrast, with FISHEP the Division is essentially "requesting" that the employer receive the consultation, or offering the consultation as an alternative to being placed on a priority list for an enforcement inspection. And in addition to the mandatory nature of the FISHEP consultations they are much more complicated in that they also require employee medical screening and close oversight by the Consultation Service of implementation of exposure control measures.

Angie Wei asked if acceptance of the consultation precluded the Division from initiating an enforcement inspection. Len Welsh responded that it would not. He said that if a complaint was received about the workplace during the period of the Consultation, or if the cooperative relationship could not be maintained, then an enforcement inspection could be initiated at the location.

David Egilman asked for details on the cases of respiratory illness in flavor manufacturing companies in California reported to the Division. Len Welsh said there had been 3 cases (at 2 locations) to date, with 2 additional possible cases at another location.

David Egilman said that the first cases reported to NIOSH were in 1985 at a bakery ingredient mixing company. He said he was thus concerned with notification of, and control of exposures in, downstream user companies of flavors and their employees. He said that NIOSH could assist with addressing the risk at user companies in California. Len Welsh acknowledged the assistance that is available from NIOSH, but said that it would take

more than government to address the problem. He also said he was not sure that NIOSH has the resources to provide the extensive assistance being suggested.

Raphael Metzger asked how the Division was making available results of industrial hygiene and medical screening at the flavor companies participating in FISHEP. Len Welsh said that they would be available upon request. Raphael Metzger responded that he had made a records request to Cal/OSHA and to the Department of Health Services for information on one of the enforcement inspections in the flavor industry. He said that since one of the conditions of company participation in FISHEP is making information available to the Consultation Service why not have it readily available by posting it on the Internet. Len Welsh said that might be an idea to consider as the Division proceeds with figuring out how to handle data appropriately so as to maintain medical confidentiality and legitimate trade secrets while still making it readily available to the public.

Barbara Materna said she wanted to have it on the record that the Occupational Health Branch in the Department of Health Services had not received a request for records as described by Raphael Metzger. Fran Schreiber said that in addition to posting information received from flavor companies on its website, the Division should also post its protocol for on-site consultations. She also asked if the Consultation Service was distributing the DHS publications developed for flavors to workers in flavor companies they are visiting. Kelly Howard responded that such materials are typically given to employers to give to their employees, but that employee interviews are also conducted where information is provided. Fran Schreiber said in the case of FISHEP it should be assured that every worker gets informational materials. Len Welsh acknowledged this as a good idea.

Nachman Brautbar said that in the medical screenings spirometry should be done consistent with the guidelines of the American Thoracic Society (ATS). He said that he had seen some results from one or more flavor companies and they did not appear to be consistently following the ATS guidelines. Janice Prudhomme of DHS said that a study on pulmonary function testing quality was being planned, and that DHS was working to assist FISHEP participants with obtaining the fully competent pulmonary function testing that they were expected to provide to their employees as part of the cooperative program.

Connie Leyva asked if exposure to diacetyl is hazardous why is it still being allowed to be used. Len Welsh responded that the relationship of diacetyl to bronchiolitis obliterans or other lung disease is not entirely clear, and that in any event OSHA and Cal/OSHA rules allow for use of hazardous substances provided the hazard to workers is controlled.

John Froines said that the situation with diacetyl was analogous to that of the soil fumigant DBCP (dibromochloropropane) in the late 1970s in terms of setting the exposure limit so that its use is phased out. He said it was not a matter of a risk assessment issue but rather how to find an appropriate and safe substitute for diacetyl. He said that given the seriousness of the disease associated with diacetyl, while it may not be the only hazard, substituting a less hazardous chemical would probably go a long way to addressing the problem.

Connie Leyva said that in terms of controlling exposure to diacetyl, it would not be practical to have a cake decorator in a retail bakery or store baking department wear a respirator in areas visually accessible to customers.

### **Cal/OSHA Consultation Service field activities and findings to date**

Kelly Howard, Senior Safety Engineer in the Cal/OSHA Consultation Service in southern California spoke as the coordinator of FISHEP field activities. He said that he is in contact with approximately 30 flavor manufacturing locations identified by FEMA, DHS, or the Division. All companies contacted to date have agreed to participate in FISHEP. He said that the companies recognize the seriousness of the problem, and also the desirability of working cooperatively with the Consultation Service rather than being prioritized for an enforcement inspection. He detailed the following key points:

- Most of the companies are located in southern California. Just 3 of the approximately 30 companies identified and contacted are in northern California.

- There is significant variability between companies in terms of quantities of chemicals of concern used and frequency of operations involving their use. Some companies manufacture flavors involving handling of diacetyl 2 or 3 times per week, while others handle it daily and quantities of use of diacetyl range from one pound per year to one ton per year.
- Diacetyl is not the only substance being evaluated for employee exposure levels and possible control measures. Other substances being looked at include acetoin, benzaldehyde, acetaldehyde, and acetic acid. All of these substances are respiratory irritants so short term operations and exposures are looked at closely and sampled if possible.
- Air sampling has in some cases shown exceedances of the ceiling level PEL for acetic acid, a respiratory irritant.
- Differences between locations militated against a single field protocol as had been requested by some meeting attendees. The basic process used in FISHEP consultations is asking where do exposures occur and then evaluating the levels of exposure and the potential for control. He said that batch tickets generally used in most locations provided a good capability for determining ingredients in use and annual quantities.
- The need to clean pumps, vessels and other components of flavor mixing system may pose limitations to the effectiveness of “closed systems” as an exposure control measure. Operations causing short term exposures need to be more fully evaluated to understand the full range of operations with significant potential for increasing the risk of respiratory disease.
- Where companies have had on-site assistance from a private industrial hygiene consultant, the Consultation Service will still conduct at least a walk-through evaluation of the location, evaluate the consultant’s findings and recommendations. Additional on-site work is conducted if deemed necessary to effectively understand and control hazards identified.
- Programs evaluated in FISHEP consultations include the Injury and Illness Prevention Program, Respiratory Protection, and Hazard Communication.
- At some companies English is not the first language of the workers. Translators are used with employees where needed to try to establish if they understand hazards and exposure control measures.
- Respirators will be a key exposure control strategy until engineering controls are implemented, so Cal/OSHA consultants focus on the competence of respirator training and fit testing.

Judi Freyman asked if there would be a report of the FISHEP activities, particularly air sampling results with different processes, as she thought these would be important to have for the discussion of risk and regulation of the food processing community beyond just flavor manufacturing. Libby Sanchez asked if key hazardous processes had been identified. Kelly Howard responded that activities and operations in the locations is highly variable. Libby Sanchez asked if any possible less hazardous substitutes had been found for the substances of particular concern. Len Welsh suggested that the discussion indicated to him two primary questions:

1. Where are exposures being found, ie. in what types of operations?
2. Can particular operations or levels of exposure be linked to disease or symptoms?

Len Welsh suggested that work by NIOSH at Carmi, the second Division enforcement inspection location, may help shed light on these two questions.

Raphael Metzger asked if the Consultation Service was looking at exposures to carageenan which he said is a potent fibrogenic agent. Kelly Howard responded that carageenan had not been a focus of field activities to date. He said that with the very large numbers of substances used in flavor manufacturing, most with minimal

standards or risk assessment to date, it would not be possible to assess all of them in the FISHEP field activities. He said that if medical screening suggested a connection of symptoms or disease with particular operations or substances those would be looked at more carefully, thus making the medical screening a critically important part of the program.

David Egilman said that it would be difficult to address the hazards of flavoring ingredients on a chemical-by-chemical basis. He said that it would be best to address exposure risk through a requirement for use of closed systems for mixing and formulating. Kelly Howard asked David Egilman what he meant by "closed system." He responded that he meant generally that closed systems would minimize exposures since it would be impossible to test for exposures to every individual potentially hazardous substance. Kelly Howard responded that closed systems are not surprisingly the initial first choice for control of exposures but that they require more system cleaning which itself can lead to significant short term exposures. David Egilman said that NIOSH could assist with development of effective closed systems. Kelly Howard said that NIOSH is in fact already working on that. Len Welsh said that this discussion illustrated the complexity of the problem.

Connie Leyva asked how the risk to bakery workers is being addressed. Len Welsh said that engineering controls such as enclosure of mixing processes are feasible in some locations but not others. John Hallagan said that enclosure and closed systems may be feasible and effective for some operations but not others. He said that operations requiring hands on mixing or handling of chemicals would need to have local exhaust ventilation installed. He said that the focus of his organization, FEMA, has been to work with member and some non-member companies to identify hazardous operations and control them.

John Froines said that as with his work on air pollution which also involves mixtures of hazardous substances, it might be appropriate to classify flavoring substances of concern as having either a "reactive oxygen effect" or a "protein inhibition effect." Len Welsh thanked John Froines for the offer of assistance with research on the problem and said also that he agreed with the concept of pursuing an overall approach geared toward control of exposing processes rather than a substance-by-substance approach to assessment and control.

### **Cases of serious lung disease reported to Cal/OSHA in the flavor manufacturing industry**

Mary Kochie briefly described her position and role as a nurse consultant and staff of the Division's Medical Unit in southern California. She said that to date 3 cases of bronchiolitis obliterans had been medically confirmed among current or former workers at California flavor manufacturing companies. She described the workers as follows:

1. A 30 year old former male employee in a flavor mixing operation, reported to the Division in 2004
2. A 44 year old female employee, and a 38 year old male employee, both mixers at a flavor manufacturing location. The first employee's illness was reported to the Division in April 2006 and the second was identified in the course of the resulting enforcement inspection.

Mary Kochie also said that there were two other possible cases of bronchiolitis obliterans related to work in flavor manufacturing being investigated and medically assessed: a 49 year old male employee in flavor mixing at the same location as those in number 2. above, and a 28 year old compounder at another flavor manufacturing location. She said that the employees with confirmed disease had seen a number of physicians before receiving the diagnosis of bronchiolitis obliterans, having previously received various diagnoses such as asthma, bronchitis, or other more common respiratory illness. She said that the confirmed cases of bronchiolitis obliterans exhibited dramatic declines in pulmonary function tests, in the range of 20 to 40 percent of normal.

Mary Kochie provided a brief overview of bronchiolitis obliterans, saying that it had only been seen rarely with chemical exposures, eg. with exposure to rocket fuel. She said that the disease can also result from immune system rejection in lung transplant patients. She said that the disease was characterized by "fixed obstruction," indicated by declines in both FEV-1 ("forced expiratory volume" in 1 second) and FEV-1/FVC (FVC being "forced vital capacity"). She said that computed tomography (CT) scans of patients with bronchiolitis obliterans typically exhibit a mosaic pattern in the affected airways. She said that open lung biopsy can provide definitive diagnosis because wedge sections are taken from several areas of the lung. However, a closed lung biopsy,

which is performed endoscopically, can give a false negative result because only one area of the lung is sampled and this may be an area where there is no disease. She said that Drs. Harber and Lubman in southern California, pulmonologists involved with one or more of the cases, had expressed to her their view that open lung biopsy is not needed for the diagnosis of bronchiolitis obliterans and is unnecessarily invasive if there is a history of rapid decline in pulmonary function and development of severe respiratory disease from a state of otherwise good health in a worker exposed occupationally to flavoring substances.

Mary Kochie said that the treatment is primarily steroid medications. She said that patients have been seen to deteriorate rapidly if they get the flu. She said that with lung transplant for the condition the average survival was only 5 years.

She said that in addition to cases of bronchiolitis obliterans found by NIOSH among mixers in microwave popcorn plants, NIOSH studies had also found less severe pulmonary function decline amounting to “mild” disease in some workers in other jobs with less exposure to flavoring substances of concern. She said it is not known if individuals with below normal pulmonary function test results will stabilize or will continue to show lung function declines even after removal from exposure to flavoring substances.

Mary Kochie said that one possibly significant difference between the microwave popcorn workers and the flavor manufacturing workers she had encountered in California is that the flavor workers tended to have worked in other flavor manufacturing locations and so may have had a longer tenure in the industry, whereas the microwave popcorn workers had worked only at the particular location where they were interviewed in the NIOSH studies.

Nachman Brautbar said that it is important for particularly clinicians to understand that bronchiolitis obliterans is a fixed obstructive lung disease and so is clearly different from asthma. David Egilman said that there can be variability in the clinical picture and that co-existing restrictive disease or some reversibility of pulmonary function decline should not be viewed as ruling out bronchiolitis obliterans. He said that in cases of bronchiolitis obliterans that he had treated he had not seen any improvement with steroids but had seen some positive effects with cytoxin. He said that he was trying to get NIOSH to study treatment options.

### **Department of Health Services activities**

Barbara Materna, Chief of the Occupational Health Branch in the California Department of Health Services, presented DHS activities. She noted that DHS has been working closely with Cal/OSHA, including:

- Assisted and provided medical consultation to Cal/OSHA on the California case of serious respiratory disease in a former flavor manufacturing worker reported in 2004. Also assisted with the enforcement inspection at the worker’s former employer.
- Gathering of medical information being generated with the Cal/OSHA Consultation Service through FISHEP and assistance in enforcement inspections, and reviewing company medical surveillance programs for quality control and providing guidance as appropriate. In addition, to learn more about this hazard, Barbara Materna and Janice Prudhomme recently visited a flavor manufacturing plant.
- During the summer of 2006, conducted a telephone survey to identify possible flavor manufacturing facilities and to determine if these manufacturers used diacetyl. The information developed identified several locations not earlier identified by the Flavor and Extract Manufacturers Association or by the earlier combined efforts of DHS and Cal/OSHA.
- Participated in the August 2006 meeting held in Denver at the National Jewish Medical Research Center (NJMRC), with other agencies that have been working on this issue, including NIOSH, FEMA, Federal OSHA and Cal/OSHA. The objective of the meeting was to share what is known about this hazard, and to continue a dialog on the problem.

Next, Julia Quint, Chief of HESIS spoke about the need to assess the extent of the problem and of raising awareness to ensure that workers are protected. Julia Quint mentioned that DHS gathered MSDSs from

manufacturers and reviewed these documents to determine if they listed or made reference to the hazards of diacetyl. Julia Quint said that if companies did not voluntarily improve their MSDSs a referral to Federal OSHA and Cal/OSHA was planned asking them to look at this problem and requesting that they take action to assure that these documents accurately convey the necessary information. Julia Quint said that HESIS had produced outreach materials and targeted the distribution of these materials to flavor manufacturers and physicians. DHS and HESIS used a document format that discusses the hazards in a non-complex way and that is printed in both English and Spanish. She said the materials point out that safe levels of exposure to hazardous flavoring substances have not yet been established, and that medical tests are needed to identify developing disease. She also noted that a list of clinics competent in pulmonary function testing that can be used for medical screening has been developed to provide to employers.

A question was asked as to how many flavor manufacturers were identified by the DHS telephone survey; Julia Quint responded that initially 175 companies thought to possibly be involved with flavor manufacturing were identified, but that there was no specific information as to whether or not they were at risk for hazardous employee exposures. She said that to date a total of 30 flavor companies had been identified for the FISHEP program. Other companies contacted in the telephone survey found to be involved with the flavor business appeared not to be conducting manufacturing that would involve exposure to diacetyl or other substances of concern, for example, sales, distribution, consulting, or handling only dried foods such as soups and sauces.

Julia Quint commented that they were glad that NIOSH had issued an Alert on working with flavor hazards. However, Julia said that when the second case of bronchiolitis obliterans occurred in California, it suggested there was probably need for additional outreach and information development and distribution. Julia Quint said that copies of the DHS outreach documents can be accessed at the NIOSH flavors web page. She added that DHS is looking into having the documents posted on their own web page. Another issue mentioned by Julia Quint was that physicians are not asking employees what chemicals they work with, so they may miss that there is a problem. As such, DHS is informing physicians of the diagnosed cases of bronchiolitis obliterans, and insurers because usually they do not understand this problem. A third concern mentioned by Julia Quint is that some of these workers need information in Spanish, so DHS worked with UCLA and Cal/OSHA to have the outreach materials translated into Spanish. One last comment provided by Julia Quint was that we have enough information to do something, and she also told attendees that they would welcome ideas about how to get this information to the downstream users.

### **Discussion of morning topics**

In regards to how to get information to the downstream users of potentially hazardous flavoring substances, Fran Schreiber commented that Cal/OSHA should request a list of companies that buy these products from the manufacturers that are participating in the Cal/OSHA Consultation program. She said also that there are companies outside of California that are shipping potentially hazardous flavoring products into California. She reiterated her concern with downstream user employees. Saying that telephone surveys were not enough to identify companies with possibly hazardous exposures, she said that AB 816 vetoed by Governor Schwarzenegger would have enabled HESIS to obtain information on user locations from chemical and other product manufacturers. She asked that DHS and Cal/OSHA put together a list of potential partners to work with on the problem including fire and environmental inspectors, and local health departments. Julia Quint said that DHS is happy to collaborate with other agencies and noted that HESIS had enlisted the Department of Toxic Substances Control to disseminate advisories to auto repair shops on hazardous substances. Fran Schreiber asked for a follow-up report on activities with agency partners and the extent to which workers are actually getting in their hands the information on the potential respiratory hazard posed by flavoring substances.

Len Welsh said that working with other agencies was a good idea, but that it is important to also work with unions and community organizations, though many food and flavor manufacturing operations are non-union. He said it was not clear how to best reach all potentially affected workers. David Egilman suggested as an “out-of-the-box” idea that rabbis who go into many food manufacturing locations seeking approval of their processes might be enlisted in identifying operations of potential concern. He suggested that state and local health inspectors going to food manufacturing operations might also be a source of assistance.

Juli Boyles suggested that hazard information could be distributed to employees through “paycheck stuffers.” She said that organizations such as the California Chamber of Commerce and the Bakers Association could assist with awareness campaigns.

Jason Schmelzer said he was confident that his association would be willing to distribute information to relevant member companies. He said that the California League of Food Processors would likely also be a good association to think about asking to pass down this information. He said that the National Federation of Independent Businesses could possibly also be of assistance.

Mark Scott noted that in regards to requesting a list of downstream users, his understanding was that manufacturers are legally prohibited from revealing who they sell to. However, this does not detract from the need to know what exposure level is safe and where high concentrations are being used. For instance, these flavoring ingredients are present in frosting, but we do not know if the exposure level is high. He said that some downstream users of butter flavorings could be identified by looking at food product labels.

Len Welsh replied that this point was well taken. He said that the exposure level is important, but we have to ask what else we can do in order to solve this problem.

Len Welsh went back to the earlier question about the scope of a possible regulation. He said that diacetyl is ubiquitous in our food, it is found in margarine, potato chips and alcohol manufacturing (wines). He said that the question is what to do about a substance that occurs naturally without apparent hazard, but then in manufacturing processes is concentrated. In regards to the downstream users, he commented that it probably would be best to start by explaining the hazard. But that it will not be easy to get a handle on or to track this. He said further that market forces are probably already operating to reduce use of diacetyl because of its apparent hazard and possibly other flavoring substances of concern as well.

John Froines said that the answer to controlling the exposure would be looking at technology for enclosed systems and respirators. He said that the emphasis should also be in the use of appropriately safe substitutes.

Connie Leyva asked whether or not the Denver meeting had included labor representatives. Len Welsh replied that the meeting in Denver organized by National Jewish Medical Research Center with the assistance of FEMA, was intended for a small group of representatives of government agencies to share what they had learned in researching the problem to date and had not included labor representatives.

Fran Schreiber said there was a need to look at downstream users. Len Welsh said that he agreed that downstream uses and hazards needed to be looked at but that the question was how best to do that with so many locations of possible concern. He said that with limited resources just doing the FISHEP process at 30 flavor manufacturing locations was proving to be a daunting task. He said he hoped that working to identify where a possible regulation might make sense in order to control significant risk could become a cooperative effort between labor and management to maximize the effectiveness of what is achieved. John Froines said that the southern California Center for Occupational and Environmental Health (COEH) based at the University of California would be happy to assist with the research effort. Len Welsh thanked John Froines again for his offer of research assistance.

Angie Wei said that a many workers in flavor manufacturing are not-unionized and she is concerned that if we scare them about this hazard, they would not have a place to go, since they have no health insurance. Julia Quint noted that DHS has a problem with getting doctors to recognize that the health problems of these workers are connected with work.

### **NIOSH activities**

After a lunch break, Len Welsh introduced Kay Kreiss, a physician and Chief of the Field Studies Branch at the NIOSH Division of Respiratory Disease Studies located in Morgantown, West Virginia.

Kay Kreiss reviewed the history of the work conducted by NIOSH. She explained that this work started in 2000, when the Missouri Department of Health and Senior Services requested assistance in response to a report

of serious respiratory illness among a group of workers at a microwave popcorn plant. NIOSH conducted a cross sectional survey and observed about 25 percent of workers had abnormal spirometry, with 19 out of 117 having fixed airways obstruction. NIOSH knew it was an occupational disease but not asthma. Prior to this study, the only hazard that had been evaluated in microwave popcorn manufacturing was dust. So, first they evaluated dust. Afterwards, they estimated that diacetyl was associated with the occurrence and severity of the illnesses seen but it could not be established as the cause. So diacetyl exposure became a marker for risk of disease. They found that 4 out of 8 flavor ingredient “mixing” workers were sick. There was so much concern with these findings that NIOSH provided powered air-purifying respirators for exposed workers to wear while engineering controls were being established.

Kay Kreiss said that after the initial visit the NIOSH team went back to the Missouri location every 4 to 6 months between 2000 and August 2003. She said her unit felt that with operation changes and engineering measures that the location had exposures under control by 2003. However, mixers still continued to be at risk even after Local Exhaust Ventilation (LEV) and Respiratory Protection was used. Another lesson was that there were employees with respiratory effects on the packaging line where exposures were substantially lower than among mixing workers. Another small group of workers affected were from quality control. Five or six workers were assigned to pop popcorn for quality control, as compared to the workers that were assigned to the packing line. Therefore, her group concluded that the time-weighted-average exposures might not be the only concern, but that the short term exposure levels might be a significant factor in risk as well. The thought was that a role might be played by the high temperature from the microwave popping process and the fact that when the workers opened the bag there could be significant exposures. Very high peak levels of exposure were observed at operations such as when workers were opening the bags and near ingredient mixing on tanks.

Kay Kreiss said that NIOSH conducted pulmonary function testing on employees involved in flavor mixing operations at the Missouri plant and that in light of the seriousness of respiratory disease identified, evaluations were initiated at other microwave popcorn manufacturing facilities. She said that medical findings consistent with bronchitis obliterans were observed in employees at 5 of these 6 locations. In some of these plants it was observed that exposure levels in non-mixing areas were lower than those found at the Missouri plant. It was speculated that this may have reflected the physical separation of these areas from the mixing process.

Kay Kreiss mentioned that there are disadvantages to cross-sectional epidemiologic studies of occupational disease, and that there are some things that these studies cannot tell us, such as which ingredient or ingredients are causing the disease. She said the NIOSH studies found diacetyl to be a marker for possible disease risk. She noted that in a short-term animal study it was observed that exposure to complex butter flavors (with several ingredients) caused severe damage to the airway epithelium. She added that in a toxicology study of diacetyl exposure alone similar results were found, but only an abstract is currently available not the full study results which should be forthcoming. She mentioned that NIOSH has only a limited capacity to do longer term toxicology studies but is talking with the National Institute of Environmental Health Sciences about possibly conducting such studies.

Kay Kreiss mentioned that control measures instituted at the Missouri plant included switching to “encapsulated” powdered butter flavoring. Although this helped reduce exposures to volatile components such as diacetyl, there was still potential for particles to reach the lung.

In regards to other studies conducted, Kay Kreiss mentioned an in-vitro study that looked at the effects of butter flavor in guinea pigs. In this study it was observed that the butter flavor had an effect on the respiratory epithelium. She added that no good biomarkers of effect have been identified. She commented further that there is an investigation currently being conducted, where it has been observed that workers exposed to very high levels of diacetyl had inflammatory cells present in the sputum. She reiterated that this investigation is still in progress.

As to publications, Kay Kreiss said that in 1985, a study conducted at a bakery ingredient mixing operation in Indiana showed that 2 young workers had findings consistent with bronchiolitis obliterans after only about 5 months of employment. She added that NIOSH also conducted pulmonary function testing on 4 other workers and that 2 had abnormalities and two had no disease. She said that smokers in their 30s usually do not develop lung disease. She stressed that while diacetyl was used at this location other flavor ingredients were used as

well and no particular substance was identified as the causative agent for the rapid onset disease that was observed. She said that at the time the company requested a Health Hazard Evaluation, NIOSH was focused primarily on particulate exposures and did not consider that the vapors or volatiles could be the problem. She also noted that an abstract of Lockey published in 2002 had identified 5 employees with rapid onset of respiratory disease diagnosed as bronchiolitis obliterans at a flavor manufacturing company but could not identify a specific causative agent.

An update on NIOSH assistance to Cal/OSHA was also provided. However, Kay Kreiss stressed that NIOSH has not embarked on development of a recommended standard for flavor-related industries or substances, and is not currently recommending an exposure limit for diacetyl or other chemicals of possible concern in flavor manufacturing.

### **Discussion of NIOSH activities**

In regards to looking at a PEL, Fran Schreiber asked if the studies conducted by NIOSH, where mixers were affected, occurred at a concentration of 0.05 ppm. She said the labor petition had requested that the PEL be set at 0.02 ppm to include a safety factor, but was concerned that they might have misread the study results and that effects were still happening at levels below 0.02 ppm.

Kay Kreiss responded that peak exposure also needs to be looked at. She mentioned also that in the studies conducted by NIOSH, in addition to breathing zone air samples, measurements were also taken at the head space of the flavor mixing tanks, and where the oil was heated, they observed 1200 ppm, suggesting a potential for risk from very high short term exposures.

Fran Schreiber asked Kay Kreiss what she thought would be the significance of a requirement for medical surveillance of workers exposed to flavoring substances. Kay Kreiss responded that it is critical to look at medical surveillance, since it isn't known if there is a safe level of exposure to diacetyl specifically or flavor substances more generally, and so it is important that we do not screen based only on symptoms reported for example in a questionnaire, but rather based on spirometry that is of good quality, because this is an irreversible disease.

She said further that NIOSH has seen problems with the quality of spirometry, so it is important that it is performed consistent with the guidelines of the American Thoracic Society including use of appropriate equipment. She said she felt that public health departments can play an important role in monitoring the quality of pulmonary function testing. She said further that NIOSH only certifies individual spirometry technicians, not the organizations providing it. She said that technician certification by itself is not a guarantee of quality spirometry.

Fran Schreiber asked if NIOSH had a recommendation or opinion on the frequency of pulmonary function testing needed to reliably catch developing disease. Kay Kreiss responded that while it does not have a formal recommendation, NIOSH does see timely spirometry as critical, in light of the rapidity with which disease has been seen to develop in some cases, such as in the 1985 Health Hazard Evaluation where serious disease developed with only 5 months of work at the location.

Jason Schmelzer suggested the Division develop a list of approved providers of spirometry. Len Welsh responded that DHS is working on that.

There was brief mention by Kay Kreiss, Julia Quint, and John Froines of additional animal toxicology testing that is underway, including a study at NIOSH on dose rate effects, and a gavage study.

Larry Reed from NIOSH commented that a new health hazard evaluation study will be conducted to focus on engineering solutions. He said this would be a 2-3 year study and that it would provide technical assistance and would look at the full spectrum of possible engineering controls. He noted that the first step would be to create a strict protocol and scientific evaluation to review the protocol and in the process work with sister associations. He said that findings would be released as the project progresses not just at its conclusion.

Fran Schreiber asked Larry Reed if the project would be looking at exposures from cleaning of mixing equipment as mentioned by Kelly Howard could pose exposure risks. Larry Reed said that all aspects of processes were being assessed and that downstream users were also being looked at. He said that this project is fully funded by the agency. However, he reiterated that it is likely to take 2 to 3 years to complete, but that the protocol being developed with the assistance of stakeholders would be ready for review in the next couple of months, maybe in December. He concluded by saying that the project was planned to generate easy-to-implement solutions to exposure control problems.

### **Discussion of possible regulatory responses**

Len Welsh summed up the purposes of the day's meeting as two-fold:

1. To describe what had been done on the flavorings issue in California thus far
2. To discuss what could be done better and the potential for rulemaking.

In its discussions to this point he felt that the meeting had met the first purpose, so he was introducing Amalia Neidhardt of the Division's Research & Standards Health Unit to introduce the second task of the meeting.

Amalia Neidhardt listed the following rulemaking elements that would be considered in a substance specific standard:

- Medical screening, including spirometry
- Hazard evaluation
- Exposure assessments, such as PELs, peaks or any other exposure metric
- Engineering controls
- Respiratory protection, both interim and on-going
- Administrative controls such as restricted access
- Housekeeping
- Training for supervisors and other employees

Len Welsh said this task could be seen in two ways. The meeting could propose an emergency standard while working towards a permanent standard as the petition to the Standards Board proposed. Len Welsh favored a different view: the interventions that have been taken in the California flavor manufacturing industry have resulted in more remediations than any standard would require. Thus Len Welsh suggested that the issue of an emergency standard versus a permanent standard be put aside for a discussion about scope, or "which employers should we capture with such a rule?"

John Hallagan commented that the elements of a regulation discussed by Amalia Neidhardt were consistent with the focus of FEMA. He agreed with earlier comments that the quality of medical screening is very important to early identification of disease. He said that screening needs to be both frequent and consistent. Even if different personnel perform the spirometry, it must be done in the same way. Screening was also a controlled opportunity for communication with workers about exposures and hazards.

Len Welsh asked what industries besides flavor manufacturing should be doing medical assessment of employees.

Fran Schreiber said that any facility using diacetyl should be required to do medical screening. It would be inappropriate to wait for certainty, given that the first cases of bronchiolitis obliterans were at downstream user locations.

Judi Freyman appreciated Fran Schreiber's concern but was unaware of any information that would support such universal medical screening. She said that most downstream users don't use enough of the substances of concern, according to a survey of members of her organization. She felt that to extend medical screening to all downstream users might be over-reaching.

Len Welsh asked Judi Freyman if there was any diacetyl monitoring data from such users. She answered that there was almost none. Fran Schreiber then asked how Judi Freyman concluded that screening was not warranted. Judi Freyman answered that the processes and quantities of use led to her conclusions.

Len Welsh said it would be good to have a guidepost about floor quantities or processes of concern. Fran Schreiber said scientific data would be needed on detectability of diacetyl in air at 0.001 ppm as there is a health risk even below this level. Barbara Materna said that NIOSH had reported 0.001 ppm as the limit of detection for diacetyl in air.

John Hallagan responded that exposure potential depended upon the industrial process. For example, he said, margarine production utilizes an almost totally closed system, so the potential for diacetyl exposure is low. However, with baked goods processes you could come to the conclusion that there are opportunities for exposure—especially if heated, he emphasized.

Len Welsh said we have to get a handle on the ubiquity of diacetyl. We don't have to know what the exposure cut off is, but we need a sense of where the heaviest risk is—where are the likely intense exposures.

Fran Schreiber proposed a different trigger for medical surveillance and engineering controls. Perhaps there should be a variance process where industry can demonstrate via monitoring where there is no risk and then they could get out of medical surveillance.

Jason Schmelzer questioned if Cal/OSHA has the ability to monitor medical surveillance in the workers comp system? Len Welsh said there was a difference between an employee going to his own physician and going to an assigned doctor for a workers compensation evaluation and the employer contracting for preventive medical surveillance.

Jason Schmelzer then asked, to the extent that consultation and enforcement efforts had been successful, what Title 8 standards have been cited, and why is it necessary to add more standards? Len Welsh agreed that one could postulate that existing standards like 8CCR 5141 and 5144 provide a degree of coverage for the circumstances of concern. But there are problems with this approach. For instance, he pointed out, in regard to there being no rule on the books that would mandate medical surveillance. Certainly the more specific the regulation is, the better. The less specific a regulation is, the more appeals tie us down. He felt that the flavor problem was so specific that the physics of litigation require a more specific regulation in order for enforcement to be effective.

Jason Schmelzer said finally that he thought a permanent regulation was preferable to an emergency regulation.

Mark Scott remarked that FISHEP was going well, and suggested waiting until the end of that process in order to accumulate data. Some companies won't comply but since the industry is doing well it would be wise to wait for NIOSH to finish its study.

Len Welsh pointed out that the flavor manufacturing industry would certainly be captured by any standard that might be adopted on diacetyl exposure because the number of companies is small, and in fact the Division and the companies are mostly in agreement. The big concern, he said, is for the people you sell to and other users of diacetyl. "Where else do we have a problem?" he asked, "It will not do to wait." Len Welsh said also that he appreciated the conversations leading up to lunch on the need to not move too fast too soon. But Len Welsh felt it was necessary to at least acknowledge that some downstream employers may have a problem and should inform employees about potential symptoms of exposures of concern.

Mark Scott replied that once it was known what the level of exposure is that causes bronchiolitis obliterans cases to arise, then it would be possible to make a judgment about downstream exposures.

John Froines said that the discussion appeared to be revolving around three items: a general duty standard, an emergency standard and a permanent standard. The general duty obligations seemed to be OK for good

employers. Standards, in his experience with cotton duct and lead, are a long ways down the road, while the general duty was here now.

David Egilman said he was unaware of any standard set up with medical surveillance alone without exposure limits. The index plant for bronchiolitis obliterans cases had doubled the amount of diacetyl in order to make low fat products. People are creatively using products; therefore he said he didn't think there is enough information to create a matrix for assessment of exposure risk for downstream users.

Fran Schreiber said there are limitations on establishing specific triggers for engineering controls or medical monitoring. She suggested a performance-based standard might work, but that it wasn't adequate to rely on the IHIP (Injury and Illness Prevention) standard alone.

Len Welsh asked what the trigger should be for any medical monitoring or screening requirements. Fran Schreiber said the use of the substance should trigger medical monitoring with an air monitoring option out of the screening requirement. When the meeting was asked who agreed with this approach only B. James Pantone voiced support. Angie Wei felt that a trigger for medical monitoring went hand-in-hand with a PEL. Len Welsh asked if 0.001 ppm in air, the limit of detection, should be the PEL. Angie Wei expressed skepticism about requiring medical surveillance for everyone as this might raise unnecessary concerns among workers only slightly exposed to diacetyl.

Len Welsh said he liked the idea of a matrix of processes; perhaps a standard could define specific processes that would trigger the requirement for medical surveillance.

Fran Schreiber said she was not opposed in principle to such an approach but recalled that there were problems with using the matrix idea in the lead standard. Peter Scholz pointed out that the inorganic lead matrix began with Mark Nicas at UC Berkeley School of Public Health, and ended up relying on a yearly use level. Julia Quint made reference to the diacetyl range of use level that Kelly Howard had reported on. Kelly Howard said that the significance of annual usage levels for assessing risk may depend in part on whether the use is concentrated in a particular period of time or spread out over the entire year.

Mark Scott asked if the Division's FISHEP program and the efforts of NIOSH would be generating data for assessing risk potential. Len Welsh replied that they might.

Len Welsh asked how workplaces using diacetyl could be identified. Robert Harrison supported the need for medical monitoring. He said he believed all agreed with the need, but the question was what was the trigger. John Froines said the standard should address the other elements noted by Amalia Neidhardt.

Angie Wei expressed appreciation for FEMA's publication and their cooperation with the Division but said it would be necessary to have a list of their customers to know where diacetyl is being used. She said she encouraged distribution of the FEMA document to the downstream users of potentially hazardous flavor substances. John Hallagan said he heard a consensus in the meeting on the idea of a process matrix as a risk assessment tool and commented that based upon FEMA's experience he would expect factors such as heating and amounts of diacetyl used to be important in determining which processes should be included in the matrix. Identifying these kinds of factors could help focus the scope.

Len Welsh said he feared we'd be in a vacuum of ignorance; it could be a massive job and he didn't know how long it would take to find out all of this information about downstream users' processes.

Fran Schreiber said the scope should be everyone—all users of diacetyl. The rest of the standard should be a narrowing of who would be covered by what particular requirements. Len Welsh said hypothetically let's say the scope is any manufactured diacetyl use. The first tier of the standard would be air monitoring, medical surveillance and training.

Jason Schmelzer questioned if it would really help if you require air monitoring without any clear level of harm. Len Welsh asked if the original proposal is too broad and if there is too much opposition, could it be said there

was agreement on the need for training? It seemed to Len Welsh that the ante goes up with medical surveillance and air monitoring.

John Hallagan said he supported training. He said that medical monitoring and air monitoring won't stop bronchiolitis obliterans cases from occurring.

Fran Schreiber said that training should definitely be required for all potential user sites and that air monitoring and medical surveillance were also important but might be more focused in scope. Charlene Gloriani said that the nature of the process used should also be considered, such as if it is used in open containers, heated, etc.

B. James Pantone said exposures have to be reduced. If the work was done in glove boxes, he said, there would be no additional bronchiolitis obliterans cases.

Jason Schmelzer asked which employees would be required to be given information, and how often. Depending on this, it could be OK. He said he wanted to avoid drawing low or no-risk employers into a regulation requiring them to take action that would not have an impact on health risk.

Len Welsh agreed that if a proposal is overly broad in scope and application it can generate opposition. He thought it would probably be best to proceed with a tiered approach starting with an informational requirement for all potentially exposed employees. He asked attendees if there was general agreement on a specific hazard communication and training requirement for all employers with employees potentially exposed to diacetyl at any level.

John Hallagan said that FEMA would support such an approach and would be happy to provide assistance with training and information distribution. Raphael Metzger said training, air monitoring and medical monitoring wouldn't prevent disease. He said that prevention would require substitution of less hazardous substances or other means of more complete control of exposures.

Judi Freyman asked if breweries would be covered where diacetyl is a natural by-product. Len Welsh said the question of naturally occurring diacetyl would have to be looked at.

Len Welsh said it appeared that there was generally agreement on the concept of a requirement for training and information provision at all locations where there might reasonably be expected to be exposure to diacetyl.

Jason Schmelzer expressed agreement with the general concept of a broad training and information requirement but said that there needed to be more specifics about where it would be required and the content of the information to be provided. He said that the requirement should not apply where there is no exposure potential.

Len Welsh asked Jason Schmelzer if a requirement for information provision to "all employees in a use area" would be sufficiently specific. Jason Schmelzer said that would probably be more appropriate.

Len Welsh said the next step would be setting up the matrix process to move toward identifying the characteristics of higher risk operations. John Hallagan pointed out that FISHEP is generating data on which jobs had high diacetyl exposures and should be focused on. Young male production workers had been found to be the group primarily exposed; for the user industries it was probably similar. Fran Schreiber commented that it would take a lot of homework to identify the more at risk population in the user industries, as there are 700 companies. Len Welsh said he suspected the number is far more than 700.

Len Welsh commented that the training required in a standard can't be a message that scares people, but it still has to be sufficient to get the message across. He then asked how scope for the next higher tier of requirements, ie. air monitoring and medical surveillance, should be defined.

Fran Schreiber said she liked the idea of using the matrix discussed earlier for assessing risk and identifying the higher risk types of operations. She said that there should at least be an emergency temporary standard for training and information while a more extensive permanent standard is developed. Angie Wei said she liked the idea of a training and information requirement being in place while a more extensive standard is worked on.

Jason Schmelzer said that if FISHEP is found to be inadequate on its own then he could see the need for regulation beyond training and information but not until that had been established. Len Welsh responded that FISHEP covers only about 30 flavor manufacturing locations not the many downstream user locations. Jason Schmelzer asked if there is any consideration being given to expanding FISHEP to those locations. Len Welsh said that it was difficult handling just the 30 FISHEP locations.

Jason Schmelzer asked John Hallagan if FEMA had circulated its information document to downstream user companies. John Hallagan said that it had been widely distributed to such locations and others. But Fran Schreiber pointed out that not all flavor manufacturers are FEMA members so it's likely many user companies have not gotten the information.

Len Welsh suggested again that it appeared there was a consensus among attendees that there should be an emergency temporary standard with requirements for information and training. Jason Schmelzer said that he would have to consult his association to be sure, but thought that this could be acceptable depending on the specifics of who the regulation would apply to, how often training or information provision would be required, and its format and content.

Fran Schreiber said that there were already requirements for training and information provision on hazardous substances. Len Welsh acknowledged hazard communication and IIP Program requirements, but said that a more specific regulation on the flavoring substances was needed to be effective.

There was discussion about who should get the training, how often and what format the training should be. Len Welsh said that the process of advisory committees was to get a consensus. A real standard will take time, he said, but the process is more streamlined than Federal OSHA's process. He asked people to send written comments on how such a training regulation would look, noting that he was unaware of any existing regulation that covered training alone.

Barbara Materna and Fran Schreiber urged that the symptoms associated with bronchiolitis obliterans be included as part of any training standard, noting that the lead standard 8CCR 5216 requires that information on the specific symptoms of lead exposure be included in the training required by that standard.

Jason Schmelzer commented that if the training is targeted at only the exposed employees and not all employees, then the impact of the training on the employees is greater and more real.

Len Welsh noted that the training message for a downstream location using flavorings that doesn't know if there is a problem needs to include the fact that exposure to diacetyl has been a problem in other industries.

### **Meeting Wrap Up**

Len Welsh summarized the discussion that had taken place. He said there had been two ideas about where a standard should kick in. There had been Fran Schreiber's idea that if diacetyl is used, you're in, while others thought a standard should be limited to workplaces with levels of use likely to cause significant exposures. He said he thought there had been general agreement, though perhaps some need for refinements on the idea, that requirements such as air monitoring, medical surveillance, and engineering controls should be triggered by, and only apply to, locations with the more significant employee exposure potential. He said this made sense but that it assumed that such locations could be effectively identified. He said more work was needed to figure out how to go about distinguishing or defining processes or operations with significant exposure or disease risk for requirements beyond information and training.

Jason Schmelzer said he would be happy to help inquire among CMTA members about potentially significant processes. He noted there are other employer groups such as the grocery association, the California League of Food Processors, the California Restaurant Association as well as employer groups like ORC, the Chamber of Commerce and the Phylmar Group that could assist in identifying significant processes using diacetyl in their industries. He felt the union side could be helpful in identifying processes of concern as well.

Larry Reed said he liked the matrix idea. It could relate to the control solutions study that NIOSH is conducting. “At the end of the day,” he said, “I’m convinced that engineering solution knowledge will grow.”

John Hallagan commented that there is a tremendous opportunity to focus on specific downstream sectors and processes. One way to find out what products involve diacetyl use is to look at product ingredient labels on grocery store shelves. If there are both milk products and artificial flavors listed on the label, then it is a downstream product from the flavor industry.

Len Welsh said that DOSH will come up with draft regulatory language that considers comments received on suggested language. Angie Wei said she would seek help from union representatives on identifying particular operations of concern.

**END**