DRAFT

MEETING SUMMARY

Second Cal/OSHA Advisory Meeting on Diacetyl and Other Flavor-Related Respiratory Hazards in Food and Flavor Manufacturing

February 13, 2007
Elihu Harris State Building
1515 Clay Street
Oakland, California

Attendees

Michael	Boyle	Bimbo Bakeries USA
Diana	Graham	Keller & Heckman LLP
Judi	Freyman	ORC Worldwide
Libby	Sanchez	Broad & Gusman LLP
Bobbie	Rabinowitz	WorkSafe
Jeremy	Smith	California Labor Federation
Mark	Scott	T. Hasagawa USA
Juli	Broyles	California Advocates
Barbara	Materna	California Dept of Health Services
Heather	Borman	State Compensation Insurance Fund
John	Hallagan	Flavor & Extract Manufacturers Association
Kevin	Thompson	Cal/OSHA Reporter
Jackie	Nowell	United Food & Commercial Workers
Fran	Schreiberg	WorkSafe
Robert	Harrison	UCSF
Pat	Verduin	Grocery Manufacturers Assoc/Food Products Assoc.
Nancy	Rachman	GMA/FPA
Bart	Selsted	Interstate Brands
Jon	Wellwood	Gold Coast Ingredients
Loren	Hormigoso	Federal OSHA
Gerald	West	UC Irvine Occupational & Environmental Medicine
Rhonda	Hrabchak	American Fruits & Flavors
George	Landers	United Food & Commercial Workers
Jeff	Jones	California Industrial Hygiene Council
Mary Ellen	Hogan	Holme Roberts & Owen LLP
Susan	Pearce	McKenna Long & Aldridge
Mike	Falaceo	Wine Institute
Adam	Loveall	UFCW 8 Golden State
John	Grant	UFCW 770
Marti	Fisher	California Chamber of Commerce
Bob	D'Amato	ASI
Janet	Aho	Mane Inc.
Caradine	Silveira	GMA/FPA
Dorothy	Dougherty	Federal OSHA
Mandy	Edens	Federal OSHA
Jennifer	Roberts	ChemRisk
Heather	Christensen	UCSF
Erika	Carrillo	Worksafe
Michael	Pulllam	DBR

Cal/OSHA Attendees

Len Welsh, Acting Chief, DOSH (meeting chair)
Steve Smith, Supervising Industrial Hygienist, DOSH
Tom Mitchell, Cal/OSHA Standards Board
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

MAIN POINTS OF DISCUSSION

Kelly Howard of the Cal/OSHA Consultation Service reviewed the status of the Flavor Safety & Health Evaluation Program being conducted at 24 California flavor manufacturing locations, including presentation of air sampling results for diacetyl and other substances of concern. Barbara Materna reviewed the activities of the California Department of Health Services since the previous meeting September 28, 2006 including her unit's focus on Material Safety Data Sheets being provided by distributors of diacetyl, quality control for medical surveillance providers, and follow-up of employees at FISHEP locations found to have mild or moderate abnormalities on spirometry.

Discussion of development of a regulation focused on whether scope should be limited to flavor manufacturing only, or should extend to coverage of all workplaces using manufactured diacetyl. Labor representatives felt that in light of the seriousness of respiratory disease found associated with diacetyl in microwave popcorn and flavor manufacturing, all diacetyl use should be regulated. They generally acknowledged however that given the current limitations in understanding of the relationship of work with flavors to bronchiolitis obliterans, and the size and diversity of the industry, an immediate regulation for food manufacturing should be viewed as an interim measure addressing the basic elements of exposure control, respirators, medical surveillance and employee training. Labor representatives also felt a Permissible Exposure Limit (PEL) for diacetyl was needed to provide a standard by which exposure control measures could be assessed. Representative of food manufacturers acknowledged the seriousness of the situation and said they would work quickly to initiate an effort to generate information needed to inform development of a regulation. However, they felt that while there is sufficient understanding to develop a regulation for flavor manufacturing, they felt there was not enough information to understand where a regulation of food production should be appropriately applied. Representatives of food producers also felt there was insufficient information to develop a fully protective PEL for diacetyl.

Len Welsh said he hoped a working group could be formed at the next meeting to convene more frequently than the public advisory meetings, in order to review relevant data and possibly work on regulatory language, as well as consider appropriate elements for enforcement and consultative activities.

There was discussion of increased outreach activities, especially to food producing locations that may use diacetyl and other substances of concern. There was discussion of working with the food producing organizations to identify locations where educational materials should be sent. John Hallagan of the Flavor and Extract Manufacturers Association offered to provide food producers with a training workshop as he had done for members of his association.

Pat Verduin of the Grocery Manufacturers Association (GMA) and the Food Products Association (FPA) said her association would work to identify food producer locations in California that might appropriately receive outreach materials, and particular locations which might have already conducted air sampling and which might allow on-site visits by Cal/OSHA Consultation to enable the Division to gain a better understanding of operations where exposure to diacetyl and other flavor substances of concern might be a problem.

MEETING SUMMARY

Len Welsh welcomed attendees. He said the first meeting on September 28, 2006 had been held primarily to gather information on what employers and others were doing to address the problem of respiratory disease associated with exposure to certain flavoring substances and to broach the question of rulemaking. He noted that this and other meetings on this topic would not function with an appointed committee of 8 to 10 participants as is sometimes done for more narrow projects, but rather as an advisory meeting where whomever

attends can participate on an equal footing. He expressed appreciation that so many different organizations and professions have been participating in the process to date.

Len Welsh said his thinking is that a fast track approach should be taken to developing a regulation to address control of risk of serious respiratory disease in flavor manufacturing where much has already been learned through the FISHEP project with flavor manufacturers in Cal/OSHA Consultation. He said the work that had been done to date in FISHEP had generated substantial information to support rulemaking in that industry. He explained briefly that with health standards, the staff work is done by the Division of Occupational Safety and Health, what is usually thought of as "Cal/OSHA," but that the administrative process for adoption is conducted through, and adoption of the regulation is by, the Cal/OSHA Standards Board, a 7-member appointed body that meets monthly. He explained that this day's meeting is part of the preliminary process to support the Division's work on the project.

Status report on Cal/OSHA Flavor Industry Safety and Health Evaluation Program

Len Welsh introduced Kelly Howard, Senior Safety Engineer in the Cal/OSHA Consultation Service who gave the following report on the the Division's cooperative compliance efforts with flavor manufacturing employers in California.

The Consultation Service is pursuing a cooperative compliance effort with the flavor industry in California. referred to as the Flavor Industry Safety and Health Evaluation Program (FISHEP). FISHEP does not involve citations or monetary penalties, but employers are required to correct violations and implement findings and recommendations to control exposures to diacetyl and other hazardous substances. It is however not traditional Cal/OSHA consulting activity in that, by necessity, given the need to gain an understanding of the problem and to develop an effective response, information obtained from participating employers is shared with the California Department of Health Services, NIOSH, and other agencies involved in the public health response effort for flavor-related workplace illness. With the many unknown factors involved, the focus of FISHEP is on development and implementation of exposure control measures in operations that have been associated with disease or found to have the potential for chemical exposure. In addition to work at FISHEP locations, Cal/OSHA has conducted enforcement at two flavor manufacturing sites where illness has been reported. Neither of these two locations is currently participating in FISHEP, though they may in the future once appeals of citations are resolved.

The staff for the Consultation Service FISHEP effort consists of Kelly Howard as lead and five industrial hygienists from Consultation field offices, primarily in southern California where most of the facilities are located. The program currently has 24 participating companies of varying sizes and usage levels of diacetyl and other substances of concern. Eight of the locations had previously used National Jewish Medical and Research Center (NJMRC) for industrial hygiene assessment of their operations. These locations were visited as part of FISHEP to verify the NJMRC reports, which were generally found to have accurately characterized the locations. Of the remaining 16 locations, priority is being placed on completing assessments at the 6 locations with the higher levels of chemical usage with a focus on assessment of exposures and possible engineering control measures, the Injury and Illness Prevention Program, the respiratory protection program, and the hazard communication program. The status of the 10 remaining locations is as follows:

- 2 locations remain to receive their initial visit – one is in the process of moving, and the other reported never using diacetyl
- 2 locations reported using less than 1 pound of diacetyl per year
- 6 locations had sufficient usage of diacetyl to warrant air sampling but its use is highly intermittent and so completion of these will take longer than for those with frequent use of the substances of concern.

There are 2 main phases to the FISHEP project, the first being the exposure assessment phase combined with development of the respirator program for interim protection, with the second phase being working with participants on implementation of engineering controls and work practices to control chemical exposures. In some situations even after engineering controls are implemented, respirators may still be warranted as supplemental protection, though a lower level respirator might be possible. Local exhaust ventilation for mixing operations will generally be a primary recommendation, although work practice recommendations such as use of chilled rather than hot water to wash mixing containers and chilling ingredients will also be important to controlling exposures to volatile flavoring substances such as diacetyl. Assistance with development of effective engineering controls is being provided by NIOSH which in Fall of 2006 spent 3 days in each of two higher usage FISHEP facilities. Based on those studies, NIOSH is using their engineering laboratory capabilities to assess what approaches to control measures is likely to be most effective in reducing exposures, for example, determining the optimum configuration of local exhaust ventilation systems for mixing tanks, as well as the maximum diameter of tanks over which such systems can be effective. Two industrial hygienists from Federal OSHA's Research & Standards Unit visited the same 2 high usage facilities in January 2007.

Air sampling for diacetyl has required some research and modification of methods to be effective. OSHA and NIOSH each has sampling and analytical methods. The OSHA method is being used in FISHEP assessments because it is simpler. For example, it does not have the short deadline for analyzing samples once they are collected that the NIOSH method does. The limits of detection and quantitation of both methods as written are much higher than the 0.02 ppm target being worked work to based on NIOSH findings in microwave popcorn plants. In consultation with the OSHA Salt Lake Laboratory, the Consultation industrial hygienists are collecting larger volumes of air at higher flow rates than the written OSHA method calls for in order to achieve lower

limits of detection and quantitation, and so far there have been no problems with sample breakthrough and loss as a result. Most full-shift air sample results for diacetyl at FISHEP locations have been in the range of <0.01 to 2.4 ppm. 15-minute Short Term exposures measured to date have been in the range of <0.9 to 9 ppm, while area samples have been as high as 1.2 ppm. It has been found that dilution ventilation used in most locations had the potential to transport chemicals to areas where they are not used, potentially exposing employees not working with the chemicals.

Air sampling has also been conducted for other substances of potential concern including benzaldehyde (with an AIHA WEEL limit of 2 ppm 8-hr TWA) for which exposures up to 1 ppm full-shift had been found, acetaldehyde (PEL Ceiling 25 ppm) found to 27 ppm – mostly in the 1-2 PPM range, and acetic acid with full-shift exposures generally less than the PEL of 10 ppm, but with short term exposures greater than the Ceiling level PEL of 40 PPM. These and other flavoring substances in addition to possibly being a factor in bronchiolitis obliternas, may also be related to other respiratory conditions, such as asthma. FISHEP work focuses on the substances designated as "high priority" for respiratory risk in the document published by the Flavor and Extract Manufacturers Association of the United States (FEMA) entitled "Respiratory Health and Safety in the Manufacturing Workplace." As suggested in the FEMA document, with uncertainty about the exact cause of bronchiolitis obliterans, the FISHEP project is focusing participating employers on overall process controls rather than measurement and control of exposures to individual substances one-at-a-time.

Len Welsh thanked Kelly for his presentation and asked him about specific challenges posed to development and implementation of effective engineering controls. Kelly Howard responded that a major challenge would be developing effective local exhaust ventilation systems for the size of mixing containers used at FISHEP sties and presumably other flavor manufacturing locations. He said it is difficult to effectively capture vapors released from the surface of mixing vessels with diameters greater than 4 feet. Because of this challenge, his group is for some situations waiting until they hear back from NIOSH about results of research in their laboratory on different system configurations before recommending undertaking installation of local exhaust ventilation systems. Given the scarcity of individuals able to reliably design effective systems, he wanted to avoid other situations he had seen where money had been spent on ineffective local exhaust ventilation.

John Hallagan asked what a push-pull ventilation system is. Kelly Howard said this is a system consisting of both exhaust and supply openings, with the supply opening, hopefully, "pushing" contaminants effectively into the capture zone of the exhaust opening. He noted such systems can be difficult to design and implement effectively. John Hallagan asked about application of local exhaust ventilation to closed mixing vessels. Kelly Howard said this can help reduce exposures and is frequently used.

Len Welsh said he hoped FISHEP participants and other flavor manufacturing locations can move toward closed systems and process containment to reduce exposures. Kelly Howard noted that National Jewish Medical and Research Center industrial hygienists had found significant exposures with pouring of liquids onto powders in some mixing operations, where the final product is in powder form. He noted that while process enclosure and containment can reduce exposures, it can lead to more cleaning of equipment containing residual flavoring substances which his group had found can cause significant exposures.

California Department of Health Services Activities

Barbara Materna, Chief of the Occupational Health Branch (OHB) in CDHS, reviewed her group's activities since the last meeting. She said OHB flavor-related activities fell into two basic areas: outreach activities including development and distribution of written information, and oversight of medical screening activities, particularly with regard to FISHEP locations. She said after the second case of serious lung disease was found in California flavor manufacturing, OHB produced fact sheets in English and Spanish and distributed them to employers, employees, and community and health professional organizations, as well as posting them on a new flavorings topic page on the OHB website (http://www.dhs.ca.gov/ohb/flavorings.htm). OHB has also alerted occupational health programs in health departments in other states about the risk of respiratory disease identified in flavor manufacturing in California. The NIOSH Education and Information Division has received internal funding to conduct more nationwide outreach, and OHB staff are providing input to this effort. She said OHB was also working on an article on California findings and activities in flavor manufacturing for the Morbidity and Mortality Weekly Report (MMWR).

Barbara Materna said since the last meeting on September 28, 2006 her group has been trying to address the question of Material Safety Data Sheets provided to California flavor manufacturers by the manufacturers or distributors of diacetyl. She said OHB had identified 11 manufacturers and distributors of diacetyl and requested their MSDSs. She said some of the MSDSs indicated they had been updated in 2006 but that all still lacked adequate hazard and/or exposure control information. She said OHB had developed recommended language for MSDSs for diacetyl and distributed it to these companies, asking that they submit any revised MSDSs to OHB.

Barbara Materna said her group had requested spirometry data collected at all FISHEP participant locations in the effort to assure that medical screening for respiratory disease at these locations is of consistently high quality. She said medical questionnaire responses, and copies of physician notifications to employees regarding their results are also being requested. She said OHB is also gathering from each FISHEP company the names and job titles of all employees, and working to assure that all employees that may have potential

exposure to diacetyl or other flavoring ingredients are receiving the medical screening. She noted that there are at least 300 or 400 employees at all FISHEP locations combined.

She said that at the last meeting she had talked about putting together a list of "approved" providers of pulmonary function tests. She said at the present time OHB was directing flavor companies to UCLA and UC Irvine clinics in the south, but that private providers chosen by employers are acceptable as long as their spirometry meets quality standards. She said OHB was working with Dr. Paul Enright, a NIOSH consultant, to evaluate all spirometry data from FISHEP locations. OHB will also be providing guidance to the medical providers on the system being utilized for grading spirometry quality and guidelines for interpreting results. She said the work by the National Jewish Medical and Research Center and some other providers reviewed to date was found to be of high quality; however Dr. Enright had found a number of problems with two spirometry providers used by FISHEP companies. She said FISHEP companies with spirometry or other aspects of medical testing found to be faulty or inadequate would be notified and asked to repeat the testing.

Barbara Materna said an important next step in the medical screening at FISHEP locations is following up with a small number of individual workers (less than 10) with mild or moderately abnormal results on spirometry. She said OHB was developing a protocol for additional testing to recommend for these workers, and also that the number of workers with abnormal results on spirometry may increase as additional reports of medical screening are received from FISHEP locations. She said that to date none of the test results OHB had reviewed suggested imminent development of bronchiolitis obliterans, and that Kelly Howard's group was being informed of employees with abnormal spirometry so that their work areas can be reviewed to ensure that necessary steps are being taken to minimize their exposures to potential respiratory hazards.

Barbara Materna reported that Assemblymember Sally Lieber had requested that CDHS prepare a written summary of the known or suspected cases of lung disease among flavor workers, and that there was some misquoting in the press of the number of confirmed cases. The document describes eight former or current flavor manufacturing workers known to CDHS as having been diagnosed with BO or other lung disease. She cautioned that there is a process by which to reach a medical diagnosis that moves from screening spirometry results, to spirometry with a bronchodilation drug (to determine if the condition is reversible or fixed), to other medical testing such as chest CT scan. Not all of the 8 workers have undergone all necessary testing, or CDHS does not have their full medical records. At this time, three are known to have a diagnosis of BO, four have fixed obstructive lung disease, and one has a diagnosis of work-related asthma.

Barbara Materna noted that since there should now be a greater awareness among medical professionals of a connection between serious respiratory disease and work with flavors, cases may be more likely to be correctly identified and come to the attention of OHB. She said also that all the medical and industrial hygiene information collected from FISHEP participants will be aggregated and a report developed that will hopefully contribute to greater understanding and prevention of respiratory disease in flavor manufacturing.

Jackie Nowell asked if medical testing results from NJMRC can reasonably be mixed with results from other providers. Barbara Materna said they could, and that OHB was in the process of putting the data into a single database.

Pat Verduin asked how the 8 cases of actual and potential disease had been identified. Barbara Materna said the first case that led to a Cal/OSHA enforcement inspection was reported to Cal/OSHA by a pulmonologist who made the connection between the patient's condition and where they worked. Two workers were reported to CDHS by a newspaper reporter and an attorney. The remaining five were found as a result of Cal/OSHA's work in flavor manufacturing, either through one of the compliance investigations or the company-sponsored medical screenings. She said a number of the cases were not initially recognized as work-related or filed as Workers' Compensation claims.

Juli Broyles asked what jobs the 8 affected employees had at the flavor manufacturing locations. Barbara Materna responded that most were "flavor compounders," all working in production. One of the employees worked packaging powdered flavor materials.

Bob D'Amoto asked if any of the disease cases had appeared on Log 300 forms. Kelly Howard said Log 300 review is standard for any visit by the Cal/OSHA Consultation Service for those locations where they are required to be kept. He said that in reviewing the Log 300 at FISHEP locations no suggestion of possible additional cases had been found.

Len Welsh said that fixed obstructive lung disease is the focus of FISHEP. He said some medical experts have suggested that lung biopsy for diagnosis of flavor-related bronchiolitis obliterans is unnecessarily invasive, especially since options for effective treatment are limited. Barbara Materna noted that NIOSH physicians had said that noninvasive testing and the progression of symptoms can be sufficient for diagnosis of flavor-related bronchiolitis obliterans, and that some patients are simply too sick to have a lung biopsy. Len Welsh reiterated that the goal of medical screening is to identify those employees who are early in the process of developing fixed obstructive disease so that interventions can be taken to remove them from exposure, and control the exposure of others in the operations where they work.

Bob D'Amoto asked how many manufacturers of diacetyl had been identified. Barbara Materna said OHB had identified 11 U.S. companies that sell diacetyl, but none were known to be manufacturers. John Hallagan said he was not aware of any manufacturers of

diacetyl in the United States. Juli Broyles asked if Barbara Materna could provide the MSDS language that had been suggested by OHB to the distributors. Barbara Materna said that could be provided. Jackie Nowell asked if the list of distributors could be provided. Barbara Materna said it could since it was obtained from public Internet websites.

Len Welsh said it was important not to ignore the MSDSs for the other 34 high priority substances identified in the FEMA publication. Barbara Materna noted that there is not a lot of toxicology information available for these other substances. John Hallagan said FEMA is providing information to member companies including suggested information on diacetyl for MSDSs for their flavor products.

Discussion of Regulatory Altenatives

Len Welsh thanked Kelly Howard and Barbara Materna for their presentations and suggested moving along to discussing what reasonably could, and perhaps could not, be accomplished through development of a regulation to address the problem. He said that as at the previous meeting in September, it would probably be easier to talk first about addressing flavor manufacturing, as the number of California sites that would be affected is very limited in number, and through FISHEP and enforcement cases the Division is already involved with most of them. This in contrast to regulation of downstream users of flavor products which is a much larger and more diverse set of workplaces. Jackie Nowell disagreed that flavor manufacturing should be discussed first. She said she applauds the work that the Division has done in flavor manufacturing and that the problem in that industry, in California, is in the process of being well-addressed through FISHEP and enforcement. She said the focus of the labor petition to the Standards Board requesting development of a regulation of flavoring products focused primarily on food product manufacturing. She said it appeared a great deal had been learned about controlling flavor exposures from the batch manufacturing processes found at FISHEP participant locations, and hoped that the attention focused on the problem and the work of the Department of Health Services helps to increase recognition of flavor-related respiratory disease before it progresses to bronchiolitis obliterans. She said the job of protecting workers from this disease would not be done until programs and standards are in place for how to handle use of flavors in food manufacturing. She said a regulation was needed to force development and implementation of exposure control technologies and to help assure that employers, employees, medical providers and industrial hygienists are better aware of the problem. She said that if diacetyl is as hazardous as it appears to be, then substitutes for it should be mandated.

Fran Schreiberg said the approach of the "precautionary principle" should be used, using what has been found in other settings and applying it to food product manufacturing. She said a regulation for this industry should address the following: exposure control, employee training, respirators, and medical surveillance. She said what she envisioned was not a full comprehensive chemical regulation with a PEL and air sampling requirements, but rather something simpler that could be implemented more rapidly as the problem, and possible solutions, hopefully become better understood. She said a regulation would be an important incentive for employers to control employee exposures to flavoring substances.

Mark Scott said that compared with flavor manufacturing, the percentage diacetyl in materials used in food product manufacturing is generally much lower and so of less concern. Pat Verduin said that food producers are concerned with risk of respiratory disease from flavors but that the information doesn't currently exist to set a PEL for diacetyl based on prevention of bronchiolitis obliterans. She said however that something should be done, starting with systematically examining the potential for hazardous chemical exposures in food product manufacturing. Len Welsh then posed to attendees the question of how best to start to identify which operations or parts of food production may place employees at risk for serious respiratory disease as seen in flavor manufacturing and microwave popcorn.

Fran Schreiberg said she had tried to develop a matrix to illustrate risk of exposure or disease and operations or characteristics such as work with open surface tanks. She said that for a full comprehensive chemical standard such a matrix would need to be more fully developed. But she suggested that with the current limited state of knowledge a more limited standard for diacetyl would probably be most appropriate and capable of being adopted. She suggested a basic requirement for awareness level training for employees working in proximity to flavor handling operations involving diacety, and requirements for training, medical surveillance, respiratory protection and exposure control for employees working directly with or handling diacetyl. She said she would define "handling" diacetyl for the purpose of scope as being working with any amount of manufactured diacetyl (as opposed to naturally occurring) in an open container.

Len Welsh asked Fran Schreiberg what she would propose to do about other substances in flavors thought to be potentially hazardous. She suggested starting with regulation of diacetyl as a stop gap measure until the risk posed by other substances is better understood. Len Welsh asked how many food producers use diacetyl in their operations. Pat Verduin said there were thousands in the United States, but many or most use only very small amounts. She said diacetyl use in these locations involved substantial process variability so it could be hard to determine what employees are exposed and so should be included in a regulation.

Len Welsh asked about requiring at least one-time medical screening assessments for employees at risk. Pat Verduin suggested this could be appropriate as a means of determining in which areas to focus attention on exposure control measures. Bob Harrison noted that the range of diacetyl concentrations found at FISHEP locations reported by Kelly Howard earlier in the meeting showed a great deal of variability but were in the same range as NIOSH findings in microwave popcorn plants, and that a regulation limited to flavor manufacturing would not, for example, cover microwave popcorn where there has been a problem although there don't appear to be

such businesses in California. Bob Harrison suggested that if such levels of exposure have been found and have been associated with disease in both flavor manufacturing and in microwave popcorn plants, it seemed reasonable that there could be similar exposures and disease risk in food product manufacturing thus appearing to support a need for a regulation in that industry.

Juli Broyles suggested a 2-part approach to addressing the problem to avoid excessive or premature regulation. The first being development of a regulation to address locations where disease has been identified in California, ie. flavor manufacturing. The second part being commitment from food producers to research and do medical screening to develop information on the location and magnitude of the problem in their industry.

Len Welsh responded that he is open to any possible approach that is effective in addressing the problem. He thought that medical screening and air sampling in food companies that are willing could help develop understanding. However he suggested the companies likely to agree to such activities may not have the worst exposures. In part because of this, he thought that Fran Schreiberg's suggestion of a basic regulation to address food production while research is ongoing should not be ruled out, saying that simultaneous regulation and research are not mutually exclusive responses. He said an important element of such research, as suggested by Pat Verduin, is identifying the particular operations of potential concern, though with the great deal of variability in food production operations it would probably never be possible to clearly establish this one hundred percent. John Hallagan suggested that with the variability of the food industry while it may not be possible to identify all safe and unsafe operations, it should be possible to identify many operations that are likely to be of concern, and many that are not such as use of fruit flavors.

Pat Verduin offered that with their scientific and engineering staffs, food industry companies may be in a position to do the research to construct the matrix being discussed linking operations with exposure and possible risk levels. She suggested that such a matrix could then be used to guide and rationalize air sampling and medical screening efforts. Len Welsh asked Pat Verduin to clarify her organization's position regarding voluntary action or development of a regulation. Pat Verduin responded that food producers are concerned with the health problem but also the absence of clarity on the science, the absence of clear information on dose response with respect, for example, to diacetyl. She said the measures she was suggested are needed to clarify the science.

Judi Freyman said she had talked with some large food producers. She said that with the diversity of processes and operations in the industry it is difficult to develop a regulation without more information. She suggested Cal/OSHA should set a timeline for the food industry to develop the information being discussed in order to determine if a regulation is warranted, and if so, in what situations. Pat Verduin agreed that her organization would work quickly on developing the information that is needed.

Fran Schreiberg responded by acknowledging the concern with the absence of more complete information correlating risk with particular operations and processes in food product manufacturing. She said that is why she is suggesting initially a minimal regulation for the food industry, in part to provide an incentive to work on the research, while in the meantime instituting the basic protective measures of exposure control, medical surveillance, employee training, and respirators are addressed.

Juli Broyles responded by endorsing the concept of a regulation for flavor manufacturing where the risk is better understood and the number of locations small and similar in their operations. She felt any regulation of food producers should wait until more information is developed, but also that the information needed to better inform development of a regulation for food producers should be put on a timeline of just a few months. Len Welsh suggested that information gathered at FISHEP locations might contribute to understanding where risk is present in downstream flavor using companies.

Len Welsh asked for response to the concept of moving forward with a regulation on flavor manufacturing with also some initial regulation for flavor producers while information is being developed. He suggested that a minimum use quantity for diacetyl might form the basis of scope for regulation of food producers.

Jackie Nowell said she was not sure she could respond at the meeting to the concept of moving forward on flavor manufacturing while waiting for more information from food producers. She said the Standards Board in granting the petition filed by organized labor said that there needs to be a fast paced response to the problem in light of the seriousness of the respiratory disease seen in microwave popcorn and flavor manufacturing.

Pat Verduin agreed that the problem demands a rapid pace of response. She gave a commitment of her organization to work diligently on the problem, saying they had already started discussing it. She said it should be possible, in consultation with Jackie Nowell, to develop a timetable for progress on the information-gathering being discussed. She said a first step in the process would be figuring out what information is needed and the best way to get it. Longer term she suggested a need to define the research needs in detail, including looking beyond diacetyl.

Libby Sanchez said that with 8 cases of illness already seen in flavor manufacturing, and the additional workers reported earlier by Barbara Materna with mild/moderate findings in medical screening that need more evaluation, she said it is imperative to err on the side of worker protection by spurring employers to stop using diacetyl. She said Kelly Howard's report on the chemical exposures from use of hot water in container washing was an example of what should be addressed in a regulation.

Bob D'Amoto, based on his experience working with a flavor manufacturer that had received a Cal/OSHA enforcement inspection as a result of an illness report, urged that it doesn't matter what industry it occurs in, exposure to diacetyl needs to be strictly controlled with a regulatory standard.

Pat Verduin asked Len Welsh to clarify what he meant by "fast-tracking" the effort in food manufacturing. Len Welsh suggested that one approach would be quickly identifying possible candidate locations and then start doing medical screening including pulmonary function testing, both to try to catch early any developing cases of disease, and also start to identify the types of operations where there may be a problem. Pat Verduin suggested that there may already be air sampling data available at some food production locations outside California. Len Welsh agreed and said it should be gathered and exploited for whatever information it may provide.

Len Welsh said he would push hard for the food industry to immediately start to do pulmonary function testing where diacetyl is used, since it is an inexpensive, quick, relatively simple approach to starting to identifying where there may be a problem, and it can also be effective in identifying possible early cases of disease where workers may need to be removed from exposure and the exposure controlled. He said further that most of the cases of bronchiolitis obliterans in flavor manufacturing in California, and in other settings, had occurred among young non-smokers, an unusual profile for occupational disease which should mitigate the problem of confounding factors where symptoms are found.

LUNCH BREAK

PEL for Diacetyl

Returning to the petition filed by organized labor with the Standards Board, he said it requested development of a Permissible Exposure Limit (PEL) for diacetyl. Fran Schreiberg said labor still hoped to have a PEL for diacetyl. Len Welsh said the toxicology and epidemiology data available for setting a PEL is still very limited. He said there is still tremendous uncertainty whether it is the average or peak exposures that present risk. He said given the uncertainty he has heard employers say their plan is to engineer exposure down as low as possible. He said if this in fact being pursued, a PEL might have the effect of limiting employers' efforts. He said that in the case of diacetyl with all of the uncertainties involved, the major value of air sampling may be in assessment of engineering control effectiveness rather than in assessment of risk of disease.

Jackie Nowell said the labor petition was filed in August 2006 at which time NIOSH work in microwave popcorn had suggested a shift-long average of 0.02 ppm had been found not to be associated with occurrence of disease. She said this suggested 0.02 ppm as a shift-long PEL. Len Welsh asked given the uncertainties what this would achieve. Jackie Nowell responded that employers need a goal to work toward in their exposure control efforts.

Len Welsh asked if there were arguments against a PEL. Pat Verduin said 0.02 ppm was the lowest level of diacetyl NIOSH found in microwave popcorn plants it studied but it was not clear that there was disease associated with this level of exposure or not. She said there is not currently enough information to support a PEL for diacetyl. In light of that she said she supported regulation based on exposure control and medical surveillance.

Barbara Materna said the NIOSH study found 0.02 ppm to be the lowest shift-long exposure measurement in a microwave popcorn plant where respiratory disease was found. Thus the NIOSH report suggested that shift-long average exposures should not exceed this level.

Len Welsh asked Kelly Howard what had been found at FISHEP locations. He said his group had found 15-minute short term exposures to diacetyl up to 9 ppm, and full-shift exposures up to 2.4 ppm as noted in his presentation.

Bob D'Amoto said a regulation should start with a PEL as a basis for employers to work toward even if it could not be established as being fully protective. He said at the flavor manufacturing location where he was assisting with control measures, there had been disease with exposure limited in time to only two to three hours per day one to two days per week. Fran Schreiberg said that given the cost of engineering controls, she had found it difficult to draft a regulation that she thought could be followed, and enforced, without a PEL for employers to work toward. Len Welsh pointed out that the Division had addressed control of exposure to tuberculosis without a PEL but rather simply by requiring installation of engineering controls in at-risk workplaces. Fran Schreiberg said it could be possible to have a regulation without a PEL if it specified use of closed systems with only minor exceptions.

Len Welsh said the level chosen for a PEL affects the level of respirator required as well for different levels of exposure. He suggested discussion of PEL last and first talking about engineering control concepts. He said he thought all in the room could agree that local exhaust ventilation, dust control, and avoidance of heating of liquids is important, and that those should be required to be used to the extent feasible. There was no disagreement with this.

Jackie Nowell said many grocery stores do scratch baking, and some locations have exhaust hoods while others do not. So she asked

Len Welsh if his concept would be that all store bakeries would have to install such hoods? Len Welsh said he was thinking first about engineering concepts for flavor manufacturing, and that if they were effective there to consider for wider application as Jackie Nowell suggested. Fran Schreiberg said she didn't think the experience of flavor manufacturing would have significant meaning for food production where operations are much more diverse in nature and potential for exposure. Len Welsh acknowledged the comment but said that a more extensive process would be required to come up with a regulation appropriate for the food industry given its much greater size and diversity of operations compared to flavor manufacturing.

Bob Harrison asked about the limit of detection for diacetyl in air. Kelly Howard said the NIOSH and OSHA analytical methods allowed for a limit of detection of about 0.02 ppm, using air volumes larger than those formally recommended in the methods. Bob Harrison suggested that if a PEL could not be set, the analytical limit of detection for diacetyl could serve as the requirement for employers to work toward in their exposure control efforts.

Mark Scott questioned the need for aggressive control requirements. He said the butter smell in movie theaters is from diacetyl but no cases of illness have been reported from that environment. Len Welsh asked if anyone had information on the odor threshold for diacetyl. John Hallagan said he had seen some studies but the results were not entirely clear for diacetyl in air.

Rhonda Hrabchak said it would be more logical to mandate control measures and medical monitoring. She said she preferred a regulation to focus on control measures rather than a PEL for diacetyl which would not provide protection.

NEXT STEPS

Len Welsh said the Division can review the findings of Kelly Howard's group to determine what might be learned from flavor manufacturing that might apply to food production where diacetyl is used. He said the Division would work on a draft proposal for a regulation for the next meeting that would address requirements for exposure control, medical surveillance, personal protective equipment, employee training, and recordkeeping. He said thought would also be given to the question of a PEL. He said with respect to respirators that it needed to be recognized that for diacetyl a cartridge respirator may not always be sufficient, but also that there can be feasibility issues with requiring supplied-air respirators.

Len Welsh said he wanted to work with food producers to come up with a workable solution. He urged them to work quickly to start on the problem as they should have significant scientific and engineering expertise to apply to the problem, as well as first hand knowledge of the industry.

Jackie Nowell said she had spoken with Pat Verduin about working together to address the problem. Fran Schreiberg said organized labor needs to be involved in deciding whether the approach in California will be primarily consultative, or will involve enforcement.

Len Welsh said it was important to work quickly to address the problem but that given the size of the food industry and likely widespread use of diacetyl and other flavor substances it would probably be several years before parties involved feel it has been completely worked out. He said a working group should be formed to meet more frequently review data and proposals as well as decide on consultation or enforcement efforts.

Jackie Nowell said the labor petition to the Standards Board in addition to seeking development of a regulation also asked while that is being done that work be undertaken to actively provide information to affected employees, employers and others. She said it is not good enough to simply post informational materials on the Internet. It is important to identify locations and parties to which informational materials should be sent. She said the first step in this process would be identifying the appropriate Standard Industrial Classification codes for facilities which may use diacetyl and other hazardous flavor ingredients and even just sending them a one-page basic information sheet to begin development of broader awareness. Len Welsh said he hoped that help could be obtained from the food industry to identify locations where materials should be sent.

Fran Schreiberg suggested that with an administrative subpoena the Division could obtain flavor manufacturers customer lists as a way of identifying where potentially hazardous flavors are being used in food product manufacturing. Len Welsh he was working on that and hoped to have something to report for the next meeting.

John Hallagan said FEMA could offer a training workshop for California food producers on respiratory hazards associated with flavoring substances. Pat Verduin acknowledged this offer and said her organization would discuss it with member companies.

Len Welsh said the audience for outreach materials includes, at least, employees, employers, and medical professionals. Barbara Materna said OHB had developed and distributed materials for physicians. Len Welsh wondered if the California Medical Association might be able to provide assistance with outreach to and education of physicians. Barbara Materna said OHB was considering developing medical guidelines for health care providers. John Hallagan said he liked the materials OHB had developed and was circulating them to various parties.

Len Welsh said that goals for the next meeting include review of a draft regulatory proposal that the Division will development, and formation of the working group discussed earlier. Len Welsh asked Jackie Nowell if unions were considering providing training for members that they could then take back into their workplaces. Jackie Nowell said the Bakery Workers union was considering this.

Jackie Nowell asked Pat Verduin what activities her organization planned prior to the next meeting. Pat Verduin said that though they were her own thoughts and would have to be discussed further approved by her organization, she thought they would work to get member companies together to identify locations in California and categorize for possible risk level. Also she hoped they would start to see if any members have air sampling data. She thought they would also talk with John Hallagan about having FEMA training for California member locations. And finally she hoped to identify possible members for the working group discussed earlier and begin work on the operational risk matrix also discussed earlier and at the first meeting.

Len Welsh said to Pat Verduin that once California food locations were identified it would be helpful if Kelly Howard could visit a few to start to obtain understanding of food production operations and relationship to potential exposures to hazardous flavoring substances. Pat Verduin agreed that this was a good idea. She said she hoped that some locations might be found for this that had already conducted air sampling. She said it had been helpful to learn in the meeting that most of the cases of illness in flavor manufacturing in California had not, as she had presumed, been identified through the Workers Compensation Insurance system.

A tentative date of March 21, 2007 was agreed to for the next meeting.

END