

# Draft Minutes of Diacetyl/Flavoring Advisory Meeting 5 18 07

## Attendees:

<u>NAME</u>	<u>AFFILIATION</u>
Aho, Janet	Mane, Inc.
Bob Barish	Cal/OSHA Research and Standards Unit
Borman, Heather	SCIF
Boyle, Michael	Bimbo Bakeries
Broyles, Juli	GMA/FPA
Dougherty, Dorothy	Federal OSHA
Dunn, Kevin	NIOSH
Falasco, Mike	Wine Institute
Fisher, Marti	CA Chamber of Commerce
Freyman, Judi	ORC Worldwide
Graham, Diana	KH Law
Hallagan, John	FEMA
Harrison, Robert Dr.	UCSF
Hermansky, Steve	ConAgra Foods
Hogan, Mary Ellen	Holme Roberts&Owen,LLP
Hormigosa, Loren	Federal OSHA
Hrabchak, Rhonda	American Fruits&Flavors
Kienitz, Joshua	Little Mendelson, PC
Kim, Thomas	CA Dept Health Svcs
Kochie, Mary	Cal/OSHA Medical Unit
Kreiss, Kay	NIOSH
Landers, George	Western Conf. UFCW
Mashayekhi, Azita	Teamsters
Materna, Barbara	Occ Health, CA DHS
McKernan,Lauralynn	NIOSH
McLea, Marcie	
Mike Horowitz	Cal/OSHA Research and Standards Unit
Plagge, Michael	ConAgra Foods
Pulliam, Michael	Drinker, Biddle &Reath LLP
Rachman, Nancy	GMA/FPA
Roberts, Jennifer	health scientist ChemRisk
Scholz, Peter	Cal/OSHA Consultation
Schrieberg, Fran	Worksafe
Scott, Mark	T. Hasegawa USA
Seymour, Michael	Federal OSHA
Silveira, Caroline	GMA/FPA
Smith, Jeremy	CA Labor Federation
Steve Smith	Cal/OSHA Supervising Industrial Hygienist
Thompson, Kevin	Cal-OSHA Reporter
Tom Mitchell	CA Occupational Safety and Health Standards Board
Tonel, Elaine A	U C Irvine Occ Med resident
Welsh, Len	Acting Chief, Cal/OSHA
Worden, Anita	Sara Lee Dir. Baking Safety

## **SUMMARY OF MAJOR DISCUSSION ITEMS AND AGREEMENTS**

### **OPENING OF THE MEETING**

Len Welsh gave a review of the Cal/OSHA advisory process. The process allows stakeholders' views to be sounded out prior to the start of the formal rulemaking process. This flavoring advisory committee had been formed at the request of the California Occupational Safety and Health Standards Board (the Board) after it received a petition from Labor asking for a new regulation governing flavorings. In California, Cal/OSHA conducts the advisory committees that involve health issues. The Board ultimately reviews the outcome of the advisory process and initiates the formal rulemaking process, Len Welsh explained. Today's advisory meeting was the third meeting since the Board asked for the committee's formation in October 2006, and the fourth meeting counting an earlier preliminary meeting last September.

Len Welsh briefly summarized the history of Cal/OSHA Consultation's efforts in the Flavoring Industry Safety and Health Emphasis Program (FISHEP) which included active collaborative efforts with the National Institute of Occupational Safety and Health (NIOSH) and the California Department of Health Services Occupational Health Branch (DHS OHB). He acknowledged the presence of NIOSH, DHS OHB and Federal OSHA representatives at today's meeting. After asking for any corrections to the minutes of the last meeting, Len Welsh asked for progress reports on recent work on flavoring related issues.

### **MINUTES OF THE MARCH 21, 2007 MEETING**

Barbara Materna stated she had some corrections to the draft minutes that she would send by email. There were no other corrections made at the meeting but attendees were asked to also send in any additional comments or corrections by email after they had more time to consider the draft minutes.

### **SUMMARY OF RECENT FISHEP ACTIVITY**

On behalf of Cal/OSHA Consultation FISHEP coordinator Dan Leiner, who was not present, Mike Horowitz gave a summary of the status of the work of FISHEP. Dan Leiner recently replaced Kelly Howard, who had lead the FISHEP effort for more than a year. One of the outcomes of the last meeting, Mike Horowitz said, was a consensus that more needed to be known about the use of diacetyl-containing flavors in downstream users; what to do about that use was also a big question. To try address these issues, at the end of the last meeting a smaller group (balanced between Labor, food industry and

government) had agreed to participate in phone discussions. Two such phone conferences had taken place. The discussion kept returning to the lack of knowledge of the range of diacetyl exposures among these downstream users. Such food manufacturers often don't know if the flavors they use contain diacetyl—especially if the flavor has <1% diacetyl and the supplying flavor manufacturer believed [probably erroneously, given what is known about the toxicity of diacetyl in animal studies] that it was not necessary to list diacetyl as an ingredient on the MSDS.

Len Welsh clarified that regarding the flavoring manufacturing industry, there was little debate on the need for a regulation; the main issue now is with regard to downstream users since the concentration and maybe the quantities of diacetyl are much lower while the uses and products in which the diacetyl flavors are present are also very varied.

Mike Horowitz said that the working group participating in the phone conferences learned that some downstream users were working to learn if the flavors they used contained diacetyl, and a few companies, including some outside of California, were beginning to do air monitoring. The phone conference participants discussed developing a matrix to be utilized to try and assemble data from such monitoring so that the data from disparate independently performed air monitoring could be usefully compared in an effort to identify downstream food manufacturing processes and flavor combinations that present or perhaps don't present a hazard.

Mike Horowitz noted that telephone working group had not gotten very far in identifying food manufacturing companies in California that utilize flavors with significant amounts of diacetyl in the flavoring. Many of the customers of California flavor manufacturing companies are outside of California; conversely, many of the California food producing manufacturers secure their flavors from sources outside of California. The telephone group discussed securing a list of the California producers' California customers, but had not succeeded yet in finding a solution to the problem perceived by the flavor companies: the customers' confidentiality.

Len Welsh interjected that this was a good place to report that the Division had received three letters from Labor that called upon the Division to subpoena the flavor companies for a list of their customers. Division attorneys were working on such a subpoena, but I am not sure, Len Welsh said, that the subpoena route is the best way to get the information, especially since California flavoring companies represent just 5% of the U.S. national supply. Len Welsh said he believed that the needed information would come to us eventually without subpoenas; some information is already coming out in lawsuits.

John Hallagan commented that for Flavor Extract Manufacturing Association (FEMA) members, supplying customer lists to Cal/OSHA is a difficult issue. Many flavor suppliers have customer agreements prohibiting even saying they are the customer's supplier. Another approach discussed in the conference calls is the possibility of FEMA identifying those flavors that have diacetyl. From such an overall California manufacturer list you can quickly and easily see which food companies should be

selected as places where the potential for diacetyl exposures are greatest. He has been assembling a draft list of the highest diacetyl percentage products.

Len Welsh asked John Hallagan if such a list would be just flavor types, or would it be food products.

John Hallagan said just the types. The diacetyl concentration is very low in many flavor categories. Even though it is true that a 1% diacetyl concentration in a flavor could lead to a 10,000 part per million concentration in air, the exposure potential is actually much lower. The diacetyl concentration in food is just a few parts per million because so much is lost in the process. He said a flavor-type list could be provided in a few days. He noted that the microwave popcorn industry reportedly had utilized butter flavorings with up to 30% diacetyl but that had been an anomaly. Sometimes a customer might want concentrated flavor in a smaller quantity in order to dilute the flavor themselves, but this is not so common now.

Fran Schrieberg stated that Worksafe's letter had requested not only subpoena's but also a Special Emphasis Program; identifying at least a few relevant locations could help set up the SEP.

Len asked how does getting information on just 5% of flavor customer locations in California help identify key California food manufacturing locations?

Fran Schrieberg replied that information on the 5% of California customers from the California flavor companies would help identify at least a few food locations to look at.

Mark Scott commented that with Hallagan's FEMA flavor list, you can see the highest percentage flavors.

Fran Schrieberg objected that the FEMA list wouldn't ID specific locations.

Len remarked that if we can get process information, that's the most critical thing in identifying specific locations to go to. We don't want to demand information that won't help out, or would be only marginally helpful. I hope FEMA will assist getting information nationally for the other 95%.

John Hallagan said most large food companies were getting flavors from large flavor companies which are mostly in New Jersey and the Midwest.

Bob Harrison asked if Hallagan had given the example of margarine as having a high % of diacetyl.

Hallagan said yes, but margarine operations are fully enclosed. Again, sometimes concentrated diacetyl flavored products are shipped in small quantities to be diluted at the receiving location.

Len Welsh said he had heard of food companies having difficulty of getting flavor companies to send the desired % diacetyl.

Jeremy Smith said so you're going to provide diacetyl concentrations of products?

John Hallagan said there is a range of concentrations in products; in a couple of days he will give the list to Len once he gets some new info.

Fran Schrieberg said, so flavor companies are shipping less concentrated diacetyl flavors now?

John Hallagan said companies are now trying to ship with lower diacetyl concentrations and we are seeing more looking at alternatives to diacetyl. The key to understand is that it is not just the percentage but also the process in which the diacetyl is used. Lots may be lost in the process, which thus has exposure potential.

Len Welsh asked how reliable is the information you're getting?

John Hallagan said he had gone to companies he had found to be reliable.

Jeremy Smith asked how many non-FEMA members there were.

John Hallagan stated FEMA has 65 flavor manufacturer members accounting for 95% of US flavor manufactured volume; there are maybe 30 fairly small operators that are not FEMA members.

Azita Mashayekhi asked if pressure from subpoenas would cause flavor companies to reveal diacetyl percentages to the food companies.

Len Welsh said Hallagan is offering concentration ranges. I haven't given up on subpoena approval, but I hope that by identifying key bad processes combined with Hallagan's percentage information, and we could go to those locations. WE are at the point now we need to start going into downstream locations.

#### SUMMARY OF RECENT FISHEP ACTIVITY

Mike Horowitz said Dan Leiner's report on FISHEP activities focused on flavor companies since that's where disease has been identified so far. He summarized the status of the FISHEP activities in the 30 California flavor plants identified. NIOSH, it was noted, had almost completed its evaluation of flavor companies. One FISHEP company had not been visited by NIOSH, but now that Cal/OSHA Enforcement activity was complete, NIOSH was now coming into that plant. FISHEP consultants meanwhile continue to follow up with the flavor companies to ensure that medical exams are performed every six months; also FISHEP is checking on respirator fit testing. All employees with possibly flavor related medical findings are being interviewed by FISHEP and FISHEP wants to look at how to protect temporary employees. FISHEP inspections are also looking at other FEMA priority chemicals.

Mike Horowitz continued reporting on FISHEP results. So far between liquid diacetyl flavors and powders, FISHEP had found that the powdered form of products tended to generate higher exposures. Consultation IHs are also looking at engineering controls. They are seeing exposures of employees working at some distances from flavor mixing. Several downstream companies using diacetyl have been identified: a tortilla plant and a baking plant have agreed to allow FISHEP to monitor for diacetyl exposures. Another bakery has agreed to allow FISHEP to monitor even though they have already monitored for diacetyl on their own, establishing some low level exposures. Finally, the Teamsters union has identified a cereal company that makes a butter flavor cereal; we are trying to find out if it is a diacetyl-containing butter flavor.

Fran Schreiber asked if in the baking and tortilla plants the companies would report to FISHEP the percentage diacetyl in their flavor supplies.

Mike Horowitz said we should find out at least the concentration ranges during the inspections. He noted also that Cal/OSHA Consultation had formed a food manufacturing Special Emphasis Program. While this SEP is focused on other problems of this industry, the consultants have been asked to watch for flavor related issues during their inspections.

Bob Harrison asked if there was any idea if the FISHEP air monitoring had found air concentration ranges similar to those at Carmi where disease was identified.

Mike Horowitz stated this was unclear as all the FISHEP data had not been put together in one place.

Mark Scott said 100 ppm was the maximum concentration.

John Hallagan said that while air concentrations at Carmi were very high, Carmi was not a FEMA member and had not benefited from the FEMA emphasis on this issue.

Len Welsh said he was working on getting NIOSH involved in working on determining a safe level of exposure.

#### SUMMARY OF RECENT DHS ACTIVITY

Barbara Materna stated that the MMWR article that had been passed out contained a good overview of what has happened in California, including case reports and what is being done now. The Department of Health Services Occupational Health Branch is getting FISHEP medical data and reviewing the quality of pulmonary function tests (PFT) and detecting abnormal PFT or drops in lung volume. DHS/OHB was working with about ten medical providers chosen by the FISHEP companies. Also she reported that DHS/OHB was developing PFT guidelines for providers. There are seven companies that are large users of diacetyl, eight with minimal and another 13 with very minimal usage.

Mark Scott asked what the criteria for determining high, medium or low diacetyl users was.

Barbara Materna said she didn't have that information with her but noted that the MMWR article reported that 22 current California flavor industry workers have been identified as presenting with abnormal spirometry results—although mostly these are mild abnormalities.

Azita Mashayekhi asked if the 22 workers had been challenged with bronchodilators.

Barbara Materna noted that bronchodilation is the follow-up test she mentioned that is used to assess if the PFT abnormality is reversible. Three have been referred, but I can't say yet if all 22 workers with abnormal PFT have had this test yet.

Len Welsh said these 22 are not being called cases; most likely won't become cases, we are being conservative, following the public health approach. He noted the difficulty in the field of public health of getting employees to do followups.

Barbara Materna added, in addition, we've worked with NIOSH on creating a standard questionnaire that could serve as an appendix to the regulation.

Jeremy Smith noted that last time the DHS had reported locating a former worker with bronchiolitis obliterans. Have any more been found?

Barbara Materna said no, just the one to this point.

Fran Schrieberg pointed out that that individual had been discovered as a result of a legal case. Is there any effort being made to identify and find former employees?

Len Welsh said FISHEP routinely asked the flavor manufacturers for former worker information.

Barbara Materna related that there was no systemic effort being made to identify former workers at this point

Len Welsh asked what a systemic effort might look like. He was fairly certain that we ask about former workers as part of the consultation, but beyond that he is not sure what a more rigorous effort would consist of.

Barbara Materna suggested a letter to the companies asking them to identify former workers might be part of such an effort although getting good results would be difficult because the companies don't have good contact information for former workers. Media attention helps attract former workers, especially to report if they are sick

Fran Schrieberg said a public service announcement in Los Angeles on Spanish language media might be effective. Len, she asked, you said the consultants ask the companies.

What has been the response? Len Welsh responded that there hadn't been much of a response. Fran Schrieberg said then it wouldn't hurt to make a PSA.

#### NIOSH REPORT: YATSKO

Next, Kay Kreiss reported on recent NIOSH activity. Recently published were the results of two Health Hazard Evaluations at the Carmi flavoring plant in California and at a small Montana popcorn popper, Yatsko. The latter was a family operated part time popcorn popping and distribution business at which a father, daughter and husband worked. The popcorn was treated with butter flavor oil and salt. The business closed in 2006 after 20 years as all three people developed respiratory disease even though exposure durations were only two to four hours two times a week. Symptoms looked like asthma. The owner died of respiratory problems at 65; he got adult onset asthma made worse on days he popped corn. He went to the hospital 22 times in a short period of time and absolutely had fixed obstructive disease within a year or two of developing asthma. The medical findings were consistent with bronchiolitis obliterans; fixed obstructive disease usually takes years to develop, not just two or three years. The daughter and husband also got asthma with a work related pattern. CT scan of one had findings consistent with bronchiolitis obliterans.

The Yatsko investigation raises the question: Is asthma part of flavoring related exposure and disease. We could measure the diacetyl over the liquid flavor tank, but it was below the detection limit in the workspace; the exposure profile was very different from microwave popcorn. Furfural and other aldehydes were found but not ketones. It turned out that butter flavored salt used to have diacetyl, but not after 2001. The oil still did have diacetyl (7 ppm measured in the head space).

Azita Mashayekhi asked how the case came to light. Kay Kreiss said a USA Today article stimulated the employer to request a NIOSH visit.

Fran Schrieberg asked if the diacetyl concentration changed over time. Kay Kreiss answered that several products had been used, 3 or 4. We don't have information on the earlier formulations.

Fran Schrieberg asked if the NIOSH data was finding that low levels can cause disease.

Kay Kreiss said one has to go back to the microwave popcorn studies and the 2006 Kanwal article. Open tanks near packagers had exposures leading to disease, so yes, low level long-term exposures can lead to disease over five to six months even without peak levels. 1 to 2 ppm was the average exposure. Most of the popcorn cases were at the index plant where you did have potential for peak exposures. So you have both categories. Also, NIOSH is performing a rat study comparing constant exposure vs. peak exposure; these experiments will help answer that question. For now we have to assume both peak and constant low level exposures are hazardous.

#### NIOSH REPORT: CARMİ

The Carmi HHE was requested by DHS/DOSH, as we can administer bronchodilators at the time of initial spirometry. We found three people out of 16 tested that had severe fixed obstructive disease. These were two former workers and one current worker. A fourth worker had abnormal spirometry indicating perhaps scarring like microwave popcorn cases but it's not clear and we don't know if this is part of the spectrum of flavor related disease or not. All the affected workers worked where there was powdered flavor where we found .2 to .25 ppm of diacetyl. In the liquid flavor production area .02 to .03 ppm were found. The highest peak exposures were STELs of 8 to 21 PPM while instantaneous peaks of 204 ppm were found using the FTIR instrument. These readings were for butter and vanilla flavors. This recalls the International Bakers HHE. International Bakers made flavors for the baking industry. Two workers were clearly sick and another two were possibly sick. At Carmi they are pouring liquid diacetyl on top of starch powder on a ribbon blender where it's plated. The key, highest exposures are when the powder is taken out of the blender and put in a box.

#### NIOSH REPORT: GOLD COAST FLAVORS

Another NIOSH study, not yet published is on Gold Coast Flavors, a California FISHEP company using one of the larger amounts of diacetyl. Nudged on a little by Kelly Howard, Gold Coast management requested this study. We were not aware that any worker had a problem but we found a long term worker who had very severe bronchiolitis obliterans. He transferred to the liquid side but his respiratory symptoms were still too severe and he couldn't do his job so he was working in the warehouse although he would meet criteria for total disability. He'd had medical attention for years, including bad PFT that were diagnosed as "bronchioectasis of unknown origin." He had been hospitalized. Clearly we see now that he has bronchiolitis obliterans. This worker was the only Gold Coast employee with a dramatically deviant PFT.

We tested people last fall. There was one other worker who had worked five months and had a small decline in the PFT ration FEV1/FVC that was abnormal but of a magnitude that was not clearly of significance. But when he was retested 4 and one half months later, he had a 25% further decline. He had no symptoms, felt OK, and wouldn't have shown up on a symptom survey.

Tests every 6 months may not be sufficiently protective. The take home message of this for NIOSH is that if you have one case of severe obstructive lung disease, then other employees are at risk. PFT should be more frequent after one case of obstructive lung disease has been identified. Those 22 people in the FISHEP program with abnormal PFT were definitely candidates for more careful PFT follow-up and their exposure controlled or they should be removed from the job. Anyone with mild obstructive disease needs to be followed more carefully. Although most workers identified with problems have been on the powder side, this doesn't mean the liquid side is safe. This worker was on the liquid side.

At Carmi we identified a worker who is not a case yet but is a case in evolution. We saw the same rapid decline in popcorn, a 1 ½ liter decline in six months but didn't control exposures and the decline continued. Medical surveillance doesn't prevent disease but it identifies key areas for control.

Len Welsh asked if the worker at Carmi was using a respirator during this period of declining lung function.

Kay Kriess said the picture was mixed. Initially a particulate respirator. There was some particulate and OV respirator use. When NIOSH returned he was using a cartridge respirator. Good respirator programs are hard to do, especially in the absence of symptoms. And this (Carmi) was a motivated company that had FISHEP involvement and that was good to work with; but it is still difficult.

Len Welsh asked about this workers current respiratory status; Kay Kreiss didn't know. But, she said, like the popcorn incidents, the Carmi worker had significant PFT declines with no symptoms. A substantial portion of workers with abnormal PFT don't have symptoms. There is no guidance of occupational doctors on what a significant fall in PFT is, and what is outside the normal range. The quality of spirometry is often not good. To be reproducible, the tester must yell at the testee, "blow, blow, blow." The typical "doc in the box" physician is not motivated enough to have quality spirometry capable of catching minor changes over time. Huge drops in pulmonary function anyone can see if they choose to look at them. With good spirometry even 150 ml drops are significant. However, to respond to the real world, our NIOSH report on popcorn used a 300 ml drop as the marker for significance. It is a huge challenge for the health department to work with providers.

Azita Mashayekhi asked John Hallagan if spirometry quality was an issue for FEMA members.

John Hallagan responded that FEMA emphasizes getting good quality spirometry.

Rhonda Hrabchak asked if we couldn't establish a proficiency program for spirometry like PATCO for IH laboratory accreditation—say send out a standardized case study and the provider would have to get the correct answers.

Len Welsh answered that if there was a way to do this it would be under DHS authority, not Cal/OSHA's. But, as we are talking about a regulation that will depend upon competent screening, we need to incorporate this thing.

Len asked if the Gold Coast worker was one of the 22. Kay Kreiss said that he hadn't met the accepted definition at the time of the first test in the fall but by March when NIOSH did spirometry again, he was one of three workers who had borderline obstruction. We recommended testing before six months passes.

Len Welsh asked if we were getting close to having a medical protocol; Barbara Materna said yes.

John Hallagan stated that a borderline case should get emphasis where there is a sentinel case. Len Welsh agreed.

Judi Freyman said the issue of quality is very concerning when including screening in any regulation. It sounds like there may not be sufficient capacity for quality spirometry. How can we advance the cause so the capacity for this quality gets built.

Kay Kreiss said there are standards, for example those of the American Thoracic Society. NIOSH dealt with this with cotton—certifying PFT course instructors, but NIOSH never reevaluated the classes. Respiratory therapists are working to certify individual with ten point tracings sent in for evaluation. The pulmonary profession is working to upgrade PFT quality, but we are not there yet. With the California flavor industry and FISHEP, the DHS is submitting each PFT trace to NIOSH consultant Enright for quality review.

Mark Scott asked Kay Kreiss if it was possible this person's decline was caused by a single high exposure. Kay Kreiss replied that from the popcorn experience it seems probable that it is indeed possible to develop symptoms within the first year without a huge peak. But in animal experiments, a large exposure over a few hours has resulted in irreversible lung changes. So you can't tell in this case whether this individual developed this decline from gradual exposure or from a high peak exposure.

Bob Harrison said it would be important to know if Gold Coast is an outlier in the flavor industry or if it is typical of flavor companies. If Gold Coast is typical it means more than the industry as a whole needs to pay closer attention.

Lauralynn McKernan said NIOSH was working with Gold Coast in a HHE study. In the sense of processes, Gold Coast is typical. But in the sense of chemicals used, it is hard to say. Gold Coast is now using full face and ½ face piece respirators and has been progressive on engineering controls.

John Hallagan noted that Gold Coast has never been a FEMA member. Since the late 1990s FEMA has had educational meetings on these flavoring issues.

#### NIOSH REPORT: ENGINEERING CONTROL STUDIES

Lauralynn McKernan noted that her NIOSH assignment went beyond diacetyl. It included dust samples, other aldehydes and the variability and range of exposures. NIOSH was continuing to look at the analytical method. NIOSH is looking at a public meeting this fall and is looking for opportunities for a three year study in the flavor and food production industries.

Kevin Dunn of NIOSH noted that Gold Coast is putting in ventilation for liquid compounding. NIOSH has given process by process engineering control advice at the end of last year and early this year. We've tried to evaluate areas without much

published about engineering controls for this industry. We are trying to develop engineering control evidence generally; we are doing lab work, analyzing mixing as Larry Reed presented in a slide show at the last meeting. Engineering controls alone are not enough, however. It's also about having good work practices.

Lauralynn McKernan noted that respiratory protection programs in the flavor industry need to emphasize cartridge change out schedules.

#### **DISCUSSION AFTER LUNCH**

Nancy Rachman said she was gratified to hear information is starting to become available. Our own members are involved in a self assessment process. One member with extensive non-California data would like to discuss how to make this information available to Cal/OSHA. Another non-California member also has data. A third member in California is considering asking for a Cal/OSHA Consultation visit. GMA/FPA sent our own sampling matrix to Mike. We are working with FEMA on workshop for our own members in late September.

Azita Mashayekhi asked what types of companies were covered by Nancy Rachman's organization. Nancy Rachman said the California company is a baking company.

John Hallagan said the level information would be faxed next week. FEMA was setting up another workshop for its members, and noted that there were two abstracts on flavor exposures on the American Thoracic Society's website—one by Dr. Richard Kanwal of NIOSH and the other by Dr. Cecile Rose of National Jewish Hospital of Denver.

#### **DISCUSSION OF DRAFT STANDARD**

Len Welsh commented that while he had thought about backing away from the cover all flavors approach to scope, after hearing Kay Kreiss' report about other substances, he wasn't so sure. He was also concerned that if the approach was to regulate diacetyl at the as low as reasonably achievable exposure, companies may phase out diacetyl, but other flavoring chemicals that have irritating effects won't be.

Juli Broyles remarked that we should focus on flavors since that and popcorn is where problems have been seen. We are not seeing a problem in downstream industries, so we could wait for downstream industries until data comes in.

Len Welsh said he proposed to continue with double rule-making--to first go forward as soon as possible with a flavor manufacturer regulation with all the bells and whistles and control requirements rather than having further discussion on flavored food production now. Then, later we may find a supportive basis for a PEL. The draft regulation is OK for the 28 flavor companies, but food companies are too variable for this sort of approach. We would have further discussion about what to do with food producers. The control measures (traditional hierarchy of controls) will be the same regardless who is covered. As we acquire data and connect the dots, we may well decide we need a PEL. Thousands of companies in California use flavorings.

Fran Schrieberg said that the picture Kay Kreiss presented of missed diagnoses of the sick and the non-identification of symptoms gave her a concern that if you separate the food producers out of this standard, the same thing will happen. You need to have data collection such as medical surveillance. There has got to be a way of structuring the regulation based upon the amount or concentration or process so as to include food processing.

Len Welsh said he was not talking about delaying food's inclusion, but he doesn't believe the information is there for food manufacturing.

Mark Scott agreed with moving ahead on the flavor companies. If we have food companies using diacetyl at a certain percentage then they could be captured too.

Len Welsh said he didn't think we have food diacetyl percentage data yet. Moving ahead with food plant visits we can get an idea of the air concentration of diacetyl associated with the percentage of diacetyl in food products.

Judi Freyman agreed we pretty much have to separate flavors from food in the absence of data, but you lose a sense of urgency. Is there a way to put in a specific timeline?

Len Welsh noted that there was now a Federal bill ordering OSHA to develop a standard on flavorings that included food manufacturers.

Rhonda Hrabchak said this was an important point. There are other standards in place already that require the use of a hierarchy of controls to prevent harmful exposure and require assessment and control.

Jeremy Smith said he didn't see a problem with covering both industries in the regulation. We need to cover both to get the food companies to assess the exposures and control them.

Mark Scott said we will say its below x% to the customer.

Fran Schreiber said maybe what we need is medical surveillance for all the companies using diacetyl.

Len Welsh responded that given the quality and quantity problems just with FISHEP, that would be hard.

Jeremy Smith said a regulation gets food companies to look at diacetyl and limit or control the exposures.

July Broyles said we don't have the evidence to support a general rule for food companies. If we have a regulation just on California companies, then California will lose jobs. I don't think anything Len said is going to take the pressure off. I truly believe we won't find problems at Good Manufacturing Practices plants (GMP). There won't be

a problem since the percentage of diacetyl are so low in comparison to the flavor industry or popcorn industries.

Jeremy Smith said the data doesn't show what percentage makes you safe. It shouldn't be too much to ask the food companies for a phone call to the flavor companies about the percentage of diacetyl in the flavor they are using.

Len Welsh said he didn't think we had anything yet about a safe percentage.

Fran Schreiber asked what the diacetyl percentage was found in the microwave popcorn industry.

Kay Kreiss said the American Popcorn Board told us that the diacetyl percentage in their flavorings ran between <1% to 20%; we thought 10% diacetyl was very high. Light popcorn workers hated making it. Light popcorn is light because it uses less oil, but the concentration of diacetyl is higher.

Fran Schreiber said if we are going to have a two part regulation lets at least cover >1%. She noted that 1% triggers the hazard communications standard's requirement to include a substance on the MSDS. For this standard, at least include 1% and above. Then we could look at <1% as the second part of the work on the regulation.

Len Welsh said there is a downside to capturing too many at levels of exposure where no problem exists. Proposition 65 was an example of a regulation being so broad that it trivialized the hazard and generate enemies of the regulation. Diacetyl is a classic case; we know it is a hazard. We could capture 100% of users, but there is a downside when you are too broad you trivialize the hazard. The 1% approach is good—but unless you can show regulated employers that there is a real basis, a real hazard to address, you can generate severe opposition.

Fran Schrieberg asked Kay Kreiss if 1% diacetyl concentrations were hazardous.

Kay Kreiss said that it was often hard to get the percentages, but we did get detectable air concentrations.

John Hallagan noted we are dealing with workplaces with what concentrations of diacetyl in air at low levels are hazardous while now we are discussing the concentration of diacetyl in a bulk flavor. I agree that in popcorn 10% diacetyl concentrations led to hazardous air concentrations, and now we are down to 1% to 5% concentrations in popcorn. John Hallagan said that clearly 5% was too high a cut off because this level wouldn't capture any downstream users.

Nancy Rachman reminded everyone that it is not just the concentration of diacetyl in the flavoring but also how the flavoring is used that determines the exposure. For example, if it's a closed process, exposures may not be a problem even if diacetyl concentration in the flavoring is high. So we need the matrix.

Bob Harrison noted that in the NIOSH studies the LOEL for diacetyl was a concentration of .02 ppm in the popcorn industry and .2 ppm at Carmi. Take .02 ppm. It's hard to decide to bifurcate flavor manufacturing and food manufacturing without an idea of the range of exposure in food manufacturing. As an MD, you would want to know if you are seeing a patient with a mild lung problem what the exposure was.

Nancy Rachman said that patient might have had a higher exposure earlier.

Kay Kreiss said Kanwal said the lowest concentration area where effect was found was at .02 ppm. She said that ConAgra said they were using closed systems, but we didn't think this was a very closed system.

Juli Broyles said it is remarkable how hard GMAG has worked to get data back. We want to show you there is good reason to believe there is not the problem in food that there is in flavor manufacturing. There have been seven or eight weeks since the last meeting—that's lightening fast for a bureaucracy.

Len said suppose the data said below x% was a PEL.

Mike Seymour noted that the Miller bill was about to be introduced in Congress and it had two parts. An emergency regulation along the lines of the NIOSH Hazard Alert covering the popcorn and flavor industries was to be issued within 90 days of passage. The second part of the bill states that within a year after that a regulation covering all diacetyl users will be issued with a PEL for diacetyl.

Len Welsh said that's how I would see us going in terms of having data to support a regulation. He didn't feel we have the data at this point to support a broad food manufacturer regulation. He viewed flavor manufacture as an interim problem requiring control to ALARA and then come later if we can to a PEL that would apply to all industries. A regulation covering flavor manufacture is feasible now; Len said, as he'd been very impressed with the risk in this industry. Len related how irritating odors of flavorings clung to Kelly Howard and other consultants after an inspection. Three Cal/OSHA inspectors had had reactions to the irritating properties of flavorings, he said. Thus, he believed that we will find other constituents of flavorings that cause asthma. He worried though that as substitutes for diacetyl are put in place, two years down the road what will this regulation do for us.

Kay Kreiss noted that animal studies would be needed to evaluate these other flavoring substances. It is very hard to sort out in workplaces with mixed exposures what's responsible for what.

Fran Schrieberg asked if there was data that would indicate what a 1% universe would capture, given that most formulated flavorings contained less than 1%. I'm hearing its not a huge net.

John Hallagan replied that most foods use flavorings with less than 1% diacetyl.

Nancy Rachman said the message of this process is we are well aware of the serious nature of the problem. I can't give an exact answer, but at 5%, there are probably only a few food manufacturers using flavorings at 5% diacetyl concentration. I can't say at 1%, but most flavors are well below 1% diacetyl.

Fran Schreiber said the GMA members are not the whole universe. A regulation provides the base to cover all, including the outliers and small companies.

Nancy Rachman commented that such companies might be smaller and less able to comply.

Fran Schreiber said that because they were small didn't mean they didn't have to comply with regulations.

John Hallagan noted that FEMA has nominated acetoin, acetaldehyde and diacetyl to the National Toxicology Program (NTP) for study. This will take several years of work.

Len Welsh said he would like John Hallagan and the GMA folks to get a handle on the number of establishments utilizing flavorings at concentrations between 1% and .1% and what kind of processes these flavorings are utilized with. We started the last meeting with the same question about what parts of the food industry we'd capture.

Mike Horowitz noted that the next week FISHEP consultants were to sample a tortilla factory using a diacetyl butter flavor for one product. They utilize ½ pound of liquid diacetyl per shift, three shifts per day. However, the company was phasing out the recipe utilizing the diacetyl flavor.

Judi Freyman asked about the timeline for the standard.

Len Welsh said 60 days after the next meeting the regulation should go to the Board. Its time.

Azita Mashayekhi said Cal/OSHA should get into some food manufacturers.

Len Welsh agreed. We've got three on tap to go into now, but we want a variety of different products and operations. In flavor manufacturing we can cover not just diacetyl but ALARA for all hazardous substances.

Juli Broyles said GMA/FPA will look at how many companies are captured by .1% and 1% diacetyl. She said she would talk with the DWC about the impact of requiring medical screening and medical removal benefits.

Len Welsh said the language on these issues was the same as in other regulations and these issues are well established as OK. He noted the difficulty of getting employees to cooperate with medical screening.

John Halligan noted the cleanest suspect was diacetyl. Other substances could be added as we go along.

Len Welsh asked if flavor manufacturers couldn't leave diacetyl out and avoid the whole regulation.

John Hallagan noted that it was a surprise to find diacetyl was a hazard, and the companies were not into avoidance.

Nancy Rachman said from her perspective you can't substitute ingredients overnight. It will take years.

Len Welsh stated that he thought subsection (a)(3) should come out. OAL would take it out, saying we were delegating our rulemaking authority. Item 2 was aimed at food production.

July 10, 2007 was selected by the body as the date of the next meeting.