

**Report of the Small Business Advocacy Review Panel on the OSHA
Draft Proposed Standard for Occupational Exposure to Diacetyl and
Food Flavorings Containing Diacetyl**

July 2, 2009

Report of the Small Business Advocacy Review Panel on Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

1. Introduction

This report has been developed by the Small Business Advocacy Review Panel (the Panel) for the Occupational Safety and Health Administration's (OSHA's) draft proposed standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl. The Panel included representatives of OSHA, the Office of the Solicitor of the Department of Labor, the Office of Advocacy within the U.S. Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. On May 5, 2009, the Panel Chairperson, Robert Burt of OSHA, convened the Panel under Section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*). A list of the Panel members and staff representatives is included in Appendix A. The Panel chose a set of small entity representatives (SERs) from potentially regulated industries that use or have potential exposures to diacetyl. The SERs reviewed the draft proposed rule and offered their suggestions and recommendations to the Panel. The Panel is deeply indebted to the SERs for taking the time to assist the Panel in examining this draft regulation.

This report consists of four parts: Part 1 is this introduction; Part 2 provides the background information on the development of the draft proposed rule; Part 3 summarizes the oral and written comments received from the SERs; and Part 4 presents the findings and recommendations of the Panel. A list of the SERs is included in Appendix B of this report, and a complete copy of all of the written comments submitted by the SERs is included as Appendix C. In addition, the principal documents sent to the SERs, the Preliminary Initial Regulatory Flexibility Analysis (PIRFA) and a table presenting alternative PEL and non-PEL versions of the draft proposed rule, are included as Appendix D to this document.

2. Reasons Why Action by the Agency is Being Considered

Diacetyl is a chemical that gives butter its familiar taste. It is found naturally in many foods and occurs as a result of natural fermentation in many other foods. Diacetyl is also added to foods to provide natural tasting flavors such as dairy, caramel, vanilla, butterscotch, fruit, and a host of other flavors. It is also used as a fragrance in a variety of products to provide similar scents.

In its current form OSHA's draft proposed rule would apply only to employers who manufacture food products or flavorings using diacetyl, and not to the end users of such products (whose exposures are typically low). In addition, the draft does not cover naturally occurring diacetyl or fragrances and other non-flavoring uses of diacetyl. However, the PIRFA considers alternatives that would include diacetyl exposures no matter how they might occur.

The potential hazards associated with butter flavoring came under scrutiny in 2000, with the diagnosis of bronchiolitis obliterans in eight former employees who had worked in mixing and packaging operations at a Missouri microwave popcorn plant. Bronchiolitis obliterans, a condition that is rarely detected in the general population, is characterized by inflammation and scarring of the tissue lining the small airways of the lung. As a result of tissue damage, the airways become thickened, narrowed, and sometimes completely obstructed, limiting the movement of air out of the lung. Obstruction is typically fixed, meaning that pulmonary function test (PFT) results show no improvement following bronchodilator treatment. Impairment has generally been irreversible. Several former employees with bronchiolitis obliterans are on waiting lists to receive lung transplants. At least three employees with flavoring-related bronchiolitis obliterans have died.

Because a diagnosis of bronchiolitis obliterans requires the use of specialized diagnostic techniques such as computed tomography scanning or invasive medical techniques such as lung biopsy, investigations of popcorn and flavoring facilities have been limited to spirometry to measure changes in lung function among employees.¹ Surveys of lung function at several microwave popcorn manufacturing plants have detected an elevated prevalence of airway obstruction.

Further investigation of six microwave popcorn plants, including the Missouri plant, found the prevalence of airway obstruction and respiratory symptoms was highest among flavorings mixers with longer work histories and packaging operators who worked in close proximity to mixing tanks of oil and flavorings. Fifteen employees engaged in these job operations, which includes the cases cited above, at five microwave popcorn plants were found to have clinical evidence consistent with bronchiolitis obliterans. The lowest rates of airway disease and respiratory symptoms were experienced among the production and non-production employees with the least exposure to butter flavoring chemicals. Additional cases of severe respiratory disease consistent with bronchiolitis obliterans were uncovered among employees of flavoring manufacturing establishments who regularly handled, blended, or packaged flavorings, including butter flavorings, during their production.

Flavorings are complex and variable mixtures, containing a number of respiratory irritants and potential airway reactive substances. Many of these compounds have not yet been carefully studied. Diacetyl is the flavoring component that has received the most attention as an independent etiological agent in the development of respiratory disease.

¹ Spirometry measures the flow of air in and out of the lungs. One common spirometry test measures forced expiratory volume in one second (FEV₁), which is the volume of air that a person can exhale through the mouthpiece of a spirometer within one second. Another common spirometry test, forced vital capacity (FVC), requires that a person inhale as deeply as possible, and then exhale as forcefully and rapidly as possible. FVC is the total volume of air that a person is capable of exhaling through a mouthpiece under these conditions. Clinically, an abnormally low ratio of FEV₁ to FVC and a reduction in FEV₁ relative to a patient's baseline indicate an "obstructive" pattern of pulmonary function loss. Patients who are diagnosed with bronchiolitis obliterans commonly demonstrate severe fixed obstructive losses in lung function.

Cumulative exposure has been associated with elevated prevalence of obstructive lung disease. Bronchiolitis obliterans was found among employees at a diacetyl production facility, where chemical exposures were largely limited to diacetyl and acetoin. In animal studies, inhalation of diacetyl vapors caused airway damage in rats and mice. Thus, the available evidence would suggest that occupational exposure to diacetyl is a respiratory hazard and likely contributes to flavoring-related airway obstruction in humans. However, since inhalation of a butter flavoring mixture led to more extensive airway damage in rats than pure diacetyl at similar concentrations and since the inhalation toxicity of other potential airway-reactive butter flavoring compounds, such as acetoin, has yet to be evaluated, it may be premature, at this time, to regard diacetyl as the sole agent responsible for flavoring-related lung disease. Some butter flavorings used in microwave popcorn are undergoing significant reformulation away from diacetyl. OSHA will continue to examine the roles of diacetyl, acetoin, other butter flavoring components and replacement mixtures when further data become available.

3. Summary of SER Comments

The Panel hosted two conference calls for the SERs, on May 19 and 20, 2009, to obtain their input on OSHA's draft proposed rule. Many of the SERs also submitted written comments to the Panel (See Appendix C). The following is a summary of the key issues raised during the course of those conference calls and in the written comments.

A description of current diacetyl use among SERs

SERs can usefully be divided into three groups. First are SERs that have implemented measures to control occupational exposure to diacetyl. These SERs are from the microwave popcorn or flavor manufacturing industries. The second group consists of SERs that use flavorings (or fragrances) containing diacetyl, but have not implemented measures to control exposure to diacetyl. These vary widely in the frequency and diacetyl content of the flavorings used. The third group consists of SERs in industries where no diacetyl is added, but where diacetyl typically appears naturally as part of the production process.

This section will describe in some detail each of these groups, their processes, and their uses of diacetyl. Some processes, such as microwave popcorn and flavoring manufacturing, have been well documented in public sources and are similar to each other. Other types of operations were less well known prior to the discussions with the SERs.

The first group of SERs is from the microwave popcorn or flavor manufacturing industries.

One SER is from a manufacturer of microwave and ready-to-serve popcorn with approximately 350 employees, only one of whom works in the "oil room." In August 2007, the manufacturer began to remove added diacetyl from its products.

The SER described the process of moving away from the use of diacetyl, preferring not to use the word “substitute.” The SER looked at a variety of alternatives. Firms in the microwave popcorn industry now use the term “no added diacetyl” because, although they no longer add diacetyl to the product, the corn releases a small amount of natural diacetyl. When news first came out about health concerns, worker protection was the SER’s primary reason for discontinuing the use of diacetyl.

The manufacturer kept in place the same worker protections after replacing diacetyl that it had employed when using diacetyl. Recipe rooms are closed, ventilated, and maintained under negative pressure. Kettles have sealed heads. Workers wear respiratory protection and other personal protective equipment (PPE) (e.g., gloves, goggles).

Another SER is from a company with 15-20 employees that also manufactures microwave popcorn. This manufacturer has 1-2 production workers who might be exposed to diacetyl. It has phased out diacetyl from its main line, but still contracts with a few private labels that use diacetyl. As a result, the SER said diacetyl-based flavoring would be handled fewer than 30 days a year to fill these orders. The company has installed ventilation. Respirators are used in the mixing room, and employees are fit-tested for their respirators.

One SER is from a family-owned popcorn manufacturer with 150 employees, sales to grocery stores in all 50 states, and some exports. Of those employees, there are two shifts of 60 employees working in production. Only four are involved in mixing. All 150 employees have been trained on the potential hazards of diacetyl.

The company began examining the diacetyl issue in 2001 and has been working with the National Institute for Occupational Safety and Health (NIOSH) since 2002. The company had two employees who developed respiratory illness that may have been a result of inhalation of flavorings containing diacetyl. The SER indicated that it currently uses a substitute for diacetyl—insurance carriers are requiring the company to use substitutes due to a heavily litigious environment. It first moved to a substitute two years ago. The SER said that while the substitute is “acceptable,” they consider the substitute inferior to diacetyl in terms of flavor quality. The potential substitutes are limited, in any case. The company does not use starter distillate. It is working with its suppliers to ensure the substitutes are not also harmful. As for labeling, two suppliers of flavorings tell the SER everything that is in the mixture used in manufacturing, along with providing very detailed material safety data sheets (MSDSs). Others have not been as forthcoming, because of legal concerns. However, the SER believes the situation is improving.

In its process, the company tries to keep flavoring as much as possible within a closed system to reduce loss from volatilization. The company conducts exposure monitoring to

check employee exposure and engineering controls. It uses a full complement of PPE—coveralls, boots, masks, eye protection, and gloves—and has onsite showers and laundry service. For the 20 employees with the greatest potential for exposure, the company opted to use air supplied respirators with hoods. The SER said the company has a much more sophisticated respirator program, in part, because the company uses aluminum phosphate to fumigate grain. It also has an on-site nurse three half-days a week.

One SER is from a company that makes flavorings for the food industry. The company has 152 employees, 35 of whom are in production operations. It has 40,000 flavor formulations on the books, with 3,000 “active,” but, the SER did not know the number with diacetyl. The SER said the company does not plan to use diacetyl in future flavor formulations.

The company uses a batch process, 35-50 production batches/day, 3 shifts/day. The SER indicated that converting to a closed system is difficult because theirs is inherently a batch process. The SER said California OSHA (Cal/OSHA) approved the system in its California plant.

The company produces powder, freeze-dry, and liquid products. It has a dust collection system in the powder room and also dust collection later in the process. It has a respirator program with fit-testing. Respirators are assigned to a variety of different job categories including warehouse workers and testers, not just production workers. Its housekeeping consists of cleaning and sanitizing equipment tanks.

In the new facility, there will be exposure monitoring and testing to validate new controls put in place. The company also performs monitoring in its current facilities.

Another SER is from a flavoring company. The plant has 65 employees, 15 of whom work in production jobs involving substantial diacetyl exposure. The plant has approximately 11,000 flavors in its “library,” but not all are made in a given year. The SER said only 500 of them contain diacetyl.

The SER said the company already has implemented engineering controls to minimize diacetyl exposures. The company worked with Cal/OSHA to develop the controls. They also have implemented protective measures, including respirators. Employees working in compounding operations change cartridges in their respirators every eight hours of use, not just daily. They also wear safety glasses and gloves and use engineering controls similar to what the other SERs from the flavoring industry described.

One SER is from a company that produces dairy flavors, including starter distillate, for the dairy product industry (dairies/creameries) and for bakeries. The company has 20 employees at its facility, including 5 production workers and 3 quality control (QC) employees. About 90% of its products contain diacetyl. In addition to producing starter distillate, which typically contains 1.5% diacetyl, the company purchases diacetyl in a 99.9% pure blend. (The SER knows of no U.S. producers of pure synthetically-derived diacetyl.) The company's flavors are used to create butter, sour cream, and buttermilk. The company also creates Kosher/Parve products for margarine manufacturing.

The process of creating starter distillate begins by adding a dairy starter culture to milk and letting it sit for 24 – 48 hours. The culture generates flavors, and then the company steam distills it to concentrate the flavors. Exposure to diacetyl is possible during fermentation and collection processes, but fermentation would normally result in little exposure. Local exhaust ventilation is counter-productive for what is required in the fermentation process. Flavor generation involves steering the metabolism of bacteria at lower temperatures (40-50° F) in the general production room. The steam distiller has its own ventilation and drips final product into a container.

Some customers had requested flavorings formulated without diacetyl, but didn't like the smell and flavor of the product; so the company discontinued the use of the substitute.

Forty percent of the company's employees (all production and QC room workers) use respirators. In addition, workers use eye protection, chemical protective suit-coveralls, and Tyvek suits. The company has an in-house laundry service and showers.

The second group of SERs is from industries that are users of the flavorings (or fragrances) containing diacetyl.

One SER is from a snack food company with 170 employees that manufactures potato chips and ready-to-eat popcorn. There are two shifts where 6 employees work in the frying room, 1 person attends to the popcorn operation, and 7-8 work in packaging.

Most of the operation is automated and unmanned. Workers use pre-made batches of butter flavoring – approximately 10 batches per week. Batches are made and weighed in a room that is separate from the main production area. The ready-to-eat popcorn is flavored with a mixture of vegetable oil (415 lbs.) and a butter flavoring containing 4% diacetyl (35 g.), or a 0.02% diacetyl end mixture, at 120 degrees F. The final concentration of diacetyl is small but has a strong butter aroma. Flavorings are added to the hot oil approximately 4 to 5 days per week. It is a generally continuous process that uses two "pots" of oil per day. The oil is applied to the popcorn in a rotating drum and makes up about 30% of the final product's weight. One person starts the process, adding the oil to the popcorn and leaving the area. The popcorn is replenished about once every two hours. In addition to exposures in the frying room, there may be some exposure to

diacetyl in the packaging room. Popcorn is packaged within 2-3 minutes of coating; it is transferred by a conveyer into a small room where it is dropped into a bag and sealed.

The area where snack foods are made is approximately 7,000 square feet and highly ventilated. The air changes in the room every 6 minutes. In addition, there are exhaust hoods over every kettle. Ventilation was originally designed to vent steam from the potato chip process, but now it also is used to control potential employee exposures in both the potato chip and popcorn processes.

Another SER is from a creamery that makes butter. Butter starter distillate is the only source of diacetyl, and it is only added to flavor unsalted butter. (The SER said that margarine manufacturers also are likely to use starter distillate to flavor the product.)

The company has 28 employees, 18 in production operations. One or two employees work in mixing operations, where the main exposure to diacetyl occurs.

The SER described the butter-making process as follows: butter distillate comes in and is stored in 45-gallon liquid containers. The ingredients are then added to a tank, mixed, pumped to churn, and then churned at 55 to 58 degrees F. The product is then pumped to packaging. Adding flavoring takes 30-40 seconds one time per day. The company sometimes makes unsalted butter twice per week, but sometimes it is only made twice per month.

Another SER is from a retail bakery with 85 employees, 30 in production operations. This SER described the bakery as a “larger small bakery.” Diacetyl products come to the facility in two forms:

- 1) Pre-blended dry mixes, used in batch mixing processes. The bakery mixes 8 to 10 Hobart mixer-size bowls per day, which takes 8 to 10 minutes per bowl, with a dusty phase at the beginning of mixing that lasts about 1 minute. The SER believes the diacetyl concentration in each mix is a trace amount.
- 2) Liquid or powder flavor that is measured and put in product (added to other ingredients).

The SER’s inquiries showed that 10-12% of the flavors the bakery uses contain diacetyl. The primary flavor is used to make butter cream icings and fillings, which involves 1 minute to measure and weigh and 15 minutes of mixing once or twice daily. The other diacetyl-containing flavors are used less frequently (i.e., other diacetyl-containing flavors are used a few times per week). The SER doesn’t know anyone who left the industry due to lung problems. The SER said older people (+65) might get lung problems (e.g., emphysema), but the SER doesn’t believe they are bakery-related.

One SER runs several restaurants. Possible exposure to diacetyl comes from cooking and sautéing with butter. The SER's typical restaurant has 70 employees, 25 of whom work in the kitchen, although almost all employees pass through the kitchen at some point.

The SER indicated that restaurants are required by law to have a ventilation hood over every cooking implement, including griddles, stoves, and ovens, in order to control smoke and flames. Hoods prevent smoke alarms from going off. The SER said the exhaust hoods tend to work well as no one wants a lot of smoke buildup in a professional kitchen. Fire departments may test hoods to be sure hoods are functioning properly. Hood systems must be cleaned regularly.

The SER noted that cooking is a fast-paced business; therefore, chefs are constantly turning back and forth between raw ingredients and the cooking station. The SER said generally cooks do not lean over cooking; rather they work at arms length since the stove is a hot environment.

The SER said that butter is an expensive fat to sauté in. The restaurants use canola oil more often, and some olive oil. Butter is often used as a finishing component – added at the last minute to risotto or brushed on meat to add to its appearance at the end of cooking.

The SER felt that most restaurant owners have not have heard of diacetyl. They will not know what level of diacetyl could occur in a restaurant, so restaurants can't make informed decisions about protecting employees. In the SER's restaurants, they don't use much butter flavor substitutes that may contain diacetyl. Such products tend not to be used at higher-end restaurants. The SER said lower-end restaurants may use butter substitutes.

One SER is from a scented candle manufacturer with 80 employees. The company has 10-14 employees in production jobs, half of whom work in the mixing operations, the other half in packing after the candles are solid. A couple of workers operate in the QC lab. The SER indicated that few fragrances use diacetyl, and then only in small concentrations. Concentrations in the fragrance component range from less than 0.1% to 2%.

The company manufactures 150 different types of candles in a year. The SER estimated that 19 of the types of scented candles produced might contain diacetyl. The company used 40,000 lbs. of fragrances last year, 6,500 lbs. of which contained diacetyl. The SER's calculation suggests that perhaps 40 lbs of diacetyl are used annually as a fragrance ingredient..

The SER briefly described the candle-making process. Fragrance is supplied from a fragrance manufacturer. A large mixing manufacturing process occurs in a room that is 150 feet x 500 feet. Fragrance is poured out of a container into a mix tank at the top. A coloring agent is added. Fragrance is added to wax. The candle line is 200 feet long, is enclosed with insulation, and well ventilated. The first half (100 feet) is liquid. The second half (100 feet) is solid; this is where the wax is cut. Each half is separated by curtains. The QC lab tests candles by burning them and develops new types of candles. The burning candles are put in separate rooms and have different employees come in to gauge them.

Fragrance mixers do not use PPE. The SER had not performed exposure monitoring for diacetyl.

Candle manufacturers are trying to engineer diacetyl out of fragrances. They have requested their suppliers to remove diacetyl. The SER did not know what is being used now in those cases, but it is a little more expensive and doesn't perform as well, so it is a little less satisfactory.

One SER is a consultant to the baking industry. The SER indicated diacetyl is used in flavoring fillings, icings, cakes, batters, and toppings for bread. Mixtures of flavorings in baking operations are usually less than 1-2% diacetyl. The amount used is dependent on orders – at certain times of the year (i.e., graduation) there are more cake orders, which may contain diacetyl (i.e., butter cream). The possible diacetyl exposures would be coming from mixing icings, cakes, and fillings. Flavorings are added at the end of the process; they are not heated because it would ruin the mixture. Diacetyl is also found sometimes in butter or cream topping for bread. Ovens are fully vented to the outside in order for the ovens to function properly; no heated flavorings are being vented into areas where workers are present.

In a typical bakery, ingredients are received, then portioned out based on orders, and moved to the mixing room. Workers measure or weigh the ingredients (mixes come in both liquid and powder forms), add them to the mixing vat, and then pour the mixture into pans to bake. The process is automated in most 100 + employee bakeries. Smaller bakeries would typically be less automated.

There has also been a drive, lead by the flavor suppliers, to substitute away from diacetyl due to bad publicity, regulation, and research associating diacetyl with adverse health effects.

A SER in the tortilla manufacturing industry said that he does not know of anyone in the industry that used diacetyl. The SER indicated it would be surprising to find a company in his industry using diacetyl because the industry is trying to eliminate the use of additives; they have found customers prefer a product with a "clean label."

The third group of SERs is from industries that generally have only naturally occurring diacetyl. This group includes representatives from the beer and wine industries.

One SER is from a winery. The winery has 12 employees, but generally one employee in production who might be exposed to diacetyl. In the winemaking operation, diacetyl occurs naturally as part of the fermentation process. The SER said the winery does not add diacetyl to wines because it would ruin the flavor. In fact, the winery closely monitors the content of the naturally occurring diacetyl to make sure it remains very low.

The SER listed the occasions for exposure to natural diacetyl:

Although wine is isolated from the environment during production, some contact with wine is possible when operators rack the wine from one tank to another, change hoses, filter the wine, or clean barrels/tanks. Typical concentrations of diacetyl in wines that have undergone malolactic fermentation can range from 5 ppm to less than 1 ppm for wines aged 100 days. Spilled wine would be expected to produce substantially lower airborne concentrations than the solution concentrations and would therefore expose workers to extremely low doses for a very limited time during a small and limited part of the calendar year. [Ault, p. 3].

The SER noted, however, that employees have no more exposure to diacetyl than wine drinkers do. The SER also said:

The production of wine is a seasonal activity, and the time for which tanks of wine undergo malolactic fermentation is a very small part of the calendar year (typically 8-10 weeks). [Ault, p. 3]

One SER is from a regional brewery. The brewery has 200 employees, 90-95% of which are in production. The SER said the brewery is considered at the high end of small brewers, making 2 million barrels per year, which accounts for 1% of the market.

While diacetyl occurs naturally in beer, the SER said the goal is to keep it below a certain level because its presence is considered a flaw in the taste of the beer. The highest diacetyl concentration the SER had seen in beer is 0.25 ppm. Diacetyl is never added to beer at the SER's brewery. The optimal diacetyl level is <0.08 ppm because there is a faint taste of diacetyl at 0.1 ppm.

One of the SER's breweries measures diacetyl using a gas chromatograph (GC):

Diacetyl is used in the laboratory of some breweries for calibration of a gas chromatograph. Only one of our three breweries uses diacetyl in the laboratory. In our company 2 people are authorized and could be said to use diacetyl, or approximately 1% of our total workforce. For these people, the possibility of

diacetyl exposure is very low. All diacetyl dilutions are done in a fume hood to negate exposure potential. A stock of 300 ppm is made approximately once annually, and a dilution to 0.030 ppm is done weekly. Each of these dilutions takes less than 15 minutes, for a yearly total of approximately 12.75 manhours/year. [Helmke, p. 2]

The SER added that only larger breweries use analytical equipment.

The brewery uses a closed process so there is no direct contact with diacetyl during fermentation. It also has sealed tanks to capture CO₂; they also capture diacetyl vapor. There is also continuous ventilation, alarms, and vents throughout the brewery.

Provisions of the Standard

During the conference calls, and in the written solicitation of comments, the SERs were asked a series of questions that generally tracked the provisions of the draft proposed rule. Below is a summary of their thoughts about the various items in the draft proposal.

Definitions

Some SERs were concerned as to exactly how the term flavoring was defined by OSHA:

If you take a pound butter flavor containing 4% diacetyl and add it to 300 lbs. of vegetable oil, is the vegetable oil considered a food flavoring containing diacetyl, or is it a finished product or intermediate product? [Potter, p. 1]

SERs also said the draft proposed rule did not make a clear distinction between “artificial” (or “synthetic”) diacetyl and “naturally-occurring” diacetyl.

More generally, some SERs wanted OSHA to carefully define terms so that both readers of the regulation and lawyers would clearly understand what was included and what was excluded. SERs felt that distinctions between flavorings and foods containing flavoring, flavorings and naturally occurring diacetyl, and flavoring and other substances (such as fragrances) containing diacetyl needed to be clearly defined.

Scope and application

The SERs generally said that some form of regulation is needed for employers with routine, significant occupational exposures to diacetyl in industries where disease had been documented.

Some SERs felt regulation should be limited solely to microwave popcorn and flavor manufacturing industries:

While studies to date identify two sectors – the flavor manufacturers that produce flavors containing diacetyl and the microwave popcorn manufacturers – where

high airborne exposures to diacetyl and food flavorings containing diacetyl posed a significant risk of harm to the respiratory system, this data is inadequate to impose the burdensome requirements of an OSHA standard on the entire food manufacturing industry. . .

[W]e submit that it would constitute poor public policy to require every employer in the food manufacturing sector that knows it uses an ingredient containing diacetyl to initiate exposure monitoring to prove there are no exposure levels above the action level, much less the threshold trigger level. OSHA's contractor analysis, conducted by ERG, shows that the final product of the flavoring manufacturer, which generally has a diacetyl concentration below 1%, is the raw material for food manufacturing sector. Further, ERG found that the incoming flavor is diluted by a factor of 100 to 1000 at the beginning of a typical food manufacturing process. This suggests that the small concentration of diacetyl present further downstream would be insignificant from a worker exposure viewpoint. [Cogswell, p. 3]

Many SERs said they were concerned that their industry was included in the draft proposed rule and that the draft proposal should include a combination of exemptions, including:

- Employers (e.g., candle manufacturers) who use very small amounts of diacetyl (e.g., small overall amount or low concentration of diacetyl) ,
- Employers who do not use diacetyl often (e.g., fewer than 30 days per year) or use it only occasionally for a specific or special product,,
- Employers who use diacetyl only briefly at any one time (e.g., bakeries), and
- Employers who only have naturally occurring diacetyl (e.g., wineries, breweries).

Some SERs said they should be exempted because no one in the industry uses diacetyl. A SER from the tortilla manufacturing industry thought that the standard should instead be directed at flavor manufacturers/suppliers.

Most opposed regulation of industries that have only naturally occurring diacetyl. For example, a SER from a brewery argued:

There is no evidence that the diacetyl that occurs naturally as a part of the fermentation process is now or has ever been a contributor to respiratory distress in brewery workers.

It is highly unlikely that atmospheric diacetyl concentrations like those listed in the suggested permissible exposure limits (PELs) could be attained during the normal brewing process, since diacetyl levels in the liquid itself are usually lower than the levels listed for atmospheric diacetyl and since the process, by its very nature, excludes beer from contact with the environment.

The cost of compliance, even a seemingly small cost, is excessive without a compelling evidence of risk. The evidence of risk as applied to the brewing industry is far from compelling, and the risk of adverse economic effects for these small firms is high. This is especially true if a non-PEL approach is adopted. [Helmke, p. 5]

A SER from the wine industry stated:

- There is no evidence that the diacetyl that develops naturally as a part of the malolactic fermentation process is now or has ever been a contributor to respiratory distress in winery workers.
- The literature cited in support of the draft proposed regulation deals exclusively with workers exposed to concentrated diacetyl flavorings that are not used in the wine making process. To our knowledge wineries do not add or use such concentrated diacetyl.
- There is also no evidence in the literature cited that the extremely low levels of naturally occurring diacetyl encountered in wine production constitute a risk to winery workers.
- Wine is produced under anaerobic conditions and is therefore isolated from the environment throughout the production process. This means that workers have virtually no exposure to any naturally occurring airborne diacetyl. [Ault, p. 1]

However, one SER from the microwave popcorn industry indicated that, while he did not see the point in regulating establishments with very low levels of diacetyl exposure, he did not see any fundamental distinction between naturally occurring and chemically derived diacetyl—they are the same chemical.

Many SERs felt that regulation should also be limited to situations in which significant amounts of diacetyl were present for a significant amount of time in the affected facility. Some SERs also suggested that there should be known cases of disease for regulation to make sense. For example, one SER argued:

The dairy industry has been around for thousands of years, and we have not noted any increased incidence of respiratory illnesses in our industry. Where flavors containing diacetyl are used within our industry, they traditionally contain less than 1% diacetyl. In dramatic contrast, the microwave popcorn industry existed for barely a decade before it was clear that something was wrong in that industry. It is our understanding that unique microwave popcorn manufacturing processes such as heating and flavoring solid oil with highly concentrated flavors with an unusually high amount of diacetyl--20 to 30% diacetyl--have contributed to high workplace atmospheric levels of diacetyl in those plants. With respect to flavor manufacturing operations, they are using diacetyl at concentrations up to and including 99.5% (essentially pure diacetyl) which clearly lends itself to

volatilization. These situations and conditions would not be found anywhere in a dairy plant.

Given the information provided here and the information that was disclosed on the SBREFA conference calls, we do not feel that the dairy processing industry should be included within the scope of any regulation of diacetyl. Any exposure that dairy workers face through the use of flavors or distillates containing diacetyl is brief--approximately a minute or less--and the natural level of diacetyl in dairy products is low and the chemical and physical properties of dairy products would cause that diacetyl to remain with the product where it performs a safe and important function in the flavor profile of these wholesome foods. [Schroeder, p. 5]

In discussions, that SER also presented the view that there are three tiers of diacetyl exposure:

- 1) flavor manufacturers—who are exposed to 5 to 95% concentration of diacetyl;
- 2) manufacturers (candle, food, etc) – exposure to flavors and fragrances that are 1% to 5% concentrations; and
- 3) consumers – exposure to concentrations at the 0.001% to 0.005% level

Many SERs using flavoring suggest employers in their industries were unlikely to be posing significant risks to their employees. Their reasons included use of only small quantities of flavoring containing diacetyl, relatively infrequent use, use in closed processes, and uses that did not involve heating. While all did not suggest they be exempted from the rule, SERs from both the tortilla and scented candle industries suggested they not be included under the rule. In the former case, the SER did not think diacetyl was being added to tortillas; in the latter case, they believed the exposures were limited. Finally, one SER questioned whether a formal regulation was needed at all, or whether the issue could be adequately addressed through a National Emphasis Program, because it seemed to him that the only industries that have significant exposures (i.e., microwave popcorn and flavoring production) have already taken steps to substitute products or control exposures.

Exposure Assessment

Only SERs in microwave popcorn and flavor manufacturing have conducted exposure assessments. Other SERs said they (and their industries) did not know whether or how much diacetyl was present in flavorings they used; therefore, they did not know employee exposure levels. One SER said that it was difficult for the company to measure diacetyl exposure because they did not make products containing diacetyl every day.

Many SERs reported that, although they had not conducted exposure assessments, they believed airborne exposures in their facilities were low for various reasons, including:

- They use diacetyl only very briefly during a work day/week or only a few days a year. For example, one SER said diacetyl was used as little as 1-2 minutes a day and only 3-4 times a week. One SER said the only potential for exposure was pouring starter distillate into the product mixture, which amounted to 20-40 seconds twice a week. Another SER said diacetyl was used only 15 minutes a week for a total of only 15 hours a year. One SER said diacetyl was used less than 30 days a year in order to prepare a private label product.
- They use very little diacetyl. For example, one SER said that only 10-12 percent of the flavorings used contained diacetyl. One SER said that of the 40,000 lbs. of fragrance used in a year, diacetyl accounted for only 40 lbs.
- They use very low concentrations of diacetyl. Several SERs said diacetyl concentrations were below 1 percent. One SER said that the company used only 35 grams of diacetyl blended into 400 pounds of vegetable oil, which is .02 percent concentration.
- They do not heat/volatilize diacetyl. For instance, some SERs said they only use diacetyl in aqueous forms or do not heat products containing diacetyl. Therefore, they say, there is no potential for volatilization.
- They have production processes that are fully enclosed. Several SERs said because they use closed processing systems, their employees do not have any direct contact with diacetyl.
- They only have naturally occurring diacetyl. SERs who only have naturally occurring diacetyl said diacetyl levels were very low in their products.

This provision was a concern for many SERs because they felt thousands of facilities with little diacetyl exposure would need to conduct expensive exposure monitoring.

There was concern about the frequency and number of persons who would need to be monitored:

The proposal suggests that an initial exposure assessment would need to take place. For the engineering standard approach it is clear that associates can be grouped and exposure monitoring can be done for each shift and each job classification. For the PEL approach it appears each and every associate has to have air monitoring data to satisfy this exposure assessment. That would be very expensive. Instead we suggest grouping associates with similar jobs and having air monitoring done for one associate from each group. [Hawk, p.3]

One SER voiced concern about having to do a complete reevaluation if “any” equipment changes occur:

Some of the wording states that if “any” ingredient changes or equipment changes occur, the risk of exposure must be reevaluated. This creates a very large “barrier-to-entry” for small businesses to get their products evaluated or

approved. It is likely customer will place the burden of risk analysis on new vendors before changes are considered. [Schroeder, pp. 17-18]

Exposure Control Plan

There was concern about the requirement for a leak detection program. One SER noted:

The engineering standard requires a written exposure control plan. Although most elements seem reasonable the "leak prevention, detection and repair procedure" seems to be more applicable to chemical plants making diacetyl; but not to food manufacturing facilities. [Hawk, p.3]

Regulated Areas

A number of SERs said they conduct all mixing in separate/closed rooms that have their own ventilation systems. In addition, several SERs said their quality control/quality assessment (QC/QA) rooms are closed and ventilated.

Methods of Compliance

A number of SERs, particularly those in the microwave popcorn industry, have discontinued using diacetyl for various reasons. Several SERs indicated that legal concerns were driving a move to replace diacetyl, although the shift out of diacetyl was not universal across the SERs. Some have discontinued using diacetyl due to employee safety and health concerns after illnesses were reported in the industry. In some sectors, SERs said they stopped using diacetyl because their customers want a "clean label" and therefore refuse to accept products containing diacetyl. (However, another SER said that only a small percentage of their customers refuse to accept flavorings containing diacetyl.) One SER in the flavor manufacturing industry said the company is phasing out its diacetyl use and does not plan to use diacetyl for future flavor formulations. Some SERs that have discontinued the use of diacetyl said that consumers have not had a negative reaction to the reformulated products. One SER indicated that immediate legal considerations were so paramount an issue for the company that they were beginning to "eclipse practical considerations"—some firms might be so keen on substituting out of diacetyl that they may be shifting into a mix of chemicals that are more hazardous.

Some SERs who have discontinued the use of diacetyl said they carefully examined and tested potential substitutes before using them. One SER said the process they followed in order to move to substitutes was extensive. The company did the following things before switching to substitutes: investigated potential liabilities of the substitutes, hired laboratories to test potential substitutes, worked with toxicologists to investigate how the substitutes would interact with other substances, and researched the scientific literature on potential substitutes. This SER also put new products through extensive monitoring. Another SER said that after the company heard about the illnesses reported at the Jasper, MO. microwave popcorn plant, it accomplished a complete substitution away from diacetyl in just three months.

Although the SERs using substitutes said that substitutes generally were more expensive than diacetyl, the SERs found them economically feasible (“doable”) because flavorings were such a small component of the overall cost of the product. Generally, these SERs said they had absorbed the costs of substitution and did not pass the cost onto customers. However, one SER said moving to substitutes was expensive because companies had to do market research to see how customers would respond to reformulated products.

Many SERs said they have not substituted away from diacetyl, and gave various reasons for this. Some SERs said they have not found any viable options to get the same taste and aroma. Others said their customers did not want to change formulas they were using because of concerns that any changes made to flavorings would affect the flavor profile and the whole product down the line. Some SERs who have not substituted away from diacetyl expressed concern as to how they could be certain that the substitutes were not also harmful.

Where diacetyl is or has been used, SERs, particularly in popcorn and flavor manufacturing, have implemented a range of engineering controls including ventilating production, mixing and recipe areas, installing closed and ventilated mixing and processing systems, and ventilating (local exhaust ventilation) mixing and processing machinery and equipment (e.g., openings in machinery for adding flavorings or testing product, kettles for flavoring blending, bowls for mixing dough). A number of SERs, particularly in popcorn and flavor manufacturing, have installed separate ventilation for mixing, recipes, and QC/QA rooms. One SER who has discontinued use of diacetyl said that the company has continued to maintain the controls it implemented to protect employees from diacetyl exposure.

SERs in some industries said that they have not installed closed systems because they do primary batch processing. One SER said it would be very hard for the company to install closed systems because it does 30-50 production batches a day

A number of SERs, particularly in popcorn and flavor manufacturing, also have respiratory protection, air monitoring, medical surveillance, and training programs. Some SERs in other industries also have respiratory protection programs or provide respirators in some operations.

Some SERs have engineering controls in place for reasons other than for specifically controlling diacetyl exposure. SERs in the beer and wine industries said their processing systems are completely enclosed and automated as a necessary element of production. Other SERs said they have vent hoods over areas where diacetyl is used (e.g., stoves) in order to meet air quality regulations and building/fire codes. One SER pointed out that most restaurants would have ventilation hoods over their stoves to meet a variety of other regulations.

Some SERs, though recognizing potential hazards to employees, have not implemented engineering controls, but instead rely on respiratory protection programs in areas where there may be significant employee exposures.

Respiratory Protection

A number of SERs said they either have respiratory protection programs at their establishments or at least provide respiratory protection in operations and areas where there may be potential diacetyl exposure, including mixing rooms and operations, QC/QA rooms, and “controlled rooms”/regulated areas. SERs in popcorn and flavor manufacturing said they have established respiratory protection programs.

Some SERs said their respiratory protection programs are expensive. For example, one SER said the company requires that filter cartridges/canisters be changed every day. Another SER said the proposed standard’s full face respirator requirement would be very expensive and said that half face respirators should be adequate for several reasons:

The proposed standard requires full face respirators. Diacetyl has very low skin permeability and therefore half face respirators should provide adequate protection. This would be an unnecessary expense and is much less comfortable for the associates. When comfort is an issue, associate compliance is also more difficult to achieve. [Hawk, p.3]

Protective Clothing

Some SERs reported use of protective clothing in their industries. A SER from the microwave popcorn industry indicated that in addition to the use of eye protection, gloves and boots, they use coveralls. They also have onsite showers and a laundry service. “Nothing follows employees home.” A SER from a dairy flavor supply company reported that when a drum of diacetyl is opened, workers use disposable chemical suits, respirators, eye protection, and gloves. Employees in that facility also use coveralls in some situations; the facility has an in-house laundry and shower.

There was concern that the requirements for dealing with contaminated clothing are more stringent than is necessary given the low diacetyl content of any contaminant on the clothes in most work settings:

The proposed standard requires that contaminated protective clothing must be stored and sealed in impermeable bags or closed impermeable containers for transportation to the laundry. This seems to be overkill for most industries that use diacetyl at very low levels. At the very low levels at which diacetyl could remain on clothing (considering the very low concentrations in the flavorings to begin with) this does not seem reasonable. This part of the standard may only be appropriate in the chemical manufacturing setting where diacetyl is present in much higher concentrations. [Hawk, p.3]

Hazard Communication

Some SERs, particularly those in popcorn and flavor manufacturing, have implemented hazard communication programs that include information, training, and labeling.

Training - One SER said that the company has provided extensive training for all production employees, including “town hall” information and training meetings with employees. Some SERs, particularly those who did not think they had extensive exposure, said that they have not trained employees about diacetyl.

Information/labels – SERs in flavor manufacturing said they provide information on diacetyl to downstream users. One SER puts information on the diacetyl content of the flavoring product on both the MSDS and label. Another SER said the company puts a warning on the MSDS but only includes it on the label if the flavoring contains an amount of diacetyl that would warrant a label.

Some SERs who use flavorings containing diacetyl have been successful in getting information on diacetyl content from flavor manufacturers; however, other SERs said labels did not include information on diacetyl and that it was difficult and “slow going” to get it. One SER said the company called the manufacturer to get information about diacetyl in flavorings since the company did not have the ability to test the flavoring product.

Medical Monitoring

Only SERs from the microwave popcorn and flavoring production industries had medical monitoring programs that included diacetyl. Several of these SERs provided detail on their current medical monitoring programs. Weaver Popcorn provided detail in a written comment:

Weaver conducts a medical surveillance program which has many facets. Associates with potentially high exposures (based on our assessment of their job duties) receive quarterly spirometry test to measure their pulmonary function ("PFTs"). All other associates receive annual PFTs. The test results and tracings are reviewed by a board certified pulmonologist. Any associate with a PFT result less than 80% of predicted is referred for a medical exam by a board certified pulmonologist. If the medical doctor recommends further testing, a high resolution CT scan is administered at the company's expense.

In addition to the PFT, associates also complete a health questionnaire that is consistent with the NIOSH health survey. The results are compared with N-HANES III and the results are statistically analyzed to develop a prevalence rate.

An annual report is prepared so that trends in the data can be more easily noted. An annual report detailing the results of air monitoring data, PFT results, and the statistical evaluation of the predicted vs. actual prevalence rate for both self-

reported symptoms and doctor-diagnosed respiratory disease is also prepared.
[Hawk, p. 1]

Another SER from the microwave popcorn industry reported that the company does baseline spirometry testing for anyone exposed in the mixing area and testing area. This is repeated annually.

A SER from the flavoring industry reported that employees at their facilities have medical exams and PFT/spirometry tests annually (2 times a year in California), and receive exit exams. The company does not have an in-house medical provider, but uses the same contract medical service year after year, so that there is continuity.

Another SER from the flavoring industry indicated all potentially exposed employees (packers and compounders) receive PFT/spirometry tests twice a year.

At least one SER believed some of the current provisions, such as frequency of exams, are excessive:

The standard requires a physical exam "every six months" or more frequently when deemed necessary by a health care professional. This is excessive. If spirometry testing is done and the associate's lung function is within normal limits, there is nothing that a physical exam will show that the pulmonary function test did not show. Furthermore, this is an unnecessary substantial expense. The requirement that a health care professional would have to prepare a written medical opinion within 30 days after every physical exam is excessive, especially when combined with the unnecessary requirement of a physical exam for every associate every six months. This requirement should apply only for physical exams of those associates who have been referred as a result of an abnormal spirometry test result. [Hawk, p.3]

There was also a desire to have more specific guidance on what results would trigger additional medical monitoring:

[I]t is important to have a common definition of what pulmonary function test result should trigger additional medical monitoring. Or, if no agreement can be reached on that issue, the standard should leave it to the licensed health care provider. [Hawk, p.3]

Other

Two SERs attached a comment from the Grocery Manufacturers Association (GMA) and a report by Toxicology Excellence for Risk Assessment (TERA) that raised additional issues about several provisions and issues concerning the best approach to risk assessment and setting a PEL. Some SERs directly expressed concerns about proper analysis of the risk involved:

OSHA has not established that there is a significant risk to employees at existing levels of exposure to diacetyl in the food manufacturing industry in general, or specifically, the baking industry. Absent this threshold determination, OSHA cannot regulate exposure to diacetyl under a substance-specific standard. OSHA must develop and use available data to determine what, if any, regulatory obligations may apply to the food industry. While OSHA is lacking the data to accurately assess the use and potential impact of diacetyl in the food industry, it must gather that information prior to the implementation of any regulatory scheme. [Cogswell, p. 3]

Economic Analysis

Most SERs did not comment on the economic analysis. Several of those that did thought the cost estimates were generally reasonable from their experience. "...we believe that the characterization of the unit costs in Table 8 are fairly accurate..." [Cogswell, p. 5].

One SER from the popcorn industry that has installed a full industrial hygiene program found that controls using a non-PEL approach cost over \$1 million, although he was unsure of the ongoing costs. He believes his unit costs are on par with those estimated in the PIRFA. The company's respirator masks/hoods cost \$600 each, but they are for air-supplied respirators--the service life is as yet unknown.

At least two SERs thought OSHA had underestimated the number of businesses in their industry:

Of the 6,101 wineries in the U.S., approximately 98% of them are small businesses. The estimate of costs of compliance in the draft underestimates the number of wineries substantially. The reasons for this are not clear. [Ault, p. 1]

Of the approximately 1,500 companies producing beer in the U.S., all but two are small businesses. The estimate of costs of compliance in the draft underestimates the number of breweries substantially. The reasons for this are not clear. [Helmke, p. 1]

In the SBREFA conference call, however, it was suggested at least part of the explanation for the asserted undercount in the beer industry was that many breweries are microbreweries, which may have a restaurant NAICS code assigned to them.

One SER raised concerns that OSHA had overestimated the profits for its industry, due to the date of the data:

[W]e have concerns about the profit margins that have been discussed elsewhere in the Agency's documentation, such as in the "*Technological and Economic Feasibility Analysis for Proposed OSHA Standard for Diacetyl and Acetoin Draft Final Report*," Task Order Nos. 27 and 37, Contract No. GS-10-F-0125P, BPA DOL Q059622303. Over the past year, the baking industry has been significantly challenged with very volatile commodity prices. These commodity price changes

have had a significant impact on the economics and profitability of baking operations across the nation. As a result, many bakers have had to make difficult choices as to whether their businesses can continue to operate, whether they can continue to provide health care for employees and whether they can find commodities for their products.

For example, wheat prices rose approximately 173% over a 6- to 9-month period. This trend made it very difficult for the baking industry to continue bringing affordable grain-based products to the marketplace. The baking industry historically has had very small profit margins and passing those costs on to the consumer always constitutes the last option. Further, many bakers already have negotiated prices with their retail customers, and they are locked-in, pricewise, regardless of other economic factors. [Cogswell, p. 5]

One SER expressed concerns that consumers would seek out foreign products if U.S. operations substitute out of diacetyl:

Unintended consequences - does this regulation result in an increase in imported microwave popcorn from Argentina & Brazil? US firms switch to non-diacetyl while the foreign companies don't worry so much about worker safety so they don't switch away from diacetyl butter flavor. [Potter, p. 1]

Two SERS attached a comment from GMA that raised a number of issues related to OSHA's cost estimates.

It was noted by a SER simply that medical exams, record keeping, and frequency of testing seemed "quite burdensome," without elaboration.

Duplicative, Overlapping, and Conflicting Regulations

One SER raised concerns about the use of glass tubes for monitoring because of other agency rules concerning the use of glass at food processing facilities.

Regulatory Alternatives

Scope-related

The SERs expressed an interest in finding ways of eliminating employers with minimal exposures to diacetyl from the scope of the standard. Some suggestions for reducing the scope included the following:

- Limit the scope to popcorn and flavor manufacturing and perhaps expanding the scope when and if disease or significant exposures were found in other industries.
- Exclude employers for whom diacetyl occurs naturally in their products.
- Exclude specific industries, such as fragrance users from the scope.

- Exclude employers who use diacetyl below a certain concentration. One SER pointed out:

Alternative provision for exclusion from scope - this makes a lot of sense to me, exclude companies where the flavoring in use has a low diacetyl content. Question - what would that % be? [Potter, p. 1]

- Exclude employers based on total diacetyl used on an annual basis:
 - [W]as an exemption considered for a facility based on annual pounds of diacetyl used, so facilities that don't use many pounds in a year, don't have to do the testing, don't have to read 100 pages of regulations or hire an engineering firm to find out if they have to do anything? [Potter, p. 1]
- Exclude employers who use diacetyl flavoring less than some specified number of days a year.
- Develop a system for exclusion based on concentration, frequency of use, and degree of heat applied to the diacetyl.

PEL versus Non-PEL Option

SERs differed with respect to whether they preferred a PEL or non-PEL alternative. A non-PEL alternative was appealing to some because it established clear requirements and was believed to assure reasonable control of all flavoring chemicals. Other SERs, particularly those with small quantities or only occasional use of diacetyl, were concerned that any use at all would trigger a full program. They generally felt the non-PEL alternative lacked flexibility for occasional and small volume users. Alternately, the concern was raised that the PEL may turn out to be either needlessly stringent, or inadequate.

Among those supporting a PEL alternative, Diane Gilinsky, of David Michael & Co., wrote

David Michael & Company, and many other FEMA-member flavor manufacturers, have already, in the absence of permissible exposure limits (PEL) for diacetyl, implemented exposure controls that address exposures to diacetyl and other flavoring substances. Therefore, we support the implementation of an appropriate permissible exposure limit for diacetyl as the primary regulatory measure to help our company and other flavor manufacturers have the safest workplaces possible.

On the other hand, Robert Hawk of Weaver Popcorn generally favored an engineering control (non-PEL) approach due to concerns about the risk assessment related to diacetyl and concerns about the current ability to measure for diacetyl. However, the company also made a suggestion for a particular PEL, if that approach was taken:

Weaver believes that an engineering standard will be more protective of worker health and safety in this situation because the science has not conclusively established that diacetyl is the cause of the bronchiolitis obliterans. To the contrary, many scientists including NIOSH scientists have suggested that acetoin, or other chemicals may be equally as harmful to workers.

The problem with a PEL is that it only protects against one chemical – diacetyl. Ten years ago we did not even know that diacetyl was a problem. An engineering standard would protect against all chemicals, whether we know today that they are harmful or not.

A second problem with the PEL standard is that the science is not far enough advanced to establish a PEL. The fact that OSHA has suggested 4 different PELs (0.05, 0.1, 0.5 or 1 ppm) is a good example of the lack of scientific certainty regarding what exposure level is safe and adequately protects associates without being unduly burdensome on employers. There is no established "No Adverse Effects Level" for diacetyl, so setting a standard is just a "shot in the dark". The most that OSHA is able to state in support of any specific PEL is that the very low PEL (0.05 ppm) describes a level below which "there is little evidence that exposures cause adverse health effects". That is a far cry from the certainty that should be the basis for regulatory decisions.

If a PEL is Adopted It Should Be At A Level That Can Be Reliably Measured.

The low end of OSHA's proposed PEL is a level which we feel is unlikely to be able to be measured reliably in a plant setting. We are not certain that the new OSHA methodology which allows measurement of this very low level has been reliably field tested. It is not practical to require employers to measure to levels that laboratories and industrial hygienists are not routinely able to measure. Weaver recommends a PEL, if one must be adopted, of 0.1 ppm and a Short Term Exposure Limit of 0.2 ppm.

We understand the comments made by some small businesses opposing an engineering standard because it removes the flexibility that many employers would like to have as to how to best achieve compliance with the standard. We are not suggesting that OSHA should adopt an engineering standard that is inflexible (for instance which applies the same engineering requirements for all industries) and does not set reasonable requirements, taking into account the competing interests of worker safety and cost. Our experience is that many employers will have to adopt the measures discussed in the proposed OSHA Non-PEL alternative even if a PEL is adopted. An engineering standard may actually assist many small businesses by removing the uncertainty of whether they will be in compliance (i.e. can they achieve the PEL) if they install specific engineering controls.

There seemed to be some ambivalence on the part of at least some of the SERs as to the best approach. For example, one SER favored an engineering-based (non-PEL) approach in the SER Panel phone call, but favored a PEL-based approach in the written comments.

Some SERs urged OSHA to consider allowing employers a choice between the PEL and non-PEL alternatives:

I believe it's critical that industries have the option of choosing PEL or non-PEL. One size does not fit all, there's a great deal of variance between industries and between companies of different sizes. [Potter, p. 1]

Two SERs raised a concern that some potential diacetyl substitutes may turn out not to be safe:

OSHA has rightfully identified the substitution issue as one that demands further exploration as it is possible that an exposed worker will have a false sense of safety with a substitute which may actually present the same risk or perhaps an even worse risk. [Schroeder, p. 5]

[One unintended consequence of the regulation might be] alternatives to diacetyl are studied and found to be as bad for worker health. [Potter, p. 1]

At least one SER indicated that the entire concept of introducing a PEL would be new to the industry and found it inherently confusing:

Upon discussing this issue with small-business customers in the dairy and bakery industries, many seemed confused [by] the differences, or do not have the expertise or experience to understand the process.

These workplaces may not be used to using PELs, so evaluating the proposed regulations or the difference of when to monitor or when to use a PEL is confusing. [Schroeder, p. 17].

One SER indicated the PEL approach would be more “efficient,” but qualified that by saying that the company also used aluminum sulfide, “which is very dangerous and [the company must] watch it very closely.” In short, the company could work with either approach.

Exposure Assessment

Many SERs were concerned about the cost of initial exposure assessment for employers unlikely to have exposures that would result in significant risks to employees. Most suggested that this issue be addressed through changes in the Scope and Application section, but SERs would welcome any approach that diminished the need for initial exposure assessment in low risk operations. One SER urged OSHA to give more careful

consideration to both the number of employees that would have to be monitored and the frequency with which they would have to be monitored in the event of changes in process or ingredients.

Exposure Control Plan

A SER opposed an alternative for updating the Exposure Control Plan (ECP) every six months, deeming annually to be sufficient:

[F]requency of ECP plan evaluation - annual would be sufficient in my opinion, rather than every 6 months, and also whenever there's a significant process change or ingredient conc[entration] change or ingredient characteristic change. [Potter, p. 1]

Regulated Areas

One SER endorsed the alternative provision for regulated areas, which would exempt those who can demonstrate they do not have detectable exposures of diacetyl:

"Alternative for regulated areas" - makes sense, doesn't waste effort where it's not needed [Potter, p. 1]

Respiratory Protection

Some SER comments suggest the Agency should consider allowing half-mask respirators in a variety of situations.

Protective Clothing

Some SER comments suggest the Agency should consider tailoring the protective clothing provisions to more closely match the risk from exposure, possibly creating at least a partial exemption in cases involving handling low concentration of diacetyl.

Medical Monitoring

As indicated earlier, a SER suggested that an automatic requirement for physical exams be less frequent than every six months, unless abnormal spirometry tests result. It was also suggested that the Agency establish a clear protocol for when additional medical monitoring should be triggered in the wake of pulmonary function testing.

Other

At least one SER expressed a desire that the Agency put forth more information on the relationship between temperature and diacetyl volatility, so that businesses could help devise their own solutions to exposure issues:

There was much discussion, but almost no data concerning the relationship between temperature and diacetyl vaporization. Given the significance of this relationship, it seems crazy not to collect and publicize temperature related data. [Potter, p. 1].

Finally, at least one SER questioned the need for this rule and suggested instead a National Emphasis Program, adding that it appears that the only two industries that have significant exposures (i.e., microwave popcorn and flavoring manufacturing) have already taken steps to substitute products or control exposures to diacetyl.

4. Panel Findings and Recommendations

Based on the input from the SERs and its own consideration of the issue, the Panel offers the following findings and recommendations to OSHA.

Benefits, costs, and economic impacts

Estimates of extent of exposure and risk

SERs were generally concerned as to whether significant risk or significant occupational exposures were present in all of the industries the regulation might cover.

The Panel recommends that OSHA carefully consider the costs, benefits, and possibility of risk associated with various regulatory approaches to this issue and ensure that any rule is tailored to generate the least cost to employers consistent with OSHA's requirement to protect worker safety.

The Panel recommends that OSHA continue to gather exposure data on diacetyl and consider exclusion or limited requirements for employers with minimal exposures.

Industry profile estimates of number of firms

Two different SERs (beer and wine) believed the Agency had underestimated the numbers of affected establishments in their industry. The Agency had relied upon Census Bureau data information to develop estimates. For the brewing industry, at least, using only one NAICS code may have been insufficient to assure inclusion of all breweries.

The Panel recommends that, if the beer and wine sectors are included in the proposed rule, OSHA look more closely at them to ensure an accurate count of affected establishments (and firms). The Panel also recommends that OSHA examine whether there might be similar undercounting in other industries.

Cost estimates

The SERs generally found the unit cost estimates to be reasonable and to include the appropriate elements. However, in an attachment submitted by two of the SERs, GMA argued that the cost estimates for exposure monitoring were underestimated.

The Panel recommends that OSHA evaluate any specific criticism of the estimates developed for the PIRFA and modify the analysis, as appropriate, for the Preliminary Economic Analysis (PEA) and Initial Regulatory Flexibility Analysis (IRFA).

Economic impacts and economic feasibility

One SER was concerned that OSHA had underestimated the economic impact on the SER's industry because OSHA had not examined recent developments concerning the impacts of cost of supplies on the profits of the industry.

Recognizing that there are invariable time lags in acquiring data, but also that even the latest data will not reflect the situation when a regulation is actually implemented, the Panel recommends that OSHA consider how to produce a PEA that best recognizes the values of timeliness and reflection of long-term business conditions. The Panel also recommends that OSHA try to remain up to date on special conditions affecting particular industries.

Benefits and Risk Assessment

Two SERs attached a comment by GMA, which was in turn provided as an attachment in the executive summary of a paper developed by TERA on the best approaches to developing occupational exposure limits for diacetyl.

The Panel recommends that OSHA evaluate these suggestions on how to develop occupational exposure limits for diacetyl.

Overlapping and duplicative regulations

A SER raised a concern about glass tubes being used for exposure monitoring at food processing facilities. The SER indicated that glass was banned by another agency from the vicinity of such operations because of the possibility of broken glass entering the food supply.

The Panel recommends that OSHA make certain that any exposure monitoring requirements are consistent with regulations of other Federal agencies.

Provisions of the draft proposed rule

Definitions

Several SERs expressed a desire for greater clarity in the definitions of the rule, particularly those that affect scope, such as the key term “flavoring.”

The Panel recommends that OSHA make sure that, whatever the scope of the draft proposed rule, the Agency states the scope in ways that are clear and easy to understand. The Panel recommends that OSHA bear in mind that many of the affected small entities may have limited experience with OSHA health standards.

Scope and application

A number of the SERs felt that various industries or classes of employers should not be within the scope of the rulemaking, because just falling within the scope could result in significant expenses. A wide variety of possible approaches to exemptions from the scope were mentioned, including exempting entire industries, limiting the proposed rule to certain industries such as producers of flavorings and microwave popcorn, exempting firms with less than some given percentage of diacetyl in products they used, exempting naturally occurring diacetyl, exempting employers who used diacetyl only occasionally, and exempting employers who used less than some total number of pounds of diacetyl per year.

The Panel agrees that the scope of the draft proposed rule may include employers who use only small amounts of diacetyl or have only minimal exposures, and recommends that OSHA carefully consider possible exemptions or limiting requirements for employers with minimal exposures. The Panel also recommends that OSHA consider exempting naturally occurring diacetyl, but recognizes that OSHA must consider how to deal with situations where employers may have both naturally occurring and added diacetyl present.

Exposure Assessment

Outside the microwave popcorn and flavoring industries, no SERs reported having done any exposure assessments. These SERs listed a number of reasons why they believed exposure was very limited in their industries—very brief exposure, low concentrations, the use of closed systems, and lack of heat/volatilization. SERs were generally concerned that even employers with no significant exposures to diacetyl would still need to undertake expensive initial monitoring to be able to prove to OSHA that there was no significant exposure. Some SERs were also concerned that the OSHA would require both more frequent and greater numbers of samples than needed to adequately characterize exposure.

The Panel recommends that OSHA consider exposure assessment provisions to minimize monitoring burden, and consider allowing the use of “objective data,” as used in other OSHA health standards, such as occupational exposure to hexavalent chromium, instead of initial monitoring, where appropriate.

Exposure Control Plan

A SER was concerned about the requirement to evaluate the exposure control plan every six months, saying that an annual evaluation whenever there is a significant process change would be sufficient.

The Panel recommends that OSHA evaluate what exposure control plan evaluation frequency is adequately protective.

A SER expressed concern that the leak detection program was better geared for a chemical plant than the typical small entity using diacetyl.

The Panel recommends OSHA consider how to better tailor the leak detection program to be consistent with the nature of the processes involved.

Methods of Compliance

A number of SERs, most notably in the microwave popcorn industry, have introduced substitutes for diacetyl into their formulations, though they noted this process was complex and the substitutes were generally more expensive. Other SERs have reduced the quantities of diacetyl in their flavor formulations. Some SERs reported failed attempts to find substitutes for diacetyl. Some expressed concern that the substitutes might create their own health problems. A number of SERs, including SERs who eliminated the use of added diacetyl, reported the use of engineering controls and respiratory protection in their operations.

The Panel recommends that OSHA continue to monitor the use of replacement substances for diacetyl in food flavorings and to evaluate potential health effects associated with exposure to these compounds.

Respiratory Protection

A number of SERs, principally in the popcorn and flavoring industries, have experience using respirators around diacetyl. A concern was noted by one SER regarding the requirement for full-facepiece respirators, because he believed that half-mask respirators were sufficient.

The Panel recommends OSHA evaluate what is adequate respiratory protection.

Protective Clothing

Some SERs questioned the need for a requirement to provide protective clothing. Other SERs questioned the need for protective clothing where diacetyl exposures or concentrations are low.

The Panel recommends that OSHA evaluate the situations where the use of protective clothing is necessary and clearly specify those situations in the standard.

Another SER also questioned the requirement to store or remove contaminated protective clothing in impermeable containers, saying that available data do not indicate that the presence of diacetyl on clothing worn at work poses any harm to persons in the home of the employee who wears the clothing.

The Panel recommends that OSHA evaluate whether it is necessary to require that diacetyl-contaminated clothing be stored in impermeable containers.

Hazard Communication

Some SERs provided training to employees on diacetyl exposure, and some did not. Most of those that did not provide training did not perceive themselves as having significant risks from exposure to diacetyl. There was some concern with how users of flavorings could determine if diacetyl was present in products they were using. However, all those who sold diacetyl to others reported putting information about diacetyl in their MSDS.

The Panel recommends that OSHA evaluate the current state of information being received by downstream users of products containing diacetyl and consider how best to assure that affected users are adequately informed on hazards related to diacetyl exposure.

Medical Monitoring

SERs from the microwave popcorn and flavoring industries reported in some detail on their current medical monitoring programs for diacetyl. Such programs were generally absent outside these industries. A concern was expressed by a SER that the requirement for semi-annual physical exams was unnecessarily frequent. Some SERs also wanted

more specific guidance on when adverse results of spirometry testing would trigger a further evaluation.

The Panel recommends that OSHA consider whether it is necessary to have employees receive physical exams every six months or whether less frequent intervals would be adequate to protect employees. Further, the Panel recommends that OSHA consider providing additional guidance about what spirometry results may trigger further medical evaluation.

Significant Overall Alternatives

PEL versus Non-PEL

SERs varied in their views concerning whether they preferred a PEL or a non-PEL approach. Some SERs favored a non-PEL approach and saw such an approach as having the advantages of providing clear directions on what employers need to do and providing control over all possibly harmful substances present in flavorings. SERs who opposed a non-PEL approach were concerned that a non-PEL approach lacked flexibility and might require major expenses for employers with relatively little employee exposure or risk. Some SERs suggested that OSHA allow individual employers to choose which approach was best for them.

The Panel recognizes that the PEL alternative, as written in OSHA’s draft proposed rule, may be more cost effective for given levels of exposure to diacetyl than the non-PEL alternative. The Panel recommends that OSHA delineate the advantages and disadvantages of each alternative and seek ways to make the non-PEL alternative as cost effective as possible. The Panel notes that determining the approach with the least burden on small business may involve gathering more information about the current levels of diacetyl exposure in the workplace and may vary by industry and situation.

Minimizing Cost to Employers with Minimal Exposure

For many SERs, the greatest concern was that OSHA would impose a regulation that would require a variety of expenses beginning with meeting requirements for initial monitoring assessment on employers with minimal employee exposure.

The Panel notes that, in at least some affected industries, the majority of employers may have minimal exposures. On the other hand, the Panel recognizes that OSHA needs to develop a rule that addresses significant risk to employees wherever it may occur. Accordingly, the Panel recommends that OSHA examine carefully any alternatives that may serve to minimize expenses for employers who have minimal exposures, consistent with Agency’s responsibilities under the OSH Act.