



Reply to the attention of:

July 2, 2009

Mr. Jordan Barab.
Deputy Assistant Secretary for Occupational Safety and Health and Acting Assistant
Secretary for Occupational Safety and Health
U. S. Department of Labor
Occupational Safety and Health Administration
200 Constitution Avenue, NW
Washington, DC 20210

Dear Mr. Barab:

The Small Business Advocacy Review Panel (Panel), established in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), is transmitting to you this report on the Occupational Safety and Health Administration's draft proposal for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl.

The Panel consisted of representatives of the Occupational Safety and Health Administration (OSHA), Department of Labor Office of the Solicitor (SOL), the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB), and the Office of Advocacy (OA) within the U.S. Small Business Administration (SBA). The Panel was chaired by Robert Burt, Director of the Office of Regulatory Analysis (ORA) within OSHA. Staff from the Agencies and SOL who participated in development of the Panel's report include: Bruce Lundegren (SBA/OA), Charles Maresca (SBA/OA), Radwan Saade (SBA/OA), John Kraemer (OMB/OIRA), David O'Connor (OSHA Division of Standards and Guidance (DSG)), Amanda Edens (DSG), Val Schaeffer (DSG), Jason Capriotti (DSG), Robin Ackerman (DSG), Sarah Shortall (SOL), Tom Mockler (ORA), Robert Stone (ORA), and Kathleen Martinez (OSHA/ORA/SBREFA Coordinator).

On May 5th, the Panel was officially convened. On May 19th and 20th the Panel members, along with the Small Entity Representatives (SERs), participated in conference calls providing the opportunity for an open discussion regarding the draft proposal. In addition to the conference calls, the SERs provided the Panel with their written comments.

The Panel Report is attached, which includes the Panel's major findings and recommendations. Also included as appendices to that report are a listing of participating SERs, the SERs' written comments, and the basic documents provided to the SERs—the Preliminary Initial Regulatory Flexibility Analysis and the draft proposed rule. SBREFA requires that this Panel Report and its attachments become part of the rulemaking record, which Mr. Burt will arrange by posting the report in the docket at <http://www.regulations.gov>, the federal eRulemaking portal.

The Panel wishes again to thank the SERs for their participation in the early stages of the rulemaking process. The Panel particularly appreciates the time that the SERs took from their busy schedules to read the considerable SBREFA materials sent to them and provide comments to the Panel.

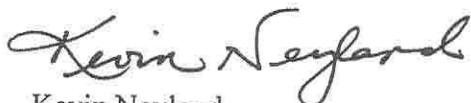
Sincerely,



Robert E. Burt
Chairperson
Small Business Advocacy Review Panel
Occupational Safety and Health Administration
U.S. Department of Labor



Shawne C. McGibbon
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**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.

Appendix A
Small Business Advocacy Review Panel Members and Staff Representatives for the
Draft OSHA Standards on Silica

Small Business Advocacy Review Panel Members and Staff Representatives for the Draft Proposed OSHA Standard on Diacetyl and Food Flavorings Containing Diacetyl

Robert E. Burt	Occupational Safety and Health Administration (OSHA)
Dorothy Dougherty	OSHA
Amanda Edens	OSHA
David O'Connor	OSHA
Jason Capriotti	OSHA
Valentine Shaeffer	OSHA
Thomas Mockler	OSHA
Kathleen Martinez	OSHA
Robin Ackerman	OSHA
Joe Woodward	Department of Labor Solicitor (DoL SOL)
Ian Moar	DoL SOL
Sarah Shortall	DoL SOL
Kevin Neyland	Office of Information and Regulatory Affairs, OMB
John Kraemer	Office of Information and Regulatory Affairs, OMB
Shawne McGibbon	Office of Advocacy, Small Business Administration
Charles Maresca	Office of Advocacy, Small Business Administration
Bruce Lundegren	Office of Advocacy, Small Business Administration
Radwan Saade	Office of Advocacy, Small Business Administration

Appendix B
List of
Small Entity Representatives

SERs for SBREFA Diacetyl/Food Flavorings Containing Diacetyl
Linda and Earl Ault Cedar Mountain Winery 7000 Tesla Road Livermore, CA 94550
David J. Brickner 12515 East Mountain View Avenue Kingsburg, CA 93631
Theresa Cogswell BakerCogs, Inc. 14740 West 159th Street, Suite 100 Olathe, KS 66062
Steve Driscoll Agilex Flavors 30322 Esperanza Way, Suite 400 Rancho Santa Margarita, CA 92688
Diane Gilinsky David Michael & Company 10801 Decatur Road Philadelphia, PA 19154
Robert E. Hawk Weaver Popcorn Co., Inc. 14470 Bergen Blvd., Suite 100 Noblesville, IN 46060
Jim Helmke Yuengling 11111 N 30th Street Tampa, FL 33612
Gregory Hoffman American Pop Corn Company P.O. Box 178 Sioux City, IA 51102
Joe and Bob Kirk Beaver Meadow Creamery, Inc. 415 Maple Avenue DuBois, PA 15801
Randall J. McArthur McArthurs Bakery 3055 Lemay Ferry Road St. Louis, MO 63125-3923

Butch Potter Martins Potato Chips 5847 Lincoln Highway, West P.O. Box 28 Thomasville, PA 17364
Leigh Anne Preston Preston Farms 3055 W. Bradford Road Palmyra, IN 47164
Charles Schroeder DairyChem Laboratories 9120 Technology Drive Fishers, IN 46038
Geoffrey Tracy C & G Universal 3201 New Mexico Avenue NW Suite 246 B Washington, DC 20016
Jim Weaver Tee Lee Popcorn 101 West Badger Street Shannon, IL 61078
John Whelan Bright of America 300 Greenbrier Road Summersville, WV 26651

Appendix C
Written Comments Submitted by
Small Entity Representatives

Discussion Summary:

Subject: OSHA Draft Proposed Standard on Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Industry: Wine

Prepared by: Linda Eve E and Earl R Ault, PhD
Owners, Cedar Mountain Winery

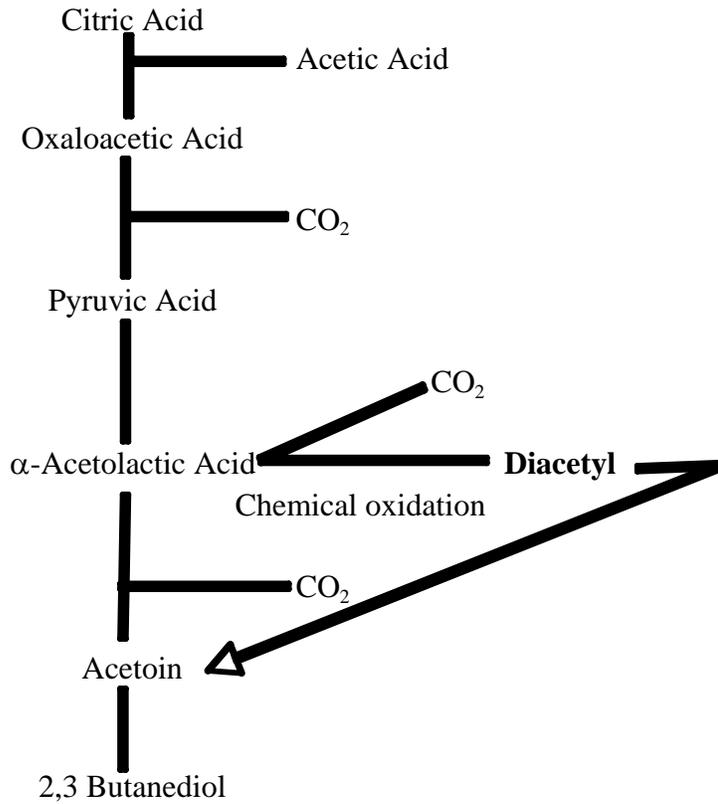
Executive Summary:

The Wine industry should be excluded from the proposed regulations:

- 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 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.
- Of the 6101 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.
- The proposed regulations would impose economic hardship on the small wineries that constitute the majority of companies producing wine in the U.S. This hardship would be justified if and only if there was compelling evidence that the level of naturally occurring diacetyl in wine constituted a risk to winery workers. Nothing in the draft establishes such evidence, compelling or otherwise.

Overview:

Diacetyl formation is an unavoidable part of the production of some wines, specifically the “malolactic” fermentation by bacteria, typically *Oenococcus oeni*, which converts the naturally occurring malic acid into lactic acid. The bacteria metabolizes the naturally occurring citric acid producing diacetyl as a by-product. The reaction pathway follows ^(a):



Discussion issues for SERs:

Direct use of diacetyl:

- Wineries do not “use” or add diacetyl or substances containing diacetyl in standard wine making. Diacetyl occurs naturally in some wines; not all wines undergo malolactic fermentation, and those that do not undergo this process do not contain any diacetyl.

Use of Food Flavorings or Fragrances Containing Diacetyl:

- Code of Federal Regulations § 24.246 lists the materials authorized for the treatment of wine and juice. In addition to the material listed in this section of the code, other material may be used in formula wine if approved by TTB for such use.
- Some wineries may occasionally use flavorings in the production of a few specialty products called “Special natural wine” or “Other than standard” wines. These products are flavored wines and as such are required under the regulations to be produced in accordance with an approved TTB formula. All of these products require an adequate statement of composition and only such products that fall under 7 percent alcohol by volume would require an ingredient and nutrition statement. The formulas for these specialty wines are confidential and winery proprietary and are on file with the Trade and Taxation Bureau.

Naturally Occurring Diacetyl:

- As above, standard wine production may contain naturally occurring diacetyl where malolactic fermentation has occurred.
- Almost everyone engaged in the production of wine will be exposed to a very small amount of wine at some time during the workday. Given the very low levels of diacetyl contained in the wine, however, it does not follow that workers would be exposed to detectable or potentially harmful levels of diacetyl in the air.
- 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).
- 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 ^(b). 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.

Other Possible Uses or Sources of Diacetyl:

- There are no other possible uses or sources of diacetyl in the wine industry other than naturally occurring except in flavorings.

Substitution Away from Diacetyl:

- There is no possibility of substituting away from diacetyl that is produced naturally as part of the malolactic fermentation process. Winemakers do not “add” diacetyl-containing flavorings to their wines; it is a natural product of the malolactic fermentation of wine.

Programs to Address Possible Diacetyl Exposure:

- Programs to control employee exposure to diacetyl would not be expected to be in place in the wine industry, given the extremely low levels of diacetyl present in wine, and given the total absence of either historical or current evidence that the diacetyl levels present in wine constitute a health hazard.

Regulatory Alternatives:

- OSHA should strongly consider excluding from these regulations those products that naturally develop extremely low levels of diacetyl, unless it can be demonstrated that such diacetyl constitutes a hazard. This has not been done. The literature cited establishes diacetyl as a risk when diacetyl is used as a flavoring or when diacetyl is produced for the production of flavorings. Wine does neither.
- Standard wine production operations should be exempt from OSHA regulation for diacetyl because there is no evidence that there is any danger from diacetyl in the production of such products.
- The alternatives presented are sufficiently clear. However, it is difficult to comment on the impact of the alternatives except in general terms.
- It is not clear at this time that any actions would be required to meet standards set in the PEL approach, since there is no evidence that levels of diacetyl encountered in wineries would exceed suggested PELs of atmospheric diacetyl.
- The application of a non-PEL approach in the absence of a demonstrated need for regulation is counter intuitive.
- It does not appear that OSHA estimates of time and unit costs are reasonable. They appear to underestimate end costs, and they appear to have substantially underestimated the number of small wine concerns that would be affected.
- The PEL approach would be most effective for all firms. The low level of diacetyl encountered in standard wine does not warrant inclusion in a non-PEL approach.

- The PIRFA draft appears to exclude the wine industry:
 - “ Although diacetyl occurs naturally in a range of foods, naturally occurring diacetyl, like the synthetic equivalents, would fall within the scope of this section only if used in the manufacture of flavorings, or if it constitutes part of a flavoring used in the manufacture of food.” - PIRFA draft, pp. 8.
 - It is stated on page 68 of the PIRFA draft that: “... some establishments in each of these industries add extra diacetyl currently; hence their inclusion in the current version of the economic analysis.” Cedar Mountain Winery certainly does not “add” diacetyl to its wine, and by TTB regulation the addition of diacetyl or any flavoring materials is not allowed in standard wines and therefore the only diacetyl would be from normal fermentation.

Conclusion:

The inclusion of the Wine Industry in the draft resolution should be reconsidered:

- OSHA should consider excluding the wine industry from these regulations under standard wine making conditions.
- 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.
- It is practically impossible that atmospheric diacetyl concentrations like those listed in the suggested PELs could be attained during the normal wine process, since diacetyl levels in the liquid itself are usually lower than the levels listed for atmospheric diacetyl.
- The wine industry does not produce diacetyl for use as a flavoring.
- Diacetyl is not added as a flavoring to wine, to our knowledge, nor are flavorings containing diacetyl added to wine.
- The cost analysis in the draft report underestimates the number of firms potentially affected by the regulations. There are approximately 6101^(c) wine producers in the U.S., of which approximately 98% are small businesses. Many of the small wineries have less than 20 employees. 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 wine 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.

(a) Applied and Environmental Microbiology, **65**, No. 2, 740-745 (1999)

(b) Martineau, Am, J. Enol. Vitic., **46**, No.4, 442-448 (1995)

(c) Wine Business Monthly, February 15, 2009, “Number of U.S. Wineries Tops 6,100” by Amber McKenney

From: David Brickner [david.brickner@prodigy.net]

Sent: Wednesday, May 20, 2009 4:34 PM

To: Martinez, Kathleen - OSHA

Cc: 'Kabbani, Jim'

Subject: May 20 meeting and conference call SBREFA regarding diacetyl
Confirming my comments regarding diacetyl;

- Keep the regulation at the supplier and manufacturer
- Do not regulate kitchens and end users
- Make regulations more readable and insert an executive summary in the regulation
- Exempt the tortilla industry from the regulation
- I heard in the conversation that the instrument us to detect diacetyl was made of glass and remember that glass is not allowed in USDA inspected meat plants.



May 28, 2009

Occupational Safety & Health Administration
Docket Office – Docket No. OSHA-2008-0046
Room N-2625
U.S. Department of Labor
200 Constitution Avenue, NW.
Washington, D.C. 20210

Re: OSHA Docket ID: OSHA-2008-0046 -- Draft Standard for Occupational
Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Dear Sir/Madam:

On behalf of BakerCogs Inc. (BCI) and the American Bakers Association (ABA), we are providing the following comments in conjunction with OSHA's Draft Standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl discussed during the May 19, 2009 SBREFA panel conference call. BakerCogs Inc. is a baking industry consulting firm. BCI represents many small- to mid-sized baking companies and ingredient suppliers to the baking industry. The ABA represents the interests of bakers before the U.S. Congress, federal agencies, state legislatures and international regulatory authorities. ABA advocates on behalf of over 250 companies of all sizes, both baking companies and their suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious baked products for America's families. The baking industry generates over \$70 billion in economic activity annually, and employs close to half-a-million highly skilled people. Both organizations share the goal of providing employees with safe and healthful workplaces.

OSHA has begun the regulatory process for a potential standard to protect employees from the adverse health effects associated with flavorings containing diacetyl. ABA has been working closely with the Grocery Manufacturers Association (GMA) on this issue, has been in contact with Cal/OSHA regarding its consideration of similar issues, and now with federal OSHA. We endorse the attached GMA comments as they pertain to the science used in determining the appropriate regulatory framework and those food manufacturing sectors that will be impacted.

Scope and Applicability

As a representative for small commercial bakeries, we note initially that there has not been a formal data collection effort to accurately determine and review the use of diacetyl in the baking industry. That said, it is our understanding that several trends have been taking place in recent years. First, many bakers are phasing out of their use of flavorings containing diacetyl, or already have moved to different flavorings that do not contain diacetyl. At this juncture, we do not have information on what these substitutes are or their success as a replacement flavor. Second, while some bakers continue to use flavorings that contain diacetyl, the amount of diacetyl in the flavorings utilized appears to be less than 5% of the total flavor. Since flavorings are typically used in the range of 0.5% to 1% based on the total weight of flour in the formula or recipe, the resulting amount of diacetyl in the finished product is actually very low (5% in flavoring x 1% use level= 0.0005%).

The ABA would like to share information from one of our larger member facilities using butter flavoring to put into perspective the small amount of such flavoring that is used by the baking industry. The numbers in the below table are based on 4 weeks of production.

Bakery Production Example

ABA member's total doughs produced	14,102
• Total doughs produced with butter flavoring	<u>91</u>
• % of doughs containing butter flavoring	0.65%
ABA member's total units produced	11,677,584
• Total units produced containing butter flavoring	<u>423,910</u>
• % of units produced containing butter flavoring	3.63%
ABA member's breakdown of the total ingredients used (lbs.)	12,641,372
• Total of butter flavoring used (lbs.)	<u>952</u>
• % of butter flavoring ingredient used	0.01%

The GMA comments outline the principles governing the overall approach to the potential regulation of workplace exposure to diacetyl. The ABA endorses these comments and further reiterates that, prior to proposing a new standard for the baking industry, OSHA should determine the scope of the standard to include only those sectors in which a significant risk of harm has been established. Section 6(b)(5) of the Occupational Safety and Health Act ("OSH Act") directs OSHA to set the standard which "most adequately assures ... that no employee will suffer material impairment of health or functional capacity." 29 U.S.C. §655(b)(5). Before OSHA can issue a standard, it must make a threshold determination that: (1) there is a significant risk to employees at existing levels of exposure; and (2) that this significant risk will be eliminated or materially reduced under the new standard. *See Industrial Union Dept't v.*

American Petroleum Inst. (Benzene), 448 U.S. 607, 8 OSH Cases 1586 (1980). OSHA may not regulate unless it makes these threshold determinations.

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. The exposure levels of concern, the bulk diacetyl concentrations of concern, and where these exposures or bulk concentrations are likely to occur, have yet to be determined. Based on this information, OSHA is unable to establish that there is truly a significant risk of harm to the entire food manufacturing industry or the entire baking industry.

Therefore, we 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.

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.

Compliance Options

Based on the materials reviewed by the Small Entity Representatives (SERs), the draft regulatory options set forth by OSHA are to set a Permissible Exposure Level (PEL) or to use a "Non-PEL" framework that is very detailed and unclear. As further detailed in the GMA comments, we believe that the available data is inadequate to establish a PEL and, therefore, OSHA should rely on the enforcement of existing requirements – e.g., the agency's Personal Protective Equipment

standards and the General Duty Clause – to provide interim protection to workers while further study and analysis is completed.

However, given the limited draft regulatory alternatives provided by OSHA, we prefer the PEL regulatory approach as it provides the most clarity on what a small business must do to meet the rules requirements. Additionally, this option would allow small commercial bakers to select the most effective and least costly ways of achieving the PEL. That said, it is important to note that many small commercial bakers will need to rely on outside consulting resources to assist in understanding the requirements of the rule in addition to providing guidance for compliance. It is necessary that the Agency provide clear regulatory language to as to make compliance easier for small entities.

Worker Classifications

OSHA's understanding of the worker that is potentially exposed is correct. A typical bakery will first encounter its ingredients in the receiving area of its facility. Receiving then "stages" the ingredients needed to make a given product. The staged ingredients will be taken to the mixing area, and the mixer operator will then scale the ingredients according to the formula card. Depending on the size and type of bakery, the mixer itself may be an open or closed vessel. The resulting batter is then deposited into pans and placed into the oven. It is our understanding that all ovens are vented to the outside to comply with the local building codes and to insure proper heat transfer in the oven. Once the baking is complete, the cake is depanned and then finished as is appropriate for the final product. In addition to the above example, the following general information about the baking industry may be relevant:

- The baking industry is a water-based manufacturing process.
- Flavorings can be added at any stage in baking – to a dough or to a component (such as icing or glaze). Some of these components can be applied after baking, so that the component is not exposed to high heat that can break down the sensitive ingredient.
- Most in-store bakeries use "par baked" products. In other words, partially baked products are delivered frozen to an in-store bakery, where they are then baked prior to consumer use.
- Prior to baking, dough is proofed to a temperature of about 95 to 100 degrees Fahrenheit. Some of the flavoring used may volatilize and be lost before the dough even reaches the oven. Proof boxes are enclosed and vented.

- During baking, the internal temperature of the product reaches at least 204 degrees Fahrenheit, so the majority of the flavoring present will volatilize and be lost to the atmosphere. Ovens are closed and vented.
- Scaling areas are typically vented, to control dust and fumes.

Cost Impact

Section 6(b)(5) of the OSH Act requires that OSHA set a standard “which most adequately assures, to the extent feasible” employee safety and health. 29 U.S.C. §655(b)(5). Feasibility has two components, and must be tested industry by industry. OSHA’s “*Preliminary Initial Regulatory Flexibility Analysis of the Draft Proposed Standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl*” discusses the estimated cost impact of a potential diacetyl regulation on the food industry.

While we believe that the characterization of the unit costs in Table 8 are fairly accurate, we 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.

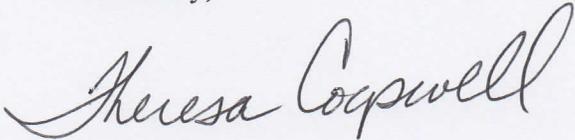
For example, wheat prices rose approximately 173% over a 6- to 9-month period. This trend made it very difficult for the baking industry to continue bringing affordable grain-based products to the marketplace. The baking industry historically has had very small profit margins and passing those costs 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, price-wise, regardless of other economic factors.

As the D.C. Circuit clearly articulated in *American Iron and Steel Institute v. OSHA*, “[a] standard is economically feasible if the costs it imposes do not threaten massive dislocation to, or imperil the existence of, the industry.” 939 F.2d 975, 980, 15 OSH Cases 1177 (D.C. Cir. 1991). In light of these recent economic issues in the baking industry, it is necessary for OSHA to accurately assess and understand the cost impacts associated with different regulatory alternatives. While the commodity market has stabilized to some extent over the last nine months, concerns remain based on crop reports.

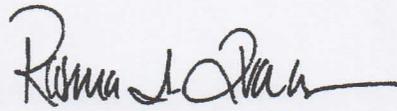
Conclusion

We thank you for the opportunity to participate in this valuable process and would welcome an ongoing dialogue on this issue and in particular its impact to small businesses. If you have further questions regarding this comment letter or any other questions, please contact Theresa Cogswell at 816-820-5364 or via email at bakercogs@sbcglobal.net or Rasma I. Zvaners at 202-789-0300 or via email at rzvaners@americanbakers.org.

Sincerely,



Theresa Cogswell
President
BakerCogs Inc.



Rasma I. Zvaners
Senior Manager, Government Relations
American Bakers Association

Attachments



TO: Theresa Cogswell
Small Entity Representative, SBREFA Panel for Diacetyl

FROM: Nancy J. Rachman, Ph.D.,
Senior Director of Science Policy, Chemical Safety
GMA

DATE: May 26, 2009

SUBJECT: OSHA Draft Standard for Occupational Exposure to Diacetyl and Food
Flavorings containing Diacetyl, OSHA Docket ID: OSHA-2008-0046 –
Comments of GMA¹

This preliminary analysis is designed to identify and explore some of the issues and concerns raised by OSHA's draft Standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl and associated materials.

I. Introduction

OSHA has initiated this rulemaking based on an initial determination that a comprehensive occupational safety and health standard is necessary to protect employees from the adverse health effects associated with flavorings containing diacetyl. Both reported animal studies (primarily Morgan et al. 2008) and a soon-to-be published epidemiology report (Lockey et al. 2008) indicate that high airborne exposures to diacetyl generated from flavorings containing high concentrations of diacetyl have been associated with a significant risk of harm to the human respiratory system and have caused significant harm to the respiratory systems of test animals. What remains to be determined are the exposure levels of concern, the bulk

¹ The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

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diacetyl concentrations of concern, and where those exposures or bulk concentrations are likely to occur.

The occurrence of the cluster of lung obstruction cases among workers at microwave popcorn plants identified in the year 2000, and the initial absence of a responsible regulatory response, have led to a situation in which the political demand for action on this issue is ahead of the science needed to responsibly develop an appropriate standard. This situation is clear from a review of the Technical and Economic Feasibility Analysis for Proposed OSHA Standard for Diacetyl and Acetoin (TEFA), and the Preliminary Initial Regulatory Flexibility Analysis (PIRFA) distributed to the Small Entity Representatives (SERs), which acknowledge the inadequacy of the exposure and toxicology data currently in OSHA's possession. Both documents state:

Given the unique challenges that OSHA has encountered in investigating and evaluating these hazards, the Agency is considering traditional and non-traditional means of regulating employee exposures.

OSHA has never attempted to, and should not attempt to adopt a substance-specific standard on the basis of the limited and inadequate data currently in its possession. In situations where the data are inadequate to establish a permissible exposure limit (PEL), the appropriate regulatory approach, from both a legal and public policy perspective, is to rely on the enforcement of OSHA's Personal Protective Equipment standards, including its Respiratory Protection Standard, and the General Duty Clause, combined with education and outreach, to provide interim protection to workers while the necessary airborne exposure and toxicology data are being developed.

By no means, however, are we suggesting that OSHA abandon this effort. As OSHA is aware, a critically important report on an epidemiological study of the association between exposure to diacetyl and lung function in workers at four microwave popcorn plants is expected to be published in July of this year. Even more significant to this rulemaking is the wealth of information in the data base of airborne exposure monitoring and medical monitoring gathered in connection with that study. Our understanding is that OSHA is in the process of arranging for access to that data base. In addition, we understand that NTP has completed two 90-day animal studies on exposure to airborne diacetyl and the analyses are underway.

Based on the information available to us at this time, it appears that the data bases assembled in connection with the Lockey et al. (2008) study and the Morgan et al. (2008) study could be utilized to develop a useful 8-hour-time weighted average (TWA) occupational exposure limit (OEL) for diacetyl and flavorings containing diacetyl. In the absence of other data, it might even be appropriate for OSHA to adopt an interim PEL based on those two data bases. Given our understanding that the two NTP studies have been completed, and that there is a much greater awareness of the potential workplace significance of diacetyl exposures, we believe the prudent course of action is to await the analyses from the NTP studies. If OSHA elects to proceed without waiting for the analyses of the NTP studies, we believe it should limit the application of the rule to the two sectors where a significant risk from exposure to diacetyl and flavorings containing diacetyl has been established -- flavor manufacturers that manufacture

flavors containing diacetyl and microwave popcorn manufacturers that continue to use flavorings with high concentrations of diacetyl.

According to the TEFA, there are approximately one million employees working at approximately 23,000 food industry establishments “where diacetyl exposures are possible.” In other words, there are approximately 23,000 establishments manufacturing or handling products that may or may not contain diacetyl, which may or may not produce exposures having any health significance. Of those 23,000 establishments, slightly over one-half (50.4%) employ fewer than 10 employees, another 16.4% employ 10 to 19 workers, and only 10% employ 100 or more workers. It seems likely that, if a rule similar to the draft rule was adopted, it would have a more significant impact on small business than any rule, other than the ergonomics standard, adopted by OSHA since the SBREFA process was established.

If one further considers the potential impact of the application of the draft rule to almost 2 million “cooks” and their places of employment (see p. 69 of PIRFA), as well as the wine, beer and dairy industries (see p. 68 of PIRFA) whose ingredients and/or products may contain naturally-occurring diacetyl, one quickly concludes that a far more refined analysis of the exposures and related scope issue is required. OSHA must identify those tasks or activities, if any, in sectors beyond flavor manufacture and microwave popcorn manufacture with high concentrations of diacetyl, and possibly high temperatures, where there is truly a significant risk of harm requiring the imposition of the burdensome requirements of a comprehensive OSHA health standard.

II. Principles Governing the Overall Approach to the Regulation of Diacetyl

A. The Basic Legal Criteria For An Occupational Safety and Health Standard Addressing Workplace Exposure To A Toxic Material Are Provided In Sections 3(8), 6(b)(5) and 6(f) Of The Occupational Safety And Health Act (OSH Act)

1. Section 3(8) of the Occupational Safety and Health Act (OSH Act) defines an occupational safety and health standard as:

A standard which requires conditions, or the adoption or use of one or more means, methods, operations, or processes, reasonably necessary or appropriate to provide safe and healthful employment and places of employment.

Section 6(b) of the OSH Act provides that:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of

standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility [emphasis added] of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Further, Section 6(f) of the OSH Act provides that:

The determinations of the Secretary shall be conclusive if supported by substantial evidence [emphasis added] in the record considered as a whole.

2. Based on the foregoing, OSHA is authorized to adopt a health standard, pursuant to Sections 3(8) and 6(b) of the OSH Act, to address those identified workplace hazards that are shown to pose a significant risk of harm – sometimes referred to a material impairment of health or functional capacity. Generally, to sustain a standard on judicial review as being reasonably necessary and appropriate, OSHA must demonstrate the following:
 - a) Current workplace exposure levels to the identified hazards pose a significant risk of harm to the workers who would be covered by the standard;²
 - b) The proposed requirements would significantly or materially reduce the workplace risk to workers exposed to those identified hazards;
 - c) The proposed requirements are technically and economically feasible and within the bounds of what are reasonable for each industrial sector;
 - d) The proposed requirements are the most cost-effective approach for achieving the reduction in risk by those identified hazards;
 - e) For health standards dealing solely with harmful physical agents, the standard must, to the extent feasible and within reasonable bounds, reduce workplace exposures to a level below that which presents a significant risk of material impairment of health or functional capacity to employees.

² *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 615 (1980) (Benzene) (vacating the benzene standard).

B. Limit Regulation to Establishments Posing a Significant Risk of Harm

As noted above, as a threshold matter, OSHA may regulate exposure to diacetyl under a substance-specific standard only to the extent that it establishes the existence of a significant risk of harm – a material impairment of health or functional capacity – at current exposure levels in the industries and portions of the establishments that would be subject to the rule.

A significant risk of harm has been established only for the manufacture of concentrated flavorings containing diacetyl and the manufacture of microwave popcorn with flavorings containing relatively high concentrations of diacetyl. OSHA has not established that exposure to diacetyl poses a significant risk of harm for the entire food manufacturing industry or any particular sectors of that industry. The reported occurrences of a few isolated cases of lung obstruction in other industrial sectors (or in a consumer who apparently chose to deeply inhale bags of freshly popped popcorn on a frequent basis) does not establish a significant risk of harm for approximately one million employees in 23,000 establishments manufacturing or handling products that may or may not contain diacetyl, at concentrations that may or may not produce exposures having any health significance.

ERG's analysis (in the TEFA) indicates that the final product of the flavoring manufacturer, which generally has a diacetyl concentration below 1%, is the incoming raw material (flavoring) for the receiving food manufacturer. ERG found that the incoming flavor is quickly diluted by a factor of 100 to 1000 at the beginning of the typical food manufacturing process, which strongly suggests that the small concentration of diacetyl that is generally present further downstream would be insignificant from the standpoint of worker health and safety.

The scope of a standard should only include those sectors in which a significant risk of harm has been established. It would not make any sense, and is beyond OSHA's authority, to require every employer in the food industry that may use an ingredient containing added diacetyl, much less natural diacetyl, to initiate exposure monitoring to prove there are no exposure levels above the action level, much less the threshold trigger level -- both initially and with each new flavor or flavor reformulation.

C. OSHA May Not Impose Regulatory Burdens Beyond Those Necessary To Address Significant Risks, Or Which Are Infeasible

1. To the extent OSHA establishes that a particular task or activity poses a significant risk of harm, OSHA must limit its regulation of that task or activity to the most cost-effective approach that will control the risk, subject to feasibility constraints.

2. To the extent that a standard is justified, a comprehensive health standard based on a PEL would be most the cost-effective approach for regulating workplace exposures to diacetyl.
 - a) Under a PEL-based approach, employers could review all feasible measures and select the most cost-effective measures that would achieve the PEL based on site-specific conditions, subject to the constraints of a hierarchy of controls provision.
 - b) The employer could choose between various engineering controls and work practices where required to achieve the PEL. The non-PEL approach would inappropriately mandate engineering controls where work practices would be more cost-effective. The non-PEL approach would inappropriately mandate work practices (e.g., setting up regulated areas and operating pursuant to the requirements governing regulated areas) where exposures are so low that no regulated area is needed.
3. An OSHA mandate to follow a non-PEL alternative would be invalid because it would effectively impose a 0.03 ppm PEL (8-hour TWA) or 0.2 ppm (STEL) – the threshold coverage trigger -- and impose burdens far beyond those reasonably necessary and appropriate to control a significant risk. An employer would be required to establish a regulated area, install engineering and administrative controls, enforce the use of respiratory protection, etc. where the employer cannot demonstrate that “all employee exposures” to a flavoring containing diacetyl, throughout the facility, do not exceed an airborne concentration of diacetyl in excess of 0.03 ppm (8-hour TWA) or a 0.2 ppm (15-minute STEL). As written, the non PEL-based standard would require an employer to implement those controls where an employee is exposed at 0.2 ppm for 15 minutes while performing a task just once per year. The employer would incur significant expense for a very intermittent task at a level where OSHA has not established that a significant risk exists.
 - a) At the time it was developed, the apparent rationale for developing a non PEL-based standard was as follows:
 - (1) Diacetyl posed a potentially significant risk of harm at some unknown dose(s) (combinations of concentration and time of exposure),
 - (2) OSHA did not know what levels/doses were hazardous, and
 - (3) Since there was no level/dose known to be “safe”, exposures had to be reduced to the lowest feasible level

through the implementation of engineering and administrative controls, and then to zero through the use of respirators, subject only to a triggering level that is not based on significant risk of material impairment.

- b) We believe this is the same basic rationale that Federal OSHA attempted to rely on, and that the U.S. Supreme Court squarely rejected in Benzene in finding a Federal OSHA standard for workplace exposure to benzene (a known human carcinogen) to be invalid.³

In Benzene, industry groups challenged a final OSHA rule, adopted under Section 6(b)(5) of the OSH Act, which would have reduced the OSHA PEL for benzene from 10 ppm to 1 ppm. The following excerpts from the Supreme Court's decision⁴ illustrate the principle in issue:

The Agency made no finding that ... any ... empirical evidence, or any opinion testimony demonstrated that exposure to benzene at or below the 10 ppm level had ever in fact caused leukemia.

....

In the end OSHA's rationale for lowering the permissible exposure limit to 1 ppm was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will *not* be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemias might result from exposure to 10 ppm and that the number of cases might be reduced by reducing the exposure level to 1 ppm. In reaching that result, the Agency first unequivocally concluded that benzene is a human carcinogen. Second, it concluded that industry had failed to prove that there is a safe threshold level of exposure to benzene below which no excess leukemia cases would occur. [Emphasis added.]

....

Third, the Agency applied its standard policy with respect to carcinogens, concluding that, in

³ Industrial Union Dept., AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 100 S.Ct. 2844 (1980).

⁴ The Court's decision was based on a plurality of four Justices and later endorsed by a majority of the Justices in American Textile Mfrs. Inst. Inc. v. Donovan, 452 U.S. 490, 101 S.Ct. 2478 (1981) ("Cotton Dust").

the absence of definitive proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer.

....

Fourth, the Agency reiterated its view of the Act, stating that it was required by § 6(b)(5) to set the standard either at the level that has been demonstrated to be safe or at the lowest level feasible, whichever is higher. If no safe level is established, as in this case, the Secretary's interpretation of the statute automatically leads to the selection of an exposure limit that is the lowest feasible.

....

In the absence of a clear mandate in the Act, it is unreasonable to assume that Congress intended to give the Secretary the unprecedented power over American industry that would result from the Government's view of §§ 3(8) and 6(b)(5), coupled with OSHA's cancer policy. Expert testimony that a substance is probably a human carcinogen--either because it has caused cancer in animals or because individuals have contracted cancer following extremely high exposures--would justify the conclusion that the substance poses some risk of serious harm no matter how minute the exposure and no matter how many experts testified that they regarded the risk as insignificant. That conclusion would in turn justify pervasive regulation limited only by the constraint of feasibility. In light of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit.

- c) The courts have also upheld the determination by OSHA that “a standard is technologically infeasible if it cannot be achieved in a typical facility without reliance on respiratory protection in more than a few, isolated operations,” United Steelworkers of America v. Marshall, 647 F.2d 1189, 1272 (D.C. Cir. 1980), [or in an excessive portion of the affected worker population]. Public

Citizen v. OSHA , (3rd Cir. 2009). This is the case even if the Agency has determined that employees remain exposed to a significant risk of harm. That policy determination is based on a finding that the harm resulting from widespread use of respiratory protection outweighs the harm posed by exposure to the chemical in issue. That policy was explicitly relied upon by OSHA in setting the PEL for hexavalent chromium at 5 ug/m³ rather than a lower level that could be achieved by greatly expanded use of respirators. While the situation is unclear, it appears there is a significant possibility that this draft rule would violate that well-established policy.

d) As stated, an OSHA mandate to follow a non-PEL alternative would be invalid. OSHA would impermissibly force compliance with requirements where no significant risk of harm was ever shown to exist or where any significant risk has already been eliminated. The Agency should derive a PEL based on an adequate data set and adopt a PEL-based standard to control occupational exposure to diacetyl, subject to the following alternative.

4. To the extent that a standard is justified, OSHA should offer a non-PEL based alternative to the PEL-based standard for those employers who find it to be more practical or cost-effective for their particular operations. Furthermore, OSHA should make it clear that the employer may use both approaches within a single facility, where practical. This hybrid method would allow an employer to follow the PEL-based approach in one area of the facility, and the non-PEL approach in others.

a) For example, an employer might prefer to use the PEL-based approach where engineering or work practice controls adequately control exposures so that the employer would not be required to go to the expense of further isolating areas [per non-PEL Section (l)(i)] that do not need further isolation. An employer may also prefer to use the PEL-based approach where the task or activity does not result in exposures above the PEL for 30 or more days per year.

I. A PEL For Diacetyl, A Non-Cancer Respiratory Risk, Should Be Developed On Application of the Benchmark Dose (BMD) Methodology

A. The Reports and Data Bases From Recent Animal And Epidemiology Studies Appear to Provide A Sufficient Data Set For Establishing An Interim OEL For Diacetyl

1. Toxicology Excellence for Risk Assessment (TERA) performed an

independent assessment of the current health effects data for diacetyl and an executive summary of its assessment is attached to these comments.⁵ Based on that assessment, TERA determined that the most appropriate measure of the adverse effects of workplace exposure to diacetyl was the inflammation of the tracheobronchial region. Most importantly, TERA determined that a dose-response analysis tied to tracheobronchial inflammation could be developed -- based on a recent subchronic study in mice (Morgan et al., 2008) and supported by a recent cohort study (Lockey et al. 2008) -- and relied upon to develop an OEL for airborne exposure to diacetyl vapors.

2. According to TERA, “the data from these studies identify the same critical effect -- tracheobronchial inflammation -- and converge on a likely OEL range making confidence in establishing an OEL from the database medium to high.” TERA derived its suggested OEL – an 8-hour TWA of 0.2 ppm -- through the well recognized BMD Methodology, which relies on an extrapolation of the health effects from the toxicology data, and addresses the uncertainties of relying on that extrapolation through the application of uncertainty factors.
3. TERA concluded that the data are sufficient to derive an OEL for diacetyl, and that an OEL “developed from the existing database [including the complete data base from the Lockey et al. 2008 study] can be refined as new studies are completed.” The question then becomes how OSHA should proceed where the current data seem to support this suggested OEL, but the body of available data is far less robust than the body of human and animal data OSHA has traditionally assembled and relied on in setting an OSHA PEL.

B. Workplace Exposures To Airborne Diacetyl Are Most Appropriately Regulated By An 8-Hour Time-Weighted-Average (TWA), And Should Not Be Subject To A Short-Term Exposure Limit (STEL).

According to TERA, a study that evaluated and compared the effects of cumulative airborne exposures to peak airborne exposures in rodents, over the course of a day, demonstrated that cumulative exposure is better than peak concentration as a predictor of tracheobronchial inflammation effects (Hubbs et. al. 2008).⁶ TERA also concluded that the tracheobronchial region effects do not appear to progress significantly from subacute to subchronic durations of exposure (Morgan et. al. 2008) and that this finding is supported by the absence of duration of employment effect on pulmonary function testing (PFT) changes reported in the microwave popcorn workers (Lockey et al., 2008). Based on these

⁵ A Current Toxicological Review of Diacetyl : Considerations and Uncertainties for Occupational Risk Assessment.

⁶ Id.

findings, TERA concluded that an OEL based on an 8-hour TWA approach was appropriate and that there was insufficient data to establish a STEL.

C. OSHA Health Standards Must be Based on the Best Available Evidence

Without attempting to establish the bounds of the best available evidence for purposes of this rulemaking, we believe it is clear that the best available evidence would include the soon-to-be-released report and the underlying database from the Lockey et al. 2008 study, which we understand has been offered to OSHA, and the two recently completed NTP 90-day animal studies and any other NTP studies, which are under the control of a Federal Government agency cooperative in which NIOSH is a core member and OSHA serves on the NTP Executive Committee.

II. Application of the Basic Principles of the OSH Act to this Draft Regulatory Package

- A. The requirements of a rule must be reasonably necessary and appropriate to protect employees from significant risks.
- B. The burdensome, overlapping, belt and suspenders approach of the ancillary provisions of a traditional substance-specific standard employed by OSHA to address the significant residual risks of exposure from genotoxic carcinogens, such as hexavalent chromium, should not be applied to a chemical, such as diacetyl, for which there is no evidence of carcinogenicity and for which there is a threshold dose below which the exposure is insignificant.
 - 1. Scope of Covered Chemicals: There is no data to support the inclusion of acetoin in any PEL-based or non PEL-based standard of the type contemplated by OSHA, and no legal basis for requiring implementation of engineering and work practice controls that would effectively impose a PEL of approximately zero for acetoin.
 - 2. Medical Surveillance:
 - a) Requiring medical examinations, every six months, for any employee with exposures above the action level for 30 days or more per year is costly, burdensome and not supported by the literature. Rapid lung function degradation would only result from extreme exposures that would not be permitted by the rule. An employer in gross violation of a PEL is not going to comply with medical monitoring provisions. This misplaced approach of “catching” the lowest common denominator simply imposes

unnecessary costs on responsible employers with no increase in workplace safety. Again, this is a substance with a no effect level; there is no evidence of carcinogenicity.

- b) A PLHCP should be able to determine the required frequency of exams for each individual based on exposure conditions in the workplace and a medical evaluation of the individual.
- c) Exposure monitoring:
 - (i) Once exposure monitoring has demonstrated that any exposures above the action level are stable, there is no reason to require employers to go through the exercise of performing costly, periodic testing to confirm those levels.
 - (ii) The rule should not be designed to impose an economic cost on employers with exposures above the action level as a way of motivating them to try to find ways to reduce exposures so they are no longer subject to expensive exposure monitoring requirements. Again, this is a substance with a no effect level; there is no evidence of carcinogenicity.
 - (iii) There is a provision in the draft standard requiring additional monitoring where there has been any change in the production process, raw materials, equipment, personnel, work practices or control methods that may result in new or additional exposures or when the employer has any reason to believe that new or additional exposures have occurred. That provision would ensure that additional sampling is performed where exposure levels may change, thus avoiding unnecessary and duplicative sampling.
 - (iv) The estimated costs of exposure monitoring are significantly understated in the current SBREFA documents:
 - a. Labor costs for Industrial Hygiene services are underestimated. They appear to be based on sampling 2 workers per 8-hour shift, which underestimates the cost of a true monitoring scenario.
 - b. Time and costs for CIH oversight and review and report writing are underestimated.
 - c. Sample cost is underestimated. Consulting costs vary

across the country and employers in some locations may be disproportionately affected. Consultants are currently reporting costs of \$130 per sample for analysis.

- d. Costs for instrumentation and overhead, travel and expenses are not adequately accounted for. A contract industrial hygienist will require travel reimbursement, which is likely to run from \$500 to \$1000 per trip.
 - e. The cost estimate does not take into account the fact that the Industrial Hygienist will need an escort while on the premises, thus leading to additional "lost work time" of a worker. It is rare that contractors are left completely alone in a manufacturing facility often because of safety. In addition, the work required to complete this monitoring will, at various points in the process, likely require at least two technicians, particularly in a large facility.
 - f. The estimated times spent on record keeping and employee notification are extremely underestimated as the suggested time is 15 minutes per sample. Depending on the PEL, any explanation of values that exceed a PEL will likely require more than a 45 minute time period (which assumed 3 samples per employee to get an 8-hr TWA). Even when values do not exceed the PEL, exposure data will have to be taken from the final contractor report and translated back to a relevant record keeping form for the affected individuals. Furthermore, exposure data will have to be included in the training materials to walk the individuals through their monitoring results as they are presented.
 - g. Most small to medium size employers do not have the ability to solicit multiple labs and consultants to obtain the lowest possible cost and ensure adequate quality of service.
- (v) It is also a serious concern that OSHA the specification of a particular sampling method will discourage the development of new, more accurate and less costly sampling methods, which could only be approved by a follow-up rulemaking. More direct sampling methods utilizing canisters and media that support thermal desorption are showing promise to be more accurate and

more sensitive than the old, retooled methods contemplated by the draft rule.

- (vi) There should also be provisions for short-term sampling methods where employee tasks involving diacetyl last only a few minutes, once or twice a day. Full-shift TWA samples for these employees would be non-productive expenditure of time and resources.
 - (vii) The standard should include provisions for screening airborne levels of diacetyl using portable direct reading instruments such as FTIR, GC-FID and PID's. If these instruments are at least as sensitive as the proposed Silica Gel method and screening yields no detectable levels at the point of operation during tasks with diacetyl, then no further sampling should be required.
- d) **Clothing Requirements:** In the absence of gross clothing contamination, available data do not indicate that the presence of diacetyl on clothing worn at work, whether or not protective clothing, poses any harm to people in the home of an employee who wears or carries the work clothing home. Information from the first SERs conference call on May 19, 2009 indicated that no protective clothing (aside from gloves) is worn or required. The reference to "protective clothing" is also ambiguous where protective clothing is worn for reasons unrelated to diacetyl, but might have been splashed with a trace amount of diacetyl.
 - e) **Engineering controls:** The costs of engineering controls in the PIRFA and TEFA are significantly underestimated. The suggested cost structure does not adequately account for material costs (stainless steel), engineering costs (design, drawings, etc.), explosion venting and obtaining environmental permits (modified air permits).
 - f) **Regulated Areas:** There is a need to recognize these would sometimes be temporary classifications for infrequent activities.

III. To The Extent That A Standard Is Justified, Appropriate Exemptions Are Needed To Avoid Imposing Significant And Unnecessary Burdens

A. Threshold Trigger for Coverage:

- 1. The draft proposed standard would exempt a facility from coverage where "all" employee exposures are below a threshold trigger level (which the draft rule sets at 0.03 ppm as an 8-hour TWA or 0.2 ppm as a 15-minute STEL).

2. Consistent with the approach of OSHA's hexavalent chromium standard (which involved a genotoxic carcinogen), the exemption should be extended to any task, process or activity reliably determined to maintain exposures below the threshold trigger level rather than the all or nothing approach reflected in the draft. We are not aware of any reason for limiting this exemption to situations where no task, process or activity would have exposure levels above the threshold trigger.

B. Bulk Concentration Exemption:

1. In developing its draft standard for diacetyl, Cal-OSHA determined, presumably based on toxicological considerations, that it would exclude flavors containing less than 1% diacetyl, and the TEFA appears to support that exemption.

- a. That approach is also consistent with the approach of the OSHA Hazard Communication Standard (HCS), which does not require the disclosure of diacetyl levels below 1% unless the chemical manufacturer has evidence that diacetyl could be released at concentrations that could pose a risk to employees.

- b. In its guidance on the application of the HCS to Food Flavors Containing Diacetyl (FFCD), OSHA states:

Chemical manufacturers and importers of food flavorings containing one percent or more diacetyl must convey information in the health effects section of an FFCD MSDS regarding the human health effects; i.e., that NIOSH has reported that employees exposed to butter flavorings containing diacetyl are at risk of developing occupational lung diseases and that in one instance, similar illnesses have been found among employees producing butter and vanilla flavorings containing diacetyl. Finally, these MSDSs must convey that contact with liquid or vapors can cause irritation to the skin, eyes, nose, and throat.

Chemical manufacturers and importers of any food flavoring containing one percent or more diacetyl must convey in the health effects section of the FFCD MSDS the hazard information regarding diacetyl from the animal studies previously discussed. They must also consider other available health effects information for all components greater than one percent, convey that information on the FFCD MSDS, and include appropriate hazard warnings on the labels.

2. As clearly stated during the first SERs conference call on May 19, 2009, there are also serious underlying hazard communication issues facing purchasers of flavors. Few flavor manufacturers currently disclose all potentially hazardous flavoring chemicals on MSDS. A review of current MSDS reveals that many flavor companies list serious hazards linked to the ingredients in their products, such as serious lung hazards and cancer, without disclosing the name of the chemical(s) posing that/those hazard(s). Some of our members have received MSDS for flavors in which the hazardous ingredients section has up to one-half dozen "trade secret" entries to let the purchaser know there are up to one-half dozen unnamed hazardous ingredients. Some flavor manufacturers will disclose chemicals upon request. Some flavor manufacturers will disclose chemicals only after signing confidentiality agreements prepared and/or reviewed by legal counsel. This process is very time consuming and resource intensive, especially with formulations changing on an ongoing basis. In addition to being resource intensive, at times it is likely to be very difficult to protect employees from unknown chemicals.

IV. Conclusion

The occurrence of the cluster of lung obstruction cases among workers at microwave popcorn plants identified in the year 2000, and the initial absence of a responsible regulatory response, have led to a situation in which the political demand for action on this issue is ahead of the science needed to responsibly develop an appropriate standard. The science is beginning to catch up, but the data currently in OSHA's hands is inadequate to support the adoption of a comprehensive standard of the type contemplated by the draft distributed to the SERs. The databases underlying the Morgan et al. 2008 and Lockey 2008 et al. studies appear adequate to formulate a useful OEL, but we believe OSHA should wait for the analyses of the completed NTP studies.

If OSHA should elect to proceed with rulemaking without waiting for the analyses of the NTP studies, we believe it should adopt an interim rule applicable only to the two industrial sectors for which the current data appear to establish a significant risk of harm from exposure to diacetyl and flavorings containing diacetyl. They are concentrated flavor compounding and the manufacture of microwave popcorn with flavoring containing high concentrations of diacetyl. Thank you for your consideration of these comments.

Attachment: Executive Summary from TERA's *Current Toxicological Review of Diacetyl: Considerations and Uncertainties for Occupational Risk Assessment*, 5.15.2009

**A Current Toxicological Review of Diacetyl:
Considerations and Uncertainties for
Occupational Risk Assessment**

Developed by:

**Toxicology Excellence for Risk Assessment
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May 26, 2009

A Current Toxicological Review of Diacetyl: Considerations and Uncertainties for Occupational Risk Assessment

Executive Summary

As knowledge about an occupational exposure risk matures there is a transition from a hazard-based risk management approach to the use of a health-based occupational exposure limit (OEL). This transition requires data that support concentration-response analyses. The health effects data for diacetyl were critically evaluated and key issues, uncertainties, and future research directions related to the occupational risk assessment needs were identified. Overall the data are sufficient to derive an OEL for diacetyl.

Examination of the health effects literature led to the consideration of several possible health effects as the basis for developing an OEL. Potential adverse effects and the conclusions regarding their use as the basis for identifying a point of departure for developing an OEL are as follows:

- Upper respiratory tract (e.g., nasal) irritation/inflammation. Acute and subchronic studies in rodents indicate that the upper respiratory tract is a significant target for the effects of diacetyl vapor exposure. The nasal inflammation and histopathology findings generally occurred at lower concentrations and shorter exposure durations than effects in more distal portions of the respiratory tract in rats and mice. However, rodents are obligate nose breathers and have very different nasal morphology than humans. Moreover, the existing case reports in workers provide very inconsistent reports of nasal irritation, suggesting that this is not a clear critical effect in humans. In addition, there is no reliable concentration-response information for evaluation of such effects in humans. Due to these considerations, rodent nasal inflammation is not the most appropriate choice as the point of departure for OEL development.
- Tracheobronchial irritation/inflammation. A subchronic inhalation study in mice (Morgan et al., 2008) is available that provides concentration-response information for sensitive indicators of inflammation of the tracheobronchial region (mild peribronchial lymphocytic inflammation). This finding is consistent with the qualitative evidence of tracheobronchial effects such as cough and breathing symptoms in several case series (e.g., Rose et al., 2007), as well as more rigorous functional measures such as decreased performance in pulmonary function tests in a cohort study (Lockey et al., 2007). The animal and human data are concordant and the animal data provide adequate concentration-response information to support OEL development. The findings in rodents demonstrate that over the course of a single exposure day cumulative exposure is better than peak concentration as a predictor of adverse tracheobronchial effects (Hubbs et al. 2008). The implication of this for developing full-shift time weighted average (TWA) versus a short-term exposure limits (STEL) is discussed below. The tracheobronchial region effects do not appear to progress significantly from subacute to subchronic durations of exposure (Morgan et al., 2008). Consistent with this finding, there was no impact of duration of employment on pulmonary function testing (PFT) changes reported in the microwave

popcorn workers (Lockey et al., 2007). These data suggest that an OEL based on an 8-hr time-weighted average (TWA) approach extrapolated from subchronic exposure data is appropriate for this endpoint.

- Fibrotic Diseases of the bronchial region (e.g., bronchiolitis obliterans). The only available longer-term inhalation study in animals is the subchronic study in mice discussed in the previous bullet (Morgan et al., 2008). No evidence of fibrotic disease was reported in that study following exposure to vapor concentrations that resulted in marked inflammatory and histopathology effects. Moreover, the results of Hubbs et al. (2008) in rats shows increasing severity of effects more distally in the respiratory tract with increasing cumulative daily dose. This result suggests that for cumulative vapor exposures the tracheobronchial effects associated with mild irritation will occur at concentrations below those that are associated with severe effects (including fibrosis). Thus, preventing exposures that generate mild tracheobronchial irritation (and initial symptoms) would be expected to protect against fibrotic disease for cumulative exposures. In contrast, the same study (Morgan et al., 2008) found that aspiration of diacetyl aerosols (presumably generating large local doses in distal portions of the tracheobronchial region) generated a rapid fibrotic response in mice. This finding in mice is supportive of the conclusion that diacetyl might contribute to bronchiolitis obliterans in workers. However, in considering the data related to bronchiolitis obliterans in food flavoring or microwave popcorn industries, there are significant uncertainties regarding the diagnosis as well as in determining the appropriate measure of dose and exposure scenario (role of peak versus cumulative exposures as well as role of vapor versus particulate exposures). The absence of a correlative finding in mice following inhalation exposure, as well as the unavailability of concentration-response data related to the human case reports, limits the use of the findings from the human case reports as a quantitative basis for OEL development. Due to the potential role of peak exposures, the traditional use of excursion limits as a supplement to a TWA-based OEL for control of very high peaks exposures might further mitigate the potential for a fibrotic effect.
- Systemic target organ effects. The available longer-term inhalation studies were limited to evaluations of the respiratory tract. Oral dosing studies can provide qualitative hazard information regarding the potential for extrarrespiratory effects. In a subchronic oral dosing study in rats (Colley et al., 1969), the only effects were observed at high doses (540 mg/kg-day), and were related to inflammation of the gastrointestinal tract, generalized inflammation (increased leukocyte count) and decreased body weight. Studies in rats and hamsters conducted by FDA (1973) did not identify any developmental effects. These studies suggest that the portal of entry is the primary target site for diacetyl, indicating that an OEL based on respiratory tract effects would be protective of systemic effects from inhalation exposure.
- Other effects. No data regarding potential respiratory sensitization effects from inhalation were identified. The results from a recent mouse local lymph node assay (Anderson et al., 2007) suggest that diacetyl is a potential skin sensitizer following

dermal application. This finding is consistent with the biochemical properties (ability to bind to amino acid residues) of diacetyl. Although the data are limited to a single assay, such information informs the assignment of hazard notations, and it might be prudent to include a notation (DSEN) until additional data are available.

A key consideration in developing an OEL is the appropriate dose-metric for the effects of concern. For diacetyl, this translates to the question of whether toxicity is driven by peak or cumulative exposure (or both). Hubbs et al. (2008) conducted a series of studies in rats to address this question, by comparing the histopathology effects of comparable TWA concentrations, resulting from either continuous exposure or a series of 15-minute pulses. They found that, for a given TWA, toxicity of the two exposure regimes was comparable, supporting the conclusion that the TWA is the primary determinant of toxicity for short exposures. However, as noted in the context of uncertainty factors (discussed below), little to no progression was seen between 6 and 12 weeks of exposure in a mouse study (Morgan et al., 2008), indicating that exposure concentration, rather than cumulative exposure, dominates toxicity at longer exposure durations. Conversely, peak exposures might be expected to play some role at very high concentrations that lead to altered kinetics of uptake and distribution in the nose. However, there is no current quantitative basis to determine at what concentrations peak exposure plays a role, and therefore what the appropriate concentration is for a short-term exposure limit (STEL). Alternatively, hybrid computational fluid dynamic (CFD)-physiologically based pharmacokinetic (PBPK) modeling, such as done by Morris and Hubbs (2009), could be used to address the issue. Overall, it is reasonable to conclude that regular high peak exposures that generate a significant daily cumulative dose are a concern for inducing tracheobronchial inflammation. However there are not adequate concentration-response data to develop a quantitative exposure limit for infrequent short-term exposures apart from evaluating the resulting cumulative daily exposure. Thus, to be prudent, control of high exposure excursions using generally accepted industrial hygiene practices is appropriate.

The hazard characterization and evaluation of potential endpoints and dose metrics suggests that a concentration-response analysis could be developed for TWA exposure to diacetyl vapors based on tracheobronchial inflammation in the subchronic study in mice (Morgan et al., 2008) and supported by the cohort study by Lockey et al. (2007). The results of Morgan et al. (2008) suggest that exposures as low as 25 ppm increased the incidence of peribronchial lymphocytic proliferation, which was the most sensitive, sustained tracheobronchial effect that increased in severity and incidence in a treatment-related manner. More severe involvement of the peribronchial epithelium, extending to the peribronchiolar epithelium, also occurred at the highest concentration of 100 ppm. The degenerative epithelial changes as well as measures of overall toxicity (decreased body weight) identify 100 ppm as a clear lowest-observed-adverse-effect-level (LOAEL) for this study. The discrimination of the transition point from a No-Observed-Adverse-Effect-Level (NOAEL) to a LOAEL is difficult and depends on the degree to which the minimal to mild lymphocytic inflammation would be considered adverse (i.e., result in functional impairment or affect the ability of the animals to respond to further exposure).

The concentration response data were adjusted to human equivalent exposures using EPA methods (U.S. EPA, 1994) and refined by the computational fluid dynamics model developed for

diacetyl for rats and humans (Morris and Hubbs, 2009). In brief, the concentrations used in the subchronic mouse study were converted to a TWA equivalent exposure for 8 hours per day and 5 days per week to derive a duration-adjusted concentration. The regional gas dose ratio (RGDR) for the tracheobronchial region was calculated using the EPA default equations for a category 1 (reactive) gas based on species-specific minute volumes and regional surface areas, without accounting for the effect of removal of diacetyl from the airstream (scrubbing) in the upper respiratory tract (URT). This latter consideration of URT scrubbing was addressed using the ratio of the relative concentration of diacetyl exiting the trachea modeled for the rat and human exposed to 100 ppm diacetyl (Morris and Hubbs 2009). At 100 ppm, Morris and Hubbs (2009) reported that the concentration exiting the trachea was 61 ppm in rats; in humans the concentration was 79 ppm for nose breathing and 96 ppm for mouth breathing (average 87.5% penetration). The human value was based on the average of concentration predictions for mouth and nose breathing. Thus, the adjustment to the human equivalent concentration calculated using the EPA default equations was the ratio of the percent penetration, or $0.61/0.875 = 0.70$. Although the modeling was available for rats and not mice, such data were considered a better estimate of potential URT uptake differences between humans and rodents than the default equations used in the EPA model.

The concentration response was determined using benchmark concentration (BMC) modeling (U.S. EPA 2000) to estimate a concentration (the BMC_{10}) associated with a 10% extra risk of peribronchial lymphocytic inflammation (of minimal severity or greater) and a 95% lower confidence bound concentration estimate (the $BMCL_{10}$). The predicted BMC_{10} and $BMCL_{10}$ were 33 mg/m^3 (9 ppm) and 9 mg/m^3 (2 ppm), respectively. This $BMCL_{10}$ of 2 ppm for sensitive tracheobronchial effects in mice is similar to the approximate cut point for observed pulmonary function decrements reported by Lockey et al. (2007) in their analysis of workers in four different plants, providing greater confidence in the relevance of the effect level derived from the toxicology data.

The typical practice in developing OEL recommendations is to identify an effect level or concentration for the most sensitive relevant adverse effect as a “point of departure” and then apply factors to address uncertainties in extrapolation from the identified effect levels. For this evaluation, mild tracheobronchial irritation (peribronchial lymphocytic inflammation) identified in a subchronic mouse study (Morgan et al., 2008) is the basis for the point of departure. Key areas of uncertainty typically considered in such analyses are as follows:

- Interspecies differences (UF_A). This factor accounts for toxicokinetic and toxicodynamic differences between the test species and the average human. In light of the application of dosimetry adjustments to address kinetic differences (see above), the remaining consideration is the magnitude of toxicodynamic differences. A central starting point with regard to toxicodynamic differences is whether the effect seen in animals is representative of the types of effects of concern in humans. As discussed in greater detail above, the tracheobronchial effects (including inflammation, cytotoxicity, and fibrotic effects) seen in rodents are considered relevant to humans, and the toxicodynamic responses in the tracheobronchial region of mice are reasonably concordant with those of humans in qualitative terms. Although the data are not adequate for quantitative evaluation of the toxicodynamic differences, a factor of 3 for differences in

toxicodynamics is generally considered appropriate for extrapolation from animal data. For assessments based on human data a factor of 1 is appropriate. In this case, a factor of 3 is used to extrapolate from the effect level in animals, in the absence of sufficient data to derive a chemical specific adjustment for toxicodynamic considerations.

- Human variability (UF_H). This factor addresses the need to extrapolate from the average human response to cover potential sensitive individuals. Current occupational risk assessment practice reflects the perspective that health-based exposure guidance should protect the majority of the worker population, but not necessarily hypersensitive individuals. For example, this perspective is reflected in the description of the ACGIH TLV[®] or AIHA WEEL as protecting “nearly all workers.” Similarly, OSHA PELs are typically based on weighing risk management considerations that result in some residual risk, reflecting this general approach/concept. A priori, one might expect that smoking would contribute to sensitivity. However, epidemiology data (Rose et al., 2007) suggest that both smoking and diacetyl exposure generate effects consistent with tracheobronchial toxicity, but that the sensitivity of smokers to the effects of diacetyl exposure does not differ markedly from that of nonsmokers. Genetic variability that can contribute to airway reactivity and asthma and that determines differences in lung fibrotic diseases may also result in individual sensitivity (reviewed in Grutters and du Bois, 2005), but the impacts of such variability is a common consideration for respiratory toxicants and is difficult to quantify. Some of these genetic factors would be more relevant for consideration of potential hypersensitive individuals. Finally, it is unclear whether diacetyl would be a cause of asthma or increase symptoms in asthmatic individuals. An increased prevalence of asthma was reported in food flavoring production workers exposed to diacetyl (Rose et al., 2007). However, the reason for this increase has not been adequately evaluated in human populations.

Occupational assessments apply to only a subset of the population; thus a factor of 3 is typically applied to account for variability in human for assessments based on animal studies. When extrapolating from a human study the need for a factor depends on the relevance and representativeness of the studied population to the intent of the OEL. A factor of 1 would be appropriate when extrapolating from a robust epidemiology study of a diverse worker population as was completed by Lockey et al. (2007). Based on the effects of diacetyl, there is no reason to expect that the default approach is not adequate and a factor of 3 is used to account for human variability when extrapolating from the effect level from the mouse subchronic study (Morgan et al., 2008).

- Extrapolation from a LOAEL (UF_L). A factor of 1 is appropriate for extrapolation from a NOAEL, a threshold estimate from human data, or a $BMCL_{10}$. The $BMCL_{10}$ is a surrogate that is comparable, on average, to NOAELs from animal studies and provides a lower bound (health protective) estimate on the threshold for an increased incidence of tracheobronchial effects. Although the BMC_{10} is an estimate of the concentration resulting in a 10% response (not a 0% response) in the animal study, statistical analyses of study sensitivity and the power of typical study designs have found that the $BMCL_{10}$ corresponds on average to the NOAEL determined for that study. Note, however, that this calculation is specific to the modeled study data, and does not take into account

interspecies differences or other considerations addressed by the uncertainty factors discussed here, and so the percentage of risk in a human population cannot generally be determined directly from the $BMCL_{10}$ in an animal study.

- Extrapolation from a shorter-term study (UF_S). This factor addresses the possibility that with longer-term exposure the effective concentration might decrease. In the absence of a chronic study the selection of this factor depends on evidence for effect progression. The absence of increased severity of the tracheobronchial effects following exposure for 6 versus 12 weeks (Morgan et al., 2008) indicates there is little effect progression with repeated exposures. This finding is consistent with the results of Lockey et al. (2007) who found no progression of effects with exposure duration in a prospective study design. These data suggest that a factor of 1 is appropriate for extrapolation from the subchronic study in mice to address the potential effects of chronic exposure.
- Other deficiencies in the database (UF_D). This factor addresses the concern that with the addition of new data a more sensitive effect would be identified. The data are compelling that the respiratory tract is the most sensitive target for diacetyl inhalation exposure. When data for the critical target and sensitive (or most relevant) species are available, a factor of 1 is considered appropriate, and so is recommended here. It is noteworthy, that there are ongoing robust inhalation studies in mice and rats being conducted by the National Toxicology Program (NTP, 2009). There is no reason to expect that these studies will yield results dramatically different from those reported by Morgan et al. (2008). However, the results of such studies would add to the robustness of the overall database (particularly in providing a longer-term study in a second species), and should be considered in modification of the OEL derivation when available.

The development of an OEL recommendation includes identifying potential adverse effects, analyzing the concentration response profiles for the sensitive effects to estimate a point of departure, and applying uncertainty factors to account for uncertainties in extrapolation. The data for diacetyl are sufficient to complete this process. Based on the current data an OEL can be derived for diacetyl vapor based on the tracheobronchial region effects in mice reported by Morgan et al. (2008) as follows:

Point of Departure: $BMCL_{10}$ of 2 ppm for mild peribronchial inflammation

Composite UF: 10

OEL Recommendation: 0.2 ppm vapor as an 8-hr TWA, with a DSEN notation

This OEL derived from the mouse inhalation study is consistent with the concentration-response for decrements in pulmonary function test performance reported by Lockey et al. (2007) in four microwave popcorn plants after accounting for additional uncertainties related to potential human variability in response and the consideration that the average exposure duration in the cohorts was less than a full working lifetime.

Acknowledgments

This review was funded by a group of member companies of the Grocery Manufacturers Association. While the sponsors were allowed to review and comment on the contents of this analysis, the scientific opinions represent the views of Toxicology Excellence for Risk Assessment.

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Occupational Safety and Health Administration
200 Constitution Avenue, N.W.
Room N3306
Washington, D.C. 20210
Attention: Kathleen Martinez

28 May 2009

Docket No. OSHA-2008-0046.
Occupational Exposure to Diacetyl
and Food Flavorings Containing Diacetyl.
By email to martinez.kathleen@dol.gov

Dear Ms. Martinez:

Thank you for the opportunity to participate as a Small Entity Representative in the Small Business Regulatory Enforcement Fairness Act (SBREFA) Panel session on 19 May 2009 regarding the Occupational Safety and Health Administration (OSHA) activities on its potential regulation of the flavoring substance, diacetyl.

David Michael & Company has long been committed to providing its employees with safe workplaces. Our company is a small business with approximately 160 employees in two facilities, one in Philadelphia (with about 150 employees) and one in California (with about 10 employees). We have made a substantial investment in assuring that we have effective workplace safety programs and especially an effective respiratory health and safety program to protect our employees from exposure to diacetyl. As a member of the Flavor and Extract Manufacturers Association of the United States (FEMA) we have participated in FEMA's extensive respiratory health and safety program. We have also been an active participant in the California Flavor Industry Safety and Health Evaluation Program (FISHEP) from the beginning of FISHEP in 2006. We have worked directly with Drs. Rose and Martyny of the National Jewish Medical and Research Center (NJRMC) in Denver, Colorado to evaluate our personnel, programs and facility with regard to respiratory safety. This evaluation was conducted at both the California and Philadelphia operation. NJRMC is regarded as the "center of excellence" with regard to respiratory health.

The Use of Diacetyl by David Michael & Company

During the SBREFA Panel conference call, we were requested to provide additional information on our company's use of diacetyl. We use a small amount of diacetyl each year, in a wide variety of flavor formulations. Diacetyl is used in small amounts well below 1.0% in approximately 5-10% of our active formulations.

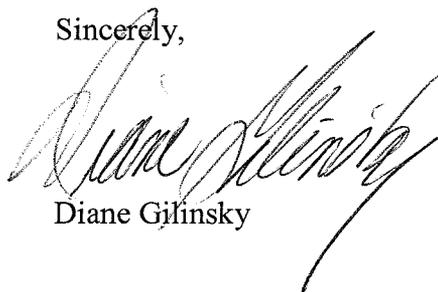
David Michael & Company has focused on issues associated with potential exposures to diacetyl in our workplaces by participating in FEMA's extensive respiratory health and safety program and as an active participant in California's FISHEP activities for our facility in California. We control potential exposures to diacetyl and other flavoring substances through engineering controls and the use of respirators when appropriate. Through our participation in FISHEP, our flavor production workers in California have participated in medical screening and we have also conducted medical screening of our production workers in our Philadelphia facility. We are aware of no David Michael & Company employees with work-related respiratory illness.

OSHA's Alternative Regulatory Strategies

OSHA has proposed several regulatory alternatives for controlling occupational exposures to diacetyl and food flavorings containing diacetyl. David Michael & Company, and many other FEMA-member flavor manufacturers, have already, in the absence of a 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.

We would be pleased to share additional information with you. Once again, thank you for the opportunity to participate.

Sincerely,

A handwritten signature in black ink, appearing to read "Diane Gilinsky", written in a cursive style.

Diane Gilinsky



May 28, 2009

Mr. Robert Burt
Chair, Small Business Advocacy review Panel
Occupational safety and Health Administration
Washington, DC 20210

Dear Bob,

Thank you again for giving Weaver Popcorn Company, Inc. ("Weaver") the opportunity to speak with your panel on the proposed approach to regulation of diacetyl in the workplace. We fully support OSHA's efforts to provide a safe and healthy workplace and we are pleased to have an opportunity to provide input on your proposed diacetyl regulatory approach.

During our conference call on May 19, 2009 we agreed to provide more detail on two specific aspects of Weaver's programs, first the medical monitoring program and second the process by which we evaluate our flavorings.

Medical Surveillance Program

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 ("PFT's"). All other associates receive annual PFT's. 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.

Weaver has not had a single associate diagnosed with bronchiolitis obliterans. Bronchiolitis obliterans is the only disease we are aware of that some scientific literature has suggested may be caused by diacetyl and does not exist in the population at large (those not exposed to diacetyl). Recent attempts to relate diacetyl to asthma and generalized, non-specific lung disease are unsupported by the science. Furthermore, attempts to regulate work place exposures to prevent illnesses common in the population is not sound public health policy.

Review of the Safety of Substitute Flavorings

When Weaver first decided to find a substitute flavoring that does not contain diacetyl we were concerned that substituting an unknown, potentially more hazardous substance for diacetyl may not be in our associates' best interests. This concern was heightened by NIOSH presentations and published papers which suggested that acetoin may also be a chemical of concern, or that irritation of the lung and nasal passages may be exacerbated by other chemicals in the overall flavoring. So Weaver established a policy that no new flavorings will be introduced without laboratory toxicology testing and evaluation by professional third party providers to determine the chemicals present in the proposed new flavoring. We have a qualified laboratory conduct both head space analysis and popping volatiles analysis and report the results to us. The methodology for the chemical analysis is designed to reflect the worst case scenario with respect to potential worker exposures, not what our workers are actually exposed to while performing their jobs.

After we have the chemical analysis completed, the results are reviewed by a toxicologist. The toxicologist we have selected has spent a considerable portion of his career reviewing the components of food flavorings and the potential health effects of the chemicals in such flavorings. If he is not familiar with a chemical reported to be present in the proposed new flavoring he undertakes a scientific literature review to determine what is known about exposures to these chemicals at the levels reported in the analysis. He then reports back to Weaver's legal advisors and to Weaver as to whether there are any chemicals present at levels which create a risk of adverse human health effects. It is only after the toxicologist has reviewed the analysis and has given us his opinion that the flavoring is safe that the flavoring is permitted to be used in the Weaver manufacturing plant. We have recently broadened this testing program to include all components of the microwave popcorn bag.

Other Chemicals Included in Weaver's Industrial Hygiene Monitoring Program

OSHA has inquired about the other chemicals that Weaver has tested for in the air monitoring program within our plant. These chemicals have changed over time; however, we have tested for the following in the personal breathing zone or ambient air in the plant: acetic acid, acetoin, acetaldehyde, propylene glycol and furfural.

In addition to those items which OSHA asked us to address, we would also like to offer our comments on the following issues with the two versions of the proposed standard.

Should OSHA issue a PEL or an Engineering Standard?

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 PEL's (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 0.1ppm and a Short Term Exposure Limit of 0.2ppm.

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.

Comments on Specifics of the Proposal

1) Lack of Clarity around Exposure Assessment

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.

2) Exposure Control Plan

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.

3) Respiratory Protection

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.

4) Protective Work Clothing

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.

5) **Medical Monitoring**

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.

6) **What This Standard Does Not Include**

The Cal OSHA proposal also set the definition of an "obstructive defect" which triggers additional medical monitoring (such as a physical exam or High Resolution CT Scan) at 90% of predicted for the FEV1/FVC ratio. This is not generally accepted in the medical community and would far overstate the number of associates with obstructive lung defects, which in turn would lead to a large number of unnecessary exams and other tests. However, it 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.

Weaver will continue to work with OSHA to develop an appropriate diacetyl standard. Please feel free to contact me directly if you have any questions or if you need additional clarification.

Sincerely,



Robert E. Hawk
Vice President
Weaver Popcorn Company, Inc.
Phone: (317) 490-6863
Email: bob.hawk@popweaver.com

Discussion Summary:

Subject: OSHA Draft Proposed Standard on Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Industry: Brewing

Prepared by: James Helmke
Plant Manager – Yuengling Tampa Brewery

Summary:

The Brewing industry should be excluded from the proposed regulations:

- There is no historical evidence that naturally occurring diacetyl produced as part of the fermentation process has ever contributed to respiratory distress in brewery workers.
- The literature cited in support of the proposed regulation deals exclusively with workers exposed to concentrated diacetyl flavorings that are not used in the brewing process. Breweries do not add or use such concentrated diacetyl.
- There is also no evidence in the literature cited, nor in any other literature, that the extremely low levels of naturally occurring diacetyl encountered in beer production constitute a risk to brewery workers.
- Beer is isolated from the environment throughout the production process.
- Of the approximately 1500 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.
- The proposed regulations would impose economic hardship on the small breweries or brewpubs that constitute the majority of companies producing beer in the U.S. This hardship would be justified if and only if there was compelling evidence that the level of naturally occurring diacetyl in beer constituted a risk to brewery workers. Nothing in the draft establishes such evidence, compelling or otherwise.

Overview:

Diacetyl formation is an unavoidable part of the brewing process, specifically the fermentation by yeast of a sugar rich liquid extracted primarily from malt. It is this process by which the sweet liquid (termed wort) is converted to beer.

There is no evidence of diacetyl in wort. Diacetyl formation is an indirect consequence of yeast metabolism and growth during the conversion of wort sugars into alcohol. The specific metabolic pathway involved is the pathway by which a few amino acids, chiefly valine, are synthesized to meet yeast growth requirements. The pathway requires the production of acetolactic acid as a valine precursor. The acetolactic acid passes freely out of the cell and into the fermenting beer, where it decomposes into diacetyl. The diacetyl thus produced is then taken up by the yeast cell and converted into compounds that make no flavor contribution to the beer.

Trace amounts of diacetyl are unavoidable in beer, but diacetyl is not considered a positive flavor attribute of an overwhelming majority of beers. Brewers go to great steps to ensure that diacetyl levels in finished beer are below a level that could be discerned by a trained taster. The threshold level is generally given as 0.080 ppm in the beer. However, this threshold value typically overstates actual diacetyl levels because brewers would include both diacetyl and its precursor acetolactic acid when referring to diacetyl levels, so actual diacetyl levels would be lower. For a short time, levels in the fermenter might approach 0.250 ppm, but this level rapidly drops as fermentation slows with the depletion of the sugars needed for yeast growth. The fermentation step of the brewing process is typically continued until the yeast has reduced the total of both diacetyl and its precursor to below a potentially discernable level, usually no higher than 0.080 ppm in the liquid. A very few brewers target slightly higher values of 0.100 – 0.120 ppm in the liquid. Others may use a maximum value of 0.060 ppm or lower.

Beer is isolated from the environment during its production. Fermentation and subsequent steps take place in sealed tanks that prevent the egress of CO₂ into the workplace in compliance with already existing PELs established by existing OSHA regulations. Further, it is an anaerobic process to avoid possible contact with atmospheric oxygen, the results of which would be a reduction in beer's taste stability.

Discussion issues for SERs:

Direct use of diacetyl:

- Breweries do not “use” diacetyl. Diacetyl occurs naturally and every effort is made to reduce its impact on beer's flavor profile to acceptable levels, usually below the taste threshold level. I know of no breweries that add diacetyl to beer as a flavoring.
- 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.

Use of Food Flavorings or Fragrances Containing Diacetyl:

- Brewers occasionally use flavorings in the production of a few specialty products, but I am unaware of the use of flavorings or fragrances that contain diacetyl. This rare addition of flavorings invariably takes place by injection into beer being transferred in a pipe or to beer under pressure in a tank. There is no contact of employee with the beer, nor of beer with the environment.

Naturally Occurring Diacetyl:

- Brewers make beer, which contains naturally occurring diacetyl.
- Almost everyone engaged in the manufacturing of beer (except office staff) will be exposed to a very small amount beer at some time during the workday. Given the very low levels of diacetyl contained in the beer, however, it does not follow that workers would be exposed to detectable or potentially harmful levels of diacetyl in the air. Nothing in this draft establishes that there is a potential for exposure to potentially harmful levels of airborne diacetyl.
- Although beer is isolated from the environment during production, some contact with beer is possible when operators change hoses, collect yeast, or clean tanks. Typical levels in diacetyl in the spilled beer would be less than 0.080 ppm in the beer. In our case, typical diacetyl levels are in the 0.030 – 0.040 ppm range in the spilled beer. It is very doubtful that atmospheric levels of diacetyl would be this high.
- Given the sealed nature of the brewing process and the infrequency of employee contact with beer containing very low levels of diacetyl, it is doubtful that the exposure of a brewery worker to diacetyl originating in the beer would exceed the exposure of bartenders or wait staff in an establishment serving beer to the public.

Other Possible Uses or Sources of Diacetyl:

- There are no other possible uses or sources of diacetyl in the brewing industry.

Substitution Away from Diacetyl:

- There is no possibility of substituting away from diacetyl naturally produced as part of the fermentation process. Brewers do not add or use diacetyl except in the restricted role in the preparation of laboratory standards mentioned above.

Programs to Address Possible Diacetyl Exposure:

- Programs to control employee exposure to diacetyl would not be expected to be in place in the brewing industry, given the extremely low levels of diacetyl present in beer, and given the total absence of either historical or current evidence that the diacetyl levels present in beer constitute a health hazard.
- Laboratory use of diacetyl for the preparation of standards is controlled by rules of Good Laboratory Practice, and diacetyl standards are prepared in ventilated fume hoods.

Regulatory Alternatives:

The alternatives presented are sufficiently clear. However, it is difficult to comment on the impact of the alternatives except in general terms:

- It is not clear at this time that any actions would be required to meet standards set in the PEL approach, since there is no evidence that levels of diacetyl encountered in breweries would exceed suggested PELs of atmospheric diacetyl.
- The application of a non-PEL approach in the absence of a demonstrated need for regulation is counter intuitive.
- It does not appear that OSHA estimates of time and unit costs are reasonable. They appear to underestimate end costs, and they appear to have substantially underestimated the number of small brewing concerns that would be affected.
- The PEL approach would be most effective for this firm. The low level of diacetyl encountered in brewing does not warrant inclusion in a non-PEL approach.
- OSHA should strongly consider excluding naturally occurring diacetyl from these regulations unless it can be demonstrated that such diacetyl constitutes a hazard. This has not been done. The literature cited establishes diacetyl as a risk when diacetyl is used as a flavoring or when diacetyl is produced for the production of flavoring. Brewing does neither.
- The PIRFA draft is ambiguous and lacks focus when discussing the possible inclusion of the brewing industry in these regulations. It appears to exclude the brewing industry:

“ Although diacetyl occurs naturally in a range of foods, naturally occurring diacetyl, like the synthetic equivalents, would fall within the scope of this section only if used in the manufacture of flavorings, or if it constitutes part of a flavoring used in the manufacture of food.” - PIRFA draft, pp. 8

However, it is later stated that:

“... some establishments in each of these industries add extra diacetyl currently; hence their inclusion in the current version of the economic analysis.” – PIRFA draft, pp 68

Yuengling certainly adds no diacetyl to its beer, and I am unaware of any company in our industry that adds diacetyl to its product. The statement that some breweries add diacetyl to their product is, to my knowledge, erroneous.

Conclusion:

The inclusion of the Brewing Industry in the draft resolution should be reconsidered:

- 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 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 brewing industry does not produce diacetyl for use as a flavoring.
- Diacetyl is not added as a flavoring to beer, to my knowledge, nor are flavorings containing diacetyl added to beer.
- The cost analysis in the draft report underestimates the number of firms potentially affected by the regulations. There are approximately 1500 brewing firms in the U.S., of which all but two are small businesses. Many have less than 10 employees. 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.

From: Butch Potter [butchpotter@martinschips.com]

Sent: Wednesday, May 27, 2009 2:54 PM

To: Martinez, Kathleen - OSHA

Subject: Diacetyl comments

A couple of important points first, then a few details, and misc questions.

1) PEL vs non-PEL - 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. If you look at any industry over the past 50 years, you see consolidation in every decade, fewer firms in each industry year after year, leads to less competition, less healthy companies, more outsourcing overseas. Virtually every parameter exterior to business is forcing this trend: banking, govt regulation, purchasing/retaining groups (Walmart, Home Depot, etc). USA needs more companies of small to medium size to be competitive into the future.

2) PEL benchmark - I believe it's critical that the PEL standard be backed up with very sound science, these benchmarks get etched in stone over time, so it's absolutely critical that they be correct - and I'm not sure that I like the idea of a measurement with only one significant digit - .03 - is it .03 plus/minus .01?

3) Measurement cost: If it cost \$1,000 to measure temperature each time, I'm not sure we'd be able to afford pasteurized milk. With diacetyl, we need to no force companies to do a lot of measuring where it's not warranted or where it's not cost effective. Idea - could a non toxic "tracer" be added to the diacetyl to make it easier to detect & measure?

4) 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.

5) UC#2 - alternatives to diacetyl are studied and found to be as bad for worker health

Comments:

1) pg 71 - draft - PIRFA - "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?

2) general - the medical exams, record keeping, frequency of testing, etc, seem to be quite burdensome

3) pg 72 - draft - PIRFA - frequency 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 change or ingredient characteristic change.

4) pg 73/74 - draft - PIRFA - "Alternative for regulated areas" - makes sense, doesn't waste effort where it's not needed

5) general - was 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?

Questions:

1) 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?

2) 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. Is there a temp vs vaporization data collection somewhere?

3)

I wish I could have been more of a contributor to the process, I had a vacation mixed into this time period and I've just been too busy with other projects.

A few thoughts on the conference call. I had my doubts that it would be functional, but it was really moderated well and everybody seemed to give each other "space". I do wish however, that people who don't have the freedom to speak in detail (probably because of legal issues), would just not participate, because if you can't add anything, why are you there?

I would also like to add that I am grateful for the opportunity to participate and happy to see that this process is in place and is being carried out in a professional manner. In all matters related to this panel, I thought all involved handled the process promptly & professionally. And I can tell you from past experience with govt agencies that unfortunately, this is the exception, not the rule.

Sincerely,

Butch Potter
President
Martin's Potato Chips, Inc.



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

May 29, 2008

Docket No. OSHA-2008-0046

Ms. Kathleen Martinez
Occupational Safety and Health Administration
200 Constitution Avenue, N.W.
Room N3306
Washington, DC 20210

Dear Ms. Martinez:

DairyChem, Inc., and the International Dairy Foods Association submit these comments in conjunction with the comments that were made at the recent SBREFA panel conference calls on May 19 and May 20, 2009.

DairyChem is a small business entity that caters and utilizes knowledge of dairy chemistry to provide dairy flavors and custom flavor blends to dairies and the food industry. Originating in 1936 as Chumlea's Laboratories, we have been known as DairyChem Laboratories since 1993.

The International Dairy Foods Association represents the dairy manufacturing and marketing industries and their suppliers, with a membership of 530 companies representing a \$110-billion a year industry. IDFA is comprised of three constituent organizations, the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members run more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. IDFA can be found online at www.idfa.org.

The comments below reiterate many of the points that were made during the SBREFA call and we are providing additional detail on diacetyl in certain dairy products and information about some the processes used in our industry.

SER QUESTIONS RAISED AT THE BREFA PANEL AND CORRESPONDING ANSWERS

Submitted as **Attachment A**, written comments are provided to the "*Issues Document*" as presented in the SBREFA Package "*Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl.*"

DAIRY PRODUCT DIACETYL LEVELS AND PROCESSES

Diacetyl is a naturally occurring byproduct of fermentation/culturing and many dairy products, but not all, contain naturally occurring diacetyl. We are not alone, many non-dairy products contain diacetyl as well, including beer, wine, snack foods, baked goods, candy, tomatoes and strawberries. Ready-to-eat foods contain very low concentrations of diacetyl and dairy foods typically have less than 10 parts-per-million (ppm) of diacetyl when it is present. For example, even strongly flavored unsalted butters probably contain less than 10ppm diacetyl, which corresponds to 0.001%.

While pure diacetyl is very rarely used as a direct flavor by food manufacturers, diacetyl is a component in many food flavorings, extracts and distillates at various levels. Flavors typically contain diacetyl at levels at or below 1%. (One percent is equivalent to 10,000 ppm.) These concentrated flavors, when used, are either diluted further prior to use or are diluted substantially by the inclusion into dairy products. Dairy flavor users, especially ice cream companies, may not be fully cognizant of the presence of diacetyl in some of the products they use because labels frequently refer to "natural" or "artificial" flavors and do not mention diacetyl. Recently this was confirmed when an IDFA staff person was visiting an ice cream company and he spent 45 minutes reviewing the labels of flavorings in the ice cream company's storage area. At the end of that time period, not a single container was identified that disclosed it contained diacetyl. We have subsequently learned from flavor manufacturers that such information is frequently limited to disclosure on Material Safety Data Sheets (MSDS.) As long as the information is provided on an MSDS whenever diacetyl is present in the concentrated flavors containers at levels at or above 1%, we believe that would be sufficient.

Butter starter distillate, or starter distillate, is mentioned by OSHA as being potentially problematic. Starter distillate is mixture of distilled flavors. Beneficial bacteria (often called aromatic cultures) are added to a substrate such as reconstituted non-fat dry milk and the mix is fermented to produce metabolic byproducts that are then distilled and used as flavorants. Starter distillate frequently is cited to have diacetyl levels up to 15,000 ppm, though we have noted at least one reference to a level of 50,000 ppm – equivalent to 5% diacetyl. Diacetyl concentration in flavors rarely exceeds 5%, except as noted by the popcorn industry during the SBREFA conference call, where diacetyl was estimated to be as high as 20-30% (200,000 – 300,000ppm) diacetyl.

Starter distillates are used as flavor enhancers in butter, particularly unsalted butter. When used, the starter distillate is poured from a 1- to 5-gallon container into a

graduated cylinder (for measurement purposes) and is then added to water. The water-diacetyl mixture is kept in a closed system and the mixture is metered into the butter. Worker exposure is minimal. As stated earlier, end product concentrations are unlikely to exceed 7 to 10 ppm, in unsalted butter with added diacetyl starter distillate. Salted butter generally does not have added diacetyl. Salt acts as a preservative for butter in addition to enhancing the natural flavor. For unsalted butter, starter distillate provides a natural flavor enhancement and acts as a preservative to increase shelf-life.

Most dairy products are processed cold or are kept cold. Flavors typically used at dairies contain less than 1% diacetyl, and exposure to these flavors is brief. Furthermore, dairy products contain water and diacetyl is hydrophilic. Finally diacetyl does not volatilize at low temperatures. "Cold and wet" keeps the diacetyl in the product and out of the air.

Fluid Milk

Unflavored traditional fluid milk (e.g. whole, 2%, 1% and fat free) is not a cultured product and does not contain diacetyl. It is possible that a very small number of flavored fluid milk products have some level of diacetyl that comes from the added flavorings. We note that strawberries have been identified as having naturally occurring diacetyl, and therefore some trace level may be present in strawberry flavorings used to make strawberry milk. We are not aware of the presence of diacetyl in flavorings used to make chocolate milk which typically is made by the addition of cocoa powder and a sweetener. Milk is processed in closed systems. Chocolate and strawberry are the two dominant flavors used in fluid milks and in many cases are the only flavors used. Milk processors do not necessarily run flavored milks every day, but would be expected to at least several days per week.

Ice Cream

Ice cream is not a cultured product therefore, the natural formation of diacetyl does not occur in the manufacture of ice cream. Some ice creams are flavored with flavor compounds that contain small amounts of diacetyl. The levels of diacetyl is typically, if not always, below 1% by volume. The flavorings are added to a cold ice cream mix and the ice cream mix is blended, quickly packaged and subsequently frozen and stored at temperatures of 20 degrees below zero or lower. With the exception of a very brief period of time where the ice cream flavoring is measured and poured into the ice cream mix, we would not anticipate and worker exposure to detectable diacetyl. With respect to the time involved in measuring and pouring the flavoring, we believe that would take less than a few minutes and a worker might not handle a diacetyl containing flavoring more than a few times per week.

Natural Cheese

Approximately 80% of the cheese made in the United States is natural cheese such as Cheddar, Monterey Jack and Mozzarella. Cheddar and Mozzarella account for approximately 80% of natural cheese sold and consumed in the United States. Cheese has been implicated by OSHA and others as potentially containing diacetyl, but IDFA thinks the assumption is overstated.

Heterofermentive starter cultures used to produce Edam, Gouda, Brie and Camembert may produce diacetyl, but the homofermentive starter cultures used to produce cheddar and mozzarella do not produce diacetyl. Additional adjunct cultures that may be used in the production of cheddar and mozzarella to affect aging and other attributes may produce diacetyl, but approximately 80% of the volume of these cheeses do not involve adjunct cultures and would therefore not produce diacetyl.

Cottage Cheese

Cottage cheese is either cultured or it is direct set by acidification. Approximately 80% is made by culturing. Like cheddar and mozzarella, cottage cheese is cultured with a homofermentative culture that does not produce diacetyl. A flavor containing usually less than 1% diacetyl is added as part of cottage cheese dressing, but that is done in a closed system after the curd has been formed, cut and removed from the large open tanks. Worker exposure to diacetyl in the flavoring used in the dressing would be very brief and episodic.

Yogurt

Yogurt fermentation may produce some diacetyl which may be present in the final product, but diacetyl in yogurt is viewed by many as a defect. Yogurt is cultured in closed systems. Yogurt is generally consumed and/or used at cold or reduced temperatures that would not support volatilization of any diacetyl contained therein.

Buttermilk

Approximately 80% of buttermilk on the market is traditionally cultured. The process of culturing buttermilk will vary somewhat between companies. Buttermilks are made by pasteurizing milk and stabilizer, and sometimes a little salt in a processor vat at a partially cooled 72-76 degrees F, then "set" by adding a culture of lactic acid producing strains of bacteria. The bacteria multiply, acid and CO₂ are produced, and the product's pH is lowered below 4.6. The isoelectric point of the proteins in the milk is reached at this point, and the mixture "sets" in the vat. Most cultures have several strains of bacteria, some to produce acid, and some to produce diacetyl, from which you get the traditional buttermilk flavor. In many cases the final concentration of diacetyl in buttermilk is approximately 1ppm (0.0001%). In some cases it may not be present at all.

Some plants include a cook step to improve the body of the buttermilk by batch cooking the tank at around 180 F for 20 minutes or so, **before the addition of the culture**. Historically, this was the pasteurization step and was longer. Most of the vats have a stainless steel vent covers over the vents located on the top side of the tank. When the tank is "cooking" at 180F, you smell cooked milk smells, not diacetyl, because this step occurs before fermentation takes place and no diacetyl has been produced at this point.

To complicate matter further, we are attaching an article from the Journal of Dairy Science which states in its abstract "no diacetyl was detected in buttermilk that was made in the traditional commercial manner," see **Attachment B**. There is a belief that the

presence of an enzyme, diacetyl reductase, from other sources is responsible for the elimination of diacetyl which forms or is otherwise present and that in such cases the resultant equilibrium is close to zero. This information highlights the complexity that is involved with culturing and is by no means limited to buttermilk production.

Ventilation in Cultured Operations

Ventilation is very important in operations where culturing is taking place. Culturing is done by the use of live beneficial bacterial cultures. The cultures are sensitive to viruses known as bacteriophages, or phage. The best way to minimize or eliminate phage from a culturing operation is to turn the air over in the facility. In warmer months, air may be turned over as many as twelve times per hour, in colder months that may be reduced to six times per hour.

CONCLUSIONS

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.

As a dairy flavoring company catering to the dairy industry, companies like DairyChem Laboratories do provide a service to their customers by providing flavors with a reduced concentrations of diacetyl when requested, but when handled properly diacetyl should not be an issue and its ramification are known versus the uncertainties that exist with substitutes. 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.

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.

In addition to the information we have provided here and in the SBREFA call, we would like to share a preliminary analysis prepared by the Grocery Manufacturers Association (GMA) Diacetyl/Flavors Workgroup which identifies and explores some of the issues and concerns raised by OSHA's draft Standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl and the associated materials. See **Attachment C**. Also provided by the GMA is **Attachment D**, "A Current Toxicological Review of Diacetyl: Considerations and Uncertainties for Occupations Risk Assessment". We believe the GMA analysis makes a valuable contribution to the discussion and urge that you give it careful consideration.

Sincerely,



Charles F. Schroeder
DairyChem, Inc.



Clay A. Detlefsen
International Dairy Foods Association

Attachment A - DairyChem Laboratories comments to “*Issues Document*” in the SBREFA Panel Package.

Discussion issues for SERs

From "Occupations Exposure to Diacetyl and Food Flavorings Containing Diacetyl SBREFA Package".

Introduction

Company and Representative	DairyChem Laboratories. Charles Schroeder, Technical Director
Description of Company	From a private joint-venture of Dr HA Ruehe (Illinois State Dairy Department) and Dr L Chumlea (Indiana Condensed Milk Corp), our company's history originates from Chumlea's Laboratoryies, established in 1936. Since 1993, we have been known as DairyChem Laboratories. We specialize in making customized Dairy flavors, including butter, buttermilk, cream, yogurt, etc. This includes dairy starter-culture (beneficial bacteria) distillates, commonly referred to as Starter Distillate.
Role Diacetyl plays in our business	<p>Butter flavor notes are in many of our favorite foods. Because substitutes have off-flavor notes, no substitute has been successfully used in a simple replacement. Reformulation of a flavor is required, and the flavor is less universal or adaptable. No one substitute provides the versatile buttery appeal as diacetyl in foods. As about 90% of our flavors contain low levels of diacetyl (0.1 – 2.0%), our operations and sales would suffer dramatically, our fermentation equipment would be obsolete, and our final flavors would be less appealing and less universally functional. The economic burden would make it difficult to recover from such a shift in business and the loss (or substantial) lag in sales.</p> <p>DairyChem specialize in Starter Distillate, a natural mixture of flavor molecules. Bacteria are grown that produce flavor molecules as a metabolic by-product. Starter Distillate is the flavor essence made by growing bacteria, then distilling the culture media to collect the flavors. For foods and food-restrictions requiring a non-dairy alternative (e.g., Kosher Parve), we blend the flavorant diacetyl with other flavors for a suitable alternative. As a flavor manufacturer, DairyChem blends flavor concentrates and/or food-grade raw materials (i.e., food acids), providing a final customized dairy flavor. In providing these flavors, we provide a service, whereby concentrated flavors are diluted to diacetyl concentrations of 0.1 – 2.0% (1,000ppm to 20,000ppm).</p> <p>Beneficial bacteria and yeast have a long history of use with food and beverages. Under certain conditions and nutrients, certain microbes produce a variety of flavor compounds as metabolic by-products, which includes diacetyl. For the purposes of making kefir, yogurt, cheese, cultured butter, etc, dairy handlers have long used adjunct bacteria to ferment milk products to produce the desired body and flavor.</p> <p>Diacetyl is a flavor molecule that has the characteristic flavor impact of butter flavor, and the "gold standard" that food manufactures try to match when searching for a substitute. Substitute flavors may have a "buttery"</p>

	nuance, but impart other undesirable flavor notes and are thus less universally adaptable. Some foods can mask these off-notes, yet it can be difficult when especially if a “natural flavor” is required.
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Direct Use of Diacetyl

Do you directly use diacetyl or substances containing diacetyl such as butter starter distillate or butter starter?	Yes. Synthetic diacetyl. Starter Distillates.
If so, please describe the form (e.g., powder, paste, liquid) and the quantity of diacetyl you use.	We handle primarily liquid flavors. We use about one drum (55-gal) diacetyl a month. Powder flavors that contain diacetyl are about 10% of our business.
For what purpose(s) do you use diacetyl?	We use synthetic diacetyl to make dairy flavors for dietary or religious restrictions that require non-dairy certification (i.e., Kosher Parve seal). We also manufacturer Starter Distillate, a natural flavor that contains diacetyl. The flavor is derived from distilling a dairy starter-culture (beneficial bacteria) grown in a dairy medium. A variety of flavor compounds are generated as by-products of a culture’s metabolism. These flavors accumulate and are collected by distillation. The final flavor is dependent upon the starter culture, the growth media, and the growth conditions. For dairies, a suitable alternative to using this flavor is to ferment dairy products on-site, yet using Starter Distillate is more cost efficient, offers better flavor control, and eliminates industrial waste (whey from fermented products have less economic valuable, thus become waste by-products).
How frequently and under what circumstances do you use diacetyl?	Daily. Concentrated distilled flavors are diluted and/or mixed with other concentrated flavors to achieve final product. Many of our products are customized flavor blends of starter distillates or synthetic diacetyl. For artificial flavor, we measure and dispense synthetic diacetyl approximately 2 times per week using personal protection (e.g., protective clothing, respirators, etc) in an isolated production room. In a cold processes (water temperature ~65°F), the diacetyl is immediately diluted and mixed in a closed tank. Exposure to high concentrates of diacetyl is a estimated at 30 minutes per day maximum. The final flavor is 0.1-2% diacetyl. The blending process is done in an isolated room in closed tanks.

	<p>Flavors are dispensed into totes, 5-gallon pails, or 1-gallon jugs. We use general-engineering controls (room ventilation with 12X air exchange per hour) and are exploring localized (above tank) ventilation. Mixing is at ambient temperatures (cold process water ~65°F). Respirators (passive or forced-air) are used when dispensing highly concentrated flavors into mixing tanks.</p>		
	<p>Yes. We blend, use, or manufacture these type of flavors.</p>	Butter flavors	0.1 – 2% diacetyl
		Buttermilk	0.1 – 0.2 % diacetyl
		Sour Cream Acid	0.1 – 0.2 % diacetyl
		Yogurt	0.1 – 0.2 % diacetyl
		Cream	0.01 – 0.05 % diacetyl
		Butterscotch	0.1 – 2% diacetyl
<p>How many employees in your firm or industry are potentially exposed to diacetyl or substances containing diacetyl? What percentage of your workforce do they represent?</p>	<p>Total of 4 employees may be exposed to diacetyl or substances containing diacetyl, either through manufacturing, dispensing, or QC operations. This is 40% of our workforce.</p> <p>1 person measures and dispenses/mixing. 2 persons involved in packaging. 1 person measures QC final products.</p>		
<p>In what job categories and operations in your firm or industry are employees potentially exposed to diacetyl? (Please consider all exposure possibilities, including such areas as quality control and product development operations.)</p>	<p>1. Mixing / Blending 2. Packaging 3. RD / QC</p> <p>Office executives and administrative personnel – minimal and passive exposure.</p>		
<p>For each job category or operation, please describe the possibilities for diacetyl exposure and how such exposure occurs.</p>	1. Mixing / Blending	<p>Direct exposure to liquid concentrations of 20% - 99% diacetyl from dispensing, measuring, pouring. Short-term, open tank exposure at ambient temperatures, personal protective equipment and room ventilation.</p>	
	2. Packaging	<p>Direct exposure to flavors containing 0.1% - 2% diacetyl during bottling. Longer-term, closed tank exposure at ambient temperatures and room ventilation.</p>	

	3. RD / QC	Direct exposure to small quantities. Various concentrations. Ambient temperatures and room ventilation.
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Use of Food Flavorings or Fragrances Containing Diacetyl

Do you use any <u>natural or artificial flavorings or fragrances</u> that may contain diacetyl, including those that you might create at your own site? (Natural or artificial flavorings that might contain diacetyl include dairy (e.g., butter, cheese, sour cream, yogurt), “brown” (e.g., caramel, butterscotch, brown sugar, maple, coffee, some tea flavors), vanilla, fruit, marshmallow, and egg flavorings.)	<p>Minor use of other flavorings that contain diacetyl.</p> <p>Daily, we use Starter Distillate as a raw material for blending. Starter Distillate is a flavoring with naturally-occurring diacetyl, so info pertaining to it is listed in the following section of questions.</p>
Do you know if any of the flavorings or fragrances you use contains diacetyl? If you do not know, is it possible to find out?	<p>Flavors that we purchase generally do not contain diacetyl information. We assume “strawberry”, “marshmallow” and “graham cracker” type flavors to contain diacetyl through flavor knowledge and expertise.</p> <p>Flavor components are generally proprietary.</p>
Do you know and could you tell us what the percentage of diacetyl that is in flavoring or fragrances you use?	No, but assume percentages low due to diacetyl’s low threshold values and strong identification with buttery as the characteristic molecule of butter. As flavors used are not “buttery”, diacetyl is a contributory, not the characteristic, flavor in these formulations.
Are any of the flavorings or fragrances you use labeled or marked with information about the contents, including diacetyl?	No. Contents are generally not listed other than processing aids (e.g., alcohol, propylene glycol, glycerin, etc).
How frequently and under what circumstances do you use flavorings or fragrances that may contain diacetyl?	Handling natural or artificial flavoring containing diacetyl 2 days per month.
How many employees in	1 employee handles the natural or artificial flavoring containing

your firm or industry are potentially exposed to flavorings or fragrances containing diacetyl?	diacetyl. ~10% of our workforce.	
In what job categories and operations are employees potentially exposed to flavorings or fragrances that may contain diacetyl?	R&D operations.	
For each job category or operation, please describe the possibilities for exposure and how such exposure occurs.	R&D	Direct exposure to small quantities through R&D efforts. Various concentrations. Ambient temperatures and room ventilation.

Naturally Occurring Diacetyl

Does your firm use, add or handle flavorings or food products that contain naturally occurring diacetyl , such as dairy products, wine or beer?	<p>Starter Distillate is a flavoring with naturally-occurring diacetyl.</p> <p>Daily, we use Starter Distillate as a raw material for blending. Production staff may be involved in dispensing flavors 3-4 hours per day, and flavors typically are 1.5% diacetyl or less. Production is done at ambient temperature (water temperature ~65°F), and mixing tanks are closed. Room ventilation is 12X per hour. Exposure to flavors with concentrations higher than 1.5% diacetyl is estimated at 30 minutes per day maximum.</p> <p>Most flavors that we manufacture contain diacetyl with the percentage of diacetyl identified within specification sheet and/or MSDS.</p>	
How many employees in your firm or industry are potentially exposed to flavorings or food products that contain naturally occurring diacetyl?	<p>Same as above with diacetyl.</p> <p>4 employees handle diacetyl daily, either through manufacturing, dispensing, or QC operations.</p> <p>This is 40% of our workforce.</p>	
In what job categories or operations in your firm or industry are employees potentially exposed to naturally occurring diacetyl?	<p>Answers the same as use with direct diacetyl.</p> <ol style="list-style-type: none"> 1. Mixing / Blending 2. Packaging 3. RD / QC 	
For each job category or operation, please describe the possibilities for	1. Mixing / Blending	Direct exposure to liquid concentrations of 20% - 99% diacetyl from dispensing,

exposure and how such exposure occurs.		measuring, pouring. Short-term (~15 min) exposure, open tank compounding, and closed tank blending at ambient temperatures. Personal protective equipment and room ventilation.
	2. Packaging	Direct exposure to water-based liquid flavors containing 0.1% - 2% diacetyl during bottling. Longer-term (~2 hour) exposure with closed tank dispensing exposure. at ambient temperatures and room ventilation.
	3. RD / QC	Direct exposure to small quantities. Various concentrations. Ambient temperatures and room ventilation.

Other Possible Uses or Sources of Diacetyl

Does your company heat margarine or use butter-flavored cooking oils or cooking sprays?	No.
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Substitution Away from Diacetyl

To what extent, if any, have you substituted away from using diacetyl or substances containing diacetyl?	<p>We have developed non-diacetyl versions of popular flavors, and some customers have switched to a non-diacetyl version (less than 10% of business).</p> <p>In general, we have been notified by a few larger customers that the lack of a permissible exposure standard has caused upper management to make the decision to eliminate diacetyl from their production floors. This rash decision is made without understanding the art or science behind diacetyl's use. Management's desire to remove the risk of potential legal actions, not necessarily safety concerns.</p> <p>Other customers have expressed difficulty to renew insurance liability policies. This push to remove diacetyl from flavors means other less characterized flavors are used that are potentially more dangerous. To cover off-flavors associated with substitutes, often greater concentrations of chemicals or greater variety chemicals are used to achieve the desired result or flavor balance. Additionally, trusted and reliable sources of diacetyl have exited the US markets due to risks of legal actions.</p>
What have been the advantages and disadvantages, for	A substitute for diacetyl is not as simple as replacing one flavor molecule for the other. Flavors are experienced when the aroma molecules are released from a food. The food matrix and flavor

<p>example, in terms of cost and product quality?</p>	<p>molecule interactions are influenced by food chemistry, which influences how a flavor molecule is released when consumed.</p> <p>In natural foods like dairy products, flavors bind to fats, lipids, and proteins. In processed foods, ingredients like starches, hydrocolloids, and emulsifiers also bind flavor molecules. As those skilled in the art of food science know, simple substitutions are rarely “simple”, and formulas and recipes will need to be evaluated individually for flavor targets and customer acceptance or appeal.</p> <p>For our company, substituting diacetyl is a hardship that means:</p> <ol style="list-style-type: none"> 1. A dramatic shift of operations. We cater to dairies, and 90% of our products contain some diacetyl. 2. Past experience with customers returning to original formulas after product launch failures. 3. Substitutes have unknown technical or safety risks. Hesitant to switch to a chemical flavorant with unknown risks that are potentially more dangerous, and less information of usage or track-record. 4. Prefer not to use raw material with unknown problems. 5. Lack of substitutes that are natural. 6. Lack of domestic available products (and customer avoidance of flavor compounds from certain countries). 7. The lack of substitutes that can be used to satisfy religious dietary laws (e.g., Kosher Parve flavors). 8. Availability of raw materials and reliability and economic stability of vendors. 9. Substitutes for diacetyl have off-flavors that are difficult to mask, especially in dairy products.
<p>If not, have you considered substituting away from using diacetyl?</p>	<p>For many mellow or non-savory flavors, the contribution of diacetyl to a desired, enjoyable flavor is nearly impossible.</p>
<p>What are the advantages and disadvantages, for example, in terms of cost and product quality?</p>	<p>Over zealous regulation of diacetyl will drive the flavor industry to use unregulated substitutes that are less characterized and have less desirable off-flavors. Diacetyl is a natural biochemical metabolite, while many substitutes are not. These substitutes may not be as easily broken down by natural biological systems, such as probiotic bacteria or industrial waste stations. Diacetyl is so endemic that it is used to classify bacteria with the MR-VP test in microbiology labs.</p> <p>Diacetyl is a natural metabolite, being part of the butylene glycol pathway (<i>Food Microbiology Laboratory, by Lynne Ann McLandsborough</i>) and ILV amino acid synthesis (<i>Handbook of Food Products Manufacturing, editor Y.H. Hui, et.al.</i>). Many substitutes are not natural metabolites, or their availability as a natural flavor is greatly limited.</p>

	<p>It has been our experience that diacetyl substitutes are more expensive and in short supply. According to suppliers, some are more difficult to manufacture, requiring 3 to 5 times the energy to produce – thus making the “global carbon footprint” of substitutes substantially greater, and generating more industrial byproducts that will end up as waste. In addition to longer manufacturing steps and time, we were told the yields are not optimal. We were warned the sheer capacity for product is currently not available, making a global shortage a great concern at the moment. Diacetyl is itself a byproduct of sugar production, and reducing its production will lead to greater biomass waste and disposal issues.</p>
<p>If you continue to use diacetyl, what are the advantages that cause you to continue to use it?</p>	<p>Diacetyl is the characteristic impact flavor of butter. It blends well with other natural flavor compounds to contribute a richness and complexity of a well-rounded flavor.</p> <p>While “buttery”, diacetyl substitutes have off-flavors that can be difficult to mask in mellow or non-savory applications, such as sweet and dairy product.</p> <p>Diacetyl is a metabolite, found naturally in fermented products. As Starter Distillate is a mix of the flavor molecules generated through natural fermentation. By foregoing batch fermentation and adding the distillate flavor, processors eliminate processing time and gain greater flavor control.</p>

Programs to Address Possible Diacetyl Exposure

<p>Do you have a program to control employee exposure to diacetyl or substances containing diacetyl?</p>	<p>Yes.</p>	
<p>Do you provide information and training for employees potentially exposed to diacetyl or substances containing diacetyl? What information and training do you provide?</p>	<p>Training description</p>	<p>Related to respirator program. Identify materials that pose a respiratory hazard.</p>
	<p>Criteria for who to train</p>	<p>Open to all employees. Mandatory for manufacturing, R&D, and QC personnel who handle raw materials and goods sold.</p>
	<p>Program content</p>	<p>Train on proper handling of materials and protective measures associated with respiratory hazards. MSDS information updated, accessible, and maintained on raw materials and goods sold.</p>
	<p>Methods of providing info</p>	<p>Classroom setting with oral and written information provided, along with respirator safety equipment packet.</p>
	<p>Length of training</p>	<p>1 hr annually</p>
	<p>Frequency of training</p>	<p>Annually</p>
<p>Do you perform personal</p>	<p>No</p>	

exposure monitoring?	
Do you isolate diacetyl exposure in separate work areas? (OSHA calls these "regulated areas.") What work areas do you isolate and what do you do to isolate these work areas?	<p>2,000 ft² limited-access and isolated room for blending, mixing, and dispensing. Exploring options for more localized ventilation. Intercom and telephones in room for outside communication. Covered tanks and room ventilation. Chilled tanks as appropriate.</p> <p>Designated manufacturing space limits usable footage. Employee down-time is increased due to limited access. Some difficulties identifying suitable personal-protective equipment that accommodates workers. Challenge to find equipment manufacturers with expertise on air handling and validation.</p>
Do you provide protective clothing and equipment for employees who handle diacetyl or substances containing diacetyl?	<p>Respirator program for training and monitoring workers. Uniforms changed daily - remain on-site. Laundered by a uniform company. Use chemical Tyvek suits and personal ventilators as appropriate. Glove use. Protective eyewear. Particle masks as appropriate (e.g., working with dry powders).</p>
Do you have a housekeeping program to control exposure to diacetyl? What methods do you use?	<p>We use a wet floor-scrubber as needed (~2X per month). Dry flavors are a minor part of our business (~10%)</p>
Do you offer physical exams or other health services/protections to employees potentially exposed to diacetyl? What exams or health services do you offer? Do you offer spirometry tests?	<p>At our facilities risks are determined by product handling and processing tasks. Personnel are checked with annual assessment at hospital-associated occupational health clinic. No noted changes in respiratory functions have been observed.</p> <p>Respirator program involves medical surveillance with annual physicals and spirometry testing at hospital-affiliated occupational clinic. Equipment training and fit tests performed to ensure proper fit. Additional positive-pressure respirators available (hooded). Chemical handling occurs in manufacturing work zone only.</p>
Do you utilize engineering controls to prevent or minimize employee exposure to diacetyl or substances containing? Such controls might include machinery or processes that limit the creation of dust, enclosure or isolation of processes, exhaust ventilation, local (added on) ventilation, and substitution of materials. What controls have you implemented and in what	<p>General manufacturing practices that we use to limit exposure risks to diacetyl include:</p> <ul style="list-style-type: none"> • Container labeling is performed outside manufacturing area. • Shipping pallets are wrapped and readied in shipping area outside of production room. • Daily workflow is choreographed by production manager so number of employees in production area is limited. Only critical employees in manufacturing area as required. Employee movement is limited while handling. Production is limited in the room to one product at a time. • Carboys are used to hold chemicals in smaller amounts so they are accessible to measure smaller amounts. This limits the need to handle or tip awkward drums (e.g., to measure propionic acid). Other similar raw materials for manufacturing are housed in smaller easy to access/handle containers too (e.g., acetoin). • When possible, stock flavors blended to limit the number of

operations?	<p>containers accessed during production.</p> <ul style="list-style-type: none"> • When possible, stock chemicals maintained as pre-diluted and accessible to limit repeated handling of concentrated chemicals. • Team meetings with production and technical staff to design production procedures to optimize manufacturing safety and practicality, especially with new processes or products. <p>Through formulations, we try to limit exposure risks to diacetyl by:</p> <ul style="list-style-type: none"> • Offer flavors with less than 20,000 ppm (2%) diacetyl. Constitutes ~95% of our business for flavors that contain diacetyl. We provide a flavor solution with reduced diacetyl concentrations (5% maximum). More than fifty percent (50%) of our sales contain less than 2% diacetyl (20,000ppm). About 20% contains less than 0.3% diacetyl (3000 ppm). By offering a blended flavor, our flavor we provides less exposure risks during handling for a less equipped to handle the risks associated using 99% pure diacetyl. We encounter occasional resistance from customer wanting more-concentrated flavors. Handling concentrated flavors boarder on chemical handling, and educated/skilled workforce, something that most direct-to-market manufacturers are not flexible enough or equipped to handle. • Eliminating or restricting oil-based products available for customers. Sometimes it is difficult to find suitable emulsions or hydrocolloids to meeting requests for oil-based or oil miscible flavors.
Do any of your employees wear respiratory protection for work potentially involving diacetyl?	Respirators are chosen according to professional rating for volatile organic vapors, and we use P-100 particle masks and Latex-free options.

Regulatory Alternatives

OSHA is considering alternative approaches for a draft proposed standard, one which provides for a permissible exposure limit, and one of which does not. Are these alternatives clear? If not, is one clearer than the other and why? Are there specific parts of either approach that are confusing? Which parts?	<p>Upon discussing this issue with small-business customers in the dairy and bakery industries, many seemed confused the differences, or do not have the expertise or experience to understand the process.</p> <p>These workplaces may not be used to using PELs's, so evaluating the proposed regulations or the difference of when to monitor or when to use a PEL is confusing.</p>
After reviewing the two	Some of the wording states that if "any" ingredient changes or

<p>approaches for draft proposed standard, what would be significant issues for your business with respect to compliance with either approach?</p>	<p>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.</p>
<p>Are OSHA’s estimates of time and unit costs of compliance reasonable? (See for example Table 13 and the Appendix PIRFA.</p>	<p>Yes.</p>
<p>Between the PEL and the non-PEL approach, would one approach be more cost-effective from your firm’s perspective? Please explain. What factors or other considerations would affect the relative effectiveness of these two alternative approaches in minimizing the compliance costs?</p>	<p>Diacetyl is a natural metabolite, yet it seems that exposure limitations are warranted yet not overly zealous. A chemical precedent might be oxygen. While important to life, oxygen is know to be toxic to cells in high concentrations. High concentrations of oxygen can cause oxidative stress and damage lung tissue. Air is ~21% oxygen, yet damage starts at oxygen concentrations of ~50%.</p> <p>It seems that a permissible exposure limit would best (PEL approach), yet flexibility is crucial in meeting any standard. Small businesses often do not have in-house expertise to modify equipment or resources for new capital equipment.</p> <p>Also, some processes pose more risk than others, and some food matrices result in more risk to exposure than others. The release of diacetyl into the workplace is dependent upon the processing temperatures, the concentration of the flavor, and the chemical polarity of the flavor-base or solvent. Heat allows vaporization. At higher concentrations, more flavor is at the surface to vaporize. While diacetyl is miscible with oil, oils interact differently with diacetyl and increase its volatility.</p> <p>Such volatility is based upon liquid-vapor partition coefficients (discussed in Chapter 9 of <i>Food Emulsions</i> (ed. David J McClements)). In this review, K.E. Ingham reported that diacetyl vapor concentrations were more than 25% higher in oil-based (hydrophobic) solutions versus water-based solutions. A food matrix with lipids and proteins (e.g., dairy), or hydrocolloids, emulsifiers, starches, etc (e.g., processed foods) with also reduce the released vapor concentrations as these components are known to bind flavors.</p>
<p>Of the regulatory alternatives identified in the PIRFA (pages 65 – 78), which do you think would be most effective in reducing negative impacts</p>	

on your firm?	
Are there other alternatives that OSHA should consider? Please explain.	

Attachment B - Journal of Dairy Science, Volume 80. No 1, 1997, A Method to Use *Leuconostoc mesenteroides* ssp. *Cremoris* 91401 to Improve Milk Fermentations.

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Leuconostic mesenteroides ssp. Cremoris 91401 to Improve Milk Fermentations.**

A Method to Use *Leuconostoc mesenteroides* ssp. *cremoris* 91404 to Improve Milk Fermentations¹

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ABSTRACT

Leuconostoc species are frequently used in mesophilic cultures to produce aroma during milk fermentations. *Leuconostoc mesenteroides* ssp. *cremoris* 91404 was selected as an aroma producer in preparation of experimental cultured buttermilk based on low diacetyl reductase activity, citrate utilization and high diacetyl production under acidic conditions, growth characteristics, and compatibility with *Lactococcus* strains. However, no diacetyl was detected in buttermilk that was made in the traditional commercial manner. Simple and direct GLC analysis without prior processing was applied to quantify volatile compounds in milk that had been fermented with *Leu. mesenteroides* ssp. *cremoris* and *Lactococcus lactis* ssp. *cremoris*. Fortification of ripened buttermilk with sodium citrate resulted in a significant increase of diacetyl and acetoin production during buttermilk storage (5°C for 2 wk). Surplus of citrate, low pH (pH 4.5 to 4.7), a sufficient number of active nongrowing aroma producers, air incorporation during curd breaking, and low temperature storage facilitated citrate metabolism toward production and conservation of flavor during 2 wk of storage. Incorporation of a rosy *Lc. lactis* ssp. *cremoris* strain 352 in starter culture significantly improved the texture and appearance of experimental cultured buttermilk.

(Key words: *Leuconostoc*, diacetyl, cultured buttermilk)

Abbreviation key: ALA = α -acetolactate, RSM = reconstituted skim milk.

INTRODUCTION

Cultured buttermilk is a very attractive dairy product because of its high nutritional value, low fat content, lack of sodium (unless salted), and good digestibility. Desired cultured buttermilk is clean,

mildly acidic, smooth, and slightly aromatic; it contains carbon dioxide and is a refreshing liquid milk drink. Although diacetyl is the key flavor compound in cultured dairy products, other volatile compounds, such as acetaldehyde, ethanol, and acetic acid, contribute to the total flavor; the carbon dioxide produced by starter cultures provides the effervescence and active mouthfeel to cultured buttermilk (10, 20). Texture plays an important role in flavor perception. The importance of the physical characteristics of fermented milks is emphasized by the increasing use of polysaccharide-producing organisms that are incorporated into multiple-strain starters used for the production of many different dairy products (21).

Although technologically buttermilk is the simplest of the cultured dairy products to produce, sampling of available brands indicates that many do not meet the acceptable industry standards for flavor, body, texture, and freshness (17, 19). The most common defects of cultured buttermilks are "lack of fine flavor" (flat flavor), "high acid" (sharp flavor), and "unclean" (off-flavor) (3). Cultures of *Leuconostoc mesenteroides*, primarily ssp. *cremoris*, and *Leuconostoc lactis* are frequently used as citrate utilizers and flavor producers in dairy fermentations. In addition, leuconostocs are desirable in dairy fermentations for their antibiosis and their relative insensitivity to bacteriophage attack (2). The role of leuconostocs as an aroma producer in mesophilic starter cultures for milk fermentations can be qualified as complementary because dairy leuconostocs need to be combined with acid-producing *Lactococcus lactis* ssp. *lactis* or *Lactococcus lactis* ssp. *cremoris* strains (4) to perform their function. Use of citrate-utilizing *Lc. lactis* ssp. *lactis* as an aroma producer in starter for buttermilk was related to excessive amounts of acetaldehyde, which impart "green apple" and harsh flavors (18).

The goal of this study was to improve the flavor and consistency of cultured buttermilk. Among the various biological and environmental factors that influence the development of buttermilk flavor, we have mainly concentrated on selection of multiple-strain starter cultures and the relationship existing between citrate utilization and production of diacetyl and acetoin during fermentation.

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MATERIALS AND METHODS

Organisms and Growth Conditions

Strain 91404 of *Leu. mesenteroides* ssp. *cremoris* and *Lc. lactis* ssp. *cremoris* strains 205 and 352 (ropy) used in this study were from the culture collection of the Dairy Microbiology Laboratory at Oregon State University (Corvallis). *Leuconostoc mesenteroides* ssp. *cremoris* 91404 (Moseley Laboratory, Indianapolis, IN) was grown for 24 h at 28°C in MRS broth (55 g/L of dehydrated powder; Difco, Detroit, MI) supplemented with 0.1% sodium citrate. *Leuconostoc* cultures were maintained in MRS broth at 4°C and were frequently subcultured. All procedures for characterization of *Leu. mesenteroides* ssp. *cremoris* 91404 are described by Levata-Jovanovic (8) and Levata-Jovanovic and Sandine (9).

Lactococcus strains were propagated in 11% reconstituted skim milk (RSM) for 18 h at 22°C. Cultures were maintained in 11% RSM at 4°C following inoculation without incubation; cultures later were incubated overnight at 22°C as needed. The identity of *Lc. lactis* ssp. *cremoris* strains 205 and 352 was confirmed by application of a subspecies-specific rRNA probe for *Lc. lactis* ssp. *cremoris* (68RCa) in the whole-cell dot blot hybridization procedure (14). Stock cultures of *Leu. mesenteroides* ssp. *cremoris* and *Lc. lactis* ssp. *cremoris* were stored at -70°C in sterile 11% RSM that had been supplemented with 20% (vol/vol) glycerol.

Growth curves of *Leu. mesenteroides* ssp. *cremoris* 91404 in pure and in mixed cultures were determined as follows. Three percent of a *Leuconostoc* MRS broth culture was used to inoculate 500 ml of sterile 11% RSM supplemented with 0.2% sodium citrate as needed. One percent of a *Lc. lactis* ssp. *cremoris* milk culture and 3% of a 91404 MRS broth culture were used as the inoculum in multiple-strain culture experiments. Five-milliliter samples were pipetted from milk cultures at hourly intervals during incubation at 22 or 28°C, and serial dilutions were prepared (15). Viable cell counts were determined on MRS agar and on MRS agar containing 30 µg/ml of vancomycin after incubation at 28°C for 24 to 36 h. In studies using mixed multiple-strain cultures, the *Leuconostoc* count was based on the number of colonies grown on MRS agar supplemented with vancomycin, and the *Lactococcus* count was determined by subtracting the *Leuconostoc* count from the total viable cell count obtained on MRS agar.

Experimental Buttermilk

Portions (500 ml) of 1% fat milk (Fred Meyer brand purchased locally) or nonfat milk (Darigold

brand, purchased locally) were fortified with 0.1% sodium citrate and were pasteurized in glass bottles by steaming for 45 min; controls without added citrate were similarly prepared. After cooling, milk was inoculated with *Leu. mesenteroides* ssp. *cremoris* 91404 (3%) and either or both *Lc. lactis* ssp. *cremoris* 205 and 352 (1%) and incubated at 22°C until pH 4.5 to 4.7 was reached (about 18 h). After incubation, the buttermilk was cooled in ice water and gently shaken to break the curd. Immediately, 0.1 to 0.15% sodium citrate was added from a 30% stock solution. Shaking was repeated after fortification with citrate. The buttermilk was then stored at 5°C. During the ripening and storage periods, 5-ml samples were taken at various time intervals and analyzed for viable cell counts and for concentrations of citrate and volatile compounds. Time was counted from the moment of inoculation (0 h).

Analyses

Citrate utilization by *Leu. mesenteroides* ssp. *cremoris* 91404 in milk was determined using an enzymatic analysis kit (Boehringer-Mannheim, GmbH Mannheim, Germany). Concentrations of volatiles in the milk samples were determined by direct GLC using a gas chromatograph (model 5170A; Hewlett Packard, Wilmington, DE) equipped with a flame ionization detector and coupled with a 3390A HP integrator. In general, the procedure was that described by Thornhill and Cogan (16). Standard curves were plotted from fresh aqueous solutions of standards (acetaldehyde, ethanol, diacetyl, acetoin, and acetic acid) and were used to quantitate the amounts of volatiles in milk cultures. The concentration of each compound was calculated by comparing the ratios of compound to internal standard (sec-butanol Sigma Chemical Co., St. Louis, MO) peak areas in the samples and standard solutions (16). Samples of milk cultures were cooled on ice, clarified by centrifugation at 13,000 rpm for 10 min, and filtered through 0.45-µm pore size filter. Filtrates were diluted (1:1 vol/vol) with 1 mM sec-butanol, and 0.5 µl of this mixture was injected into the gas chromatograph. To investigate whether or not components of milk interfered with GLC analyses, peak areas from injection of aqueous standard solutions were compared with peak areas of milk-based standards. Milk-based standards were prepared by adding the known amount of volatile compounds to the supernatant of uninoculated milk acidified with lactic acid (60%, vol/vol) to pH 4.5. After filtration through a 0.45-µm acrodisc filter and dilution with 1 mM sec-butanol (1:1, vol/vol), milk-based standards (0.5 µl) were injected into the GLC glass column (Supelco,

Nellefonte, PA) packed with 80/120 Carbowax B AW/ 0.6% Carbowax 20M.

Organoleptic Evaluation

Buttermilk samples were presented to five experienced panelists. Panelists were asked to comment on flavor, texture, mouthfeel, and acidity characteristics of the experimental buttermilk samples.

RESULTS AND DISCUSSION

Characteristics of *Leu. mesenteroides* ssp. *cremoris* 91404

Use of *Leu. mesenteroides* ssp. *cremoris* 91404 in the manufacture of experimental buttermilk was based on its satisfactory characteristics, such as citrate utilization under initial neutral (pH 6.5) conditions, high diacetyl production under acidic conditions created by addition of citric acid (pH 4.3), and low diacetyl reductase activity (9). Although the citrate that had been added to milk was catabolized by strain 91404 under initial conditions of neutrality (Figure 1), no diacetyl nor acetoin was detected. Addition of yeast extract to the milk stimulated citrate utilization without concomitant production of diacetyl or acetoin.

Complete disappearance of citrate from milk supplemented with 0.3% yeast extract occurred in 9 h and was most likely stimulated by some components of yeast extract and by generation of acidic conditions (pH 4.8). Importantly, data presented by Levata-Jovanovic and Sandine (9) show that diacetyl and acetoin production was favored in preincubated *Leu. mesenteroides* ssp. *cremoris* cultures that had been additionally fortified with citric acid (11). Acidified, active, but nongrowing *Leu. mesenteroides* ssp. *cremoris* 91404 milk culture with 0.1 to 0.15% added sodium citrate after an initial 18 h incubation produced 75 ppm of diacetyl and 326 ppm of acetoin after an additional 18 h of incubation.

For functionality, associative culturing of lactococci and leuconostocs needs compatible strains and also sufficient numbers of the bacteria that produce acid and aroma. Compared with previous observations on growth rate and generation time of *Leu. mesenteroides* ssp. *cremoris* (1), strain 91404 tended to have a shorter generation time during incubation in milk. The growth curves for the culture grown in 11% RSM at 22°C were similar to the growth curves in 11% RSM fortified with citrate to 0.2%. Mean generation time at 22°C was 86 min, and populations of each reached about 18×10^7 in 12 h. Balanced growth of lactococci and leuconostocs in milk at 22°C was ob-

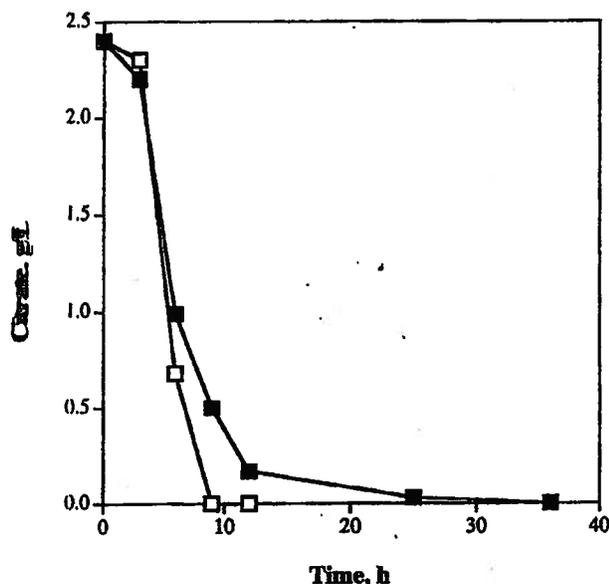


Figure 1. Citrate utilization by *Leuconostoc mesenteroides* ssp. *cremoris* 91404 in 11% reconstituted skim milk supplemented with 0.2% sodium citrate (■) and with 0.2% sodium citrate plus 0.3% yeast extract (□).

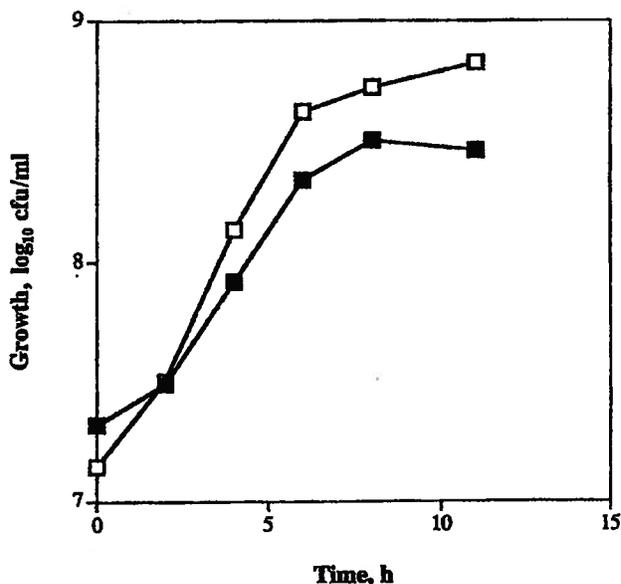


Figure 2. Growth of *Leuconostoc mesenteroides* ssp. *cremoris* 91404 (■) and *Lactococcus lactis* ssp. *cremoris* 205 (□) in mixed culture in 11% reconstituted skim milk at 22°C.

TABLE 1. Peak area ratios¹ for acetaldehyde, diacetyl, and acetoin as measured by GLC.

Compound	Area ratio									
	2 ppm		5 ppm		10 ppm		25 ppm		50 ppm	
	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD	\bar{X}	SD
Acetaldehyde	1.31	0.2	1.19	0.18	1.04	0.04	1.07	0.13	0.96	0.01
Diacetyl	0.97	0.05	1.05	0.17	0.96	0.07	0.95	0.04	1.08	0.08
Acetoin	ND ²	...	0.92	0.08	1.16	0.11	1.03	0.11	0.95	0.08

¹Area (A) ratio: [A (aqueous)/A (milk)] measured in parts per million (micrograms per milliliter).

²Not determined.

served in experiments with mixed starter cultures (Figure 2). The mean generation time of *Leu. mesenteroides* ssp. *cremoris* 91404 in multiple-strain culture (85 min) did not differ from the estimated generation time of the pure culture (86 min), indicating that growth of 91404 was neither stimulated nor inhibited by *Lc. lactis* ssp. *cremoris* 205. The mean generation time of the metabolically more active *Lc. lactis* ssp. *cremoris* was 65 min. In cultured buttermilk production, it is important to maintain the incubation temperature between 21 and 25°C because the ratio is skewed toward faster growing lactococci at temperatures above 25°C.

GLC Analysis

Direct and fast GLC analysis was found to be suitable for determination of volatile compounds in milk products without prior processing (16). For GLC analyses, 80/120 Carbowax B AW/6.6% Carbowax 20M (Supelco) was used as the column packing matrix and provided symmetric, sharp peaks of the tested volatiles (data not shown). The internal standard used was sec-butanol because sec-butanol is not a known product of lactic acid bacteria and its retention time did not overlap with the other compounds of interest. Use of temperature programming (temperature increase from 90 to 130°C at rate of 2°C/min) also improved resolution of peaks. A removable glass inlet provided protection of the column by trapping accompanying nonvolatile substances of the sample. The reproducibility of the peaks was checked to ascertain whether components in the media interfered with the analysis. Area ratios of aqueous solution to milk-based solution for standard compounds at selected concentrations are listed in Table 1 along with corresponding standard deviations. Values are means of three replications per sample. Although highly comparable responses of given compounds in aqueous and milk-based solutions were observed, serial injections of the complex milk samples can

cause baseline disturbances and the appearance of irregularly shaped peaks as well as the ghost peaks. Occasional conditioning at 150°C and flushing with deionized water (0.5 μ l) are recommended in order to stabilize packing material and to ensure that the column had no residual material to interfere with further sample runs. Finally, possible inaccuracies in the determination of diacetyl by GLC analysis can be associated with instability of α -acetolactate (ALA), which is presumably an intermediate in diacetyl formation. Spontaneous decarboxylation of ALA at high temperature during the analysis of diacetyl may lead to overestimation of the true diacetyl content (7).

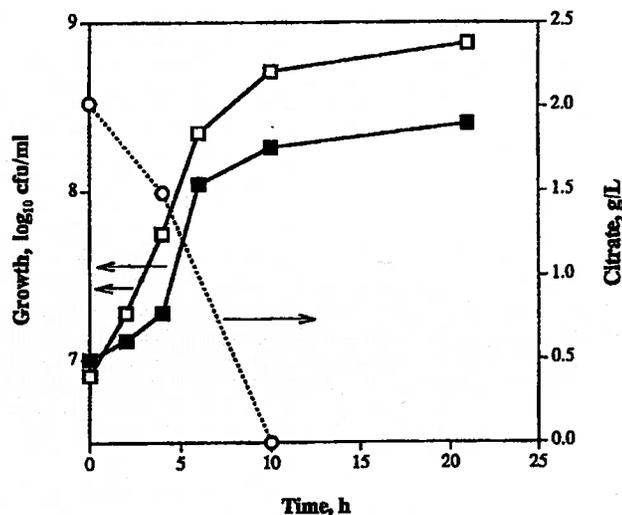


Figure 3. Citrate utilization (○) and growth of starter culture, containing *Leuconostoc mesenteroides* ssp. *cremoris* 91404 (■) and *Lactococcus lactis* ssp. *cremoris* 205 (□), during milk fermentation (buttermilk ripening).

Analysis of Experimental Buttermilk

The process used to prepare buttermilk was based on commercial practice. Traditionally, manufacture of cultured buttermilk includes inoculation of pasteurized, cooled milk with a lactic starter culture containing acid and aroma producers, incubation (the ripening or fermentation period), breaking the coagulum, and cooling, followed by bottling and distribution of the final product. Milk used for fermentation is usually deficient in citrate and needs to be fortified with sodium citrate. In addition to providing more substrate for flavor production, the inducible nature of some enzymes for citrate metabolism in leuconostocs (12) has been the reason for citrate fortification prior to fermentation.

Growth of the starter culture containing *Leu. mesenteroides* ssp. *cremoris* 91404 as the aroma producer during the ripening period is presented in Figure 3. Citrate utilization began as soon as growth was initiated, and citrate was completely depleted by 10 h after incubation, when growth slowed. Because citrate permease has an optimum pH of around 5.4, a lag in citrate uptake would have been expected; our results suggest that citrate use in this strain may follow some inward diffusion prior to maximum activation of the permease. This possibility is being studied further. Also, after a lag of about 2 h, the pH linearly decreased from 6.5 to 4.5. *Lactococcus lactis*

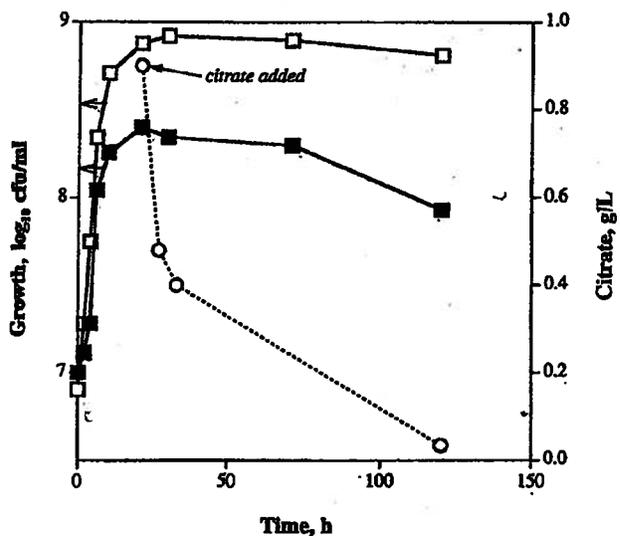


Figure 4. Citrate utilization (○) and growth of starter culture, containing *Leuconostoc mesenteroides* ssp. *cremoris* 91404 (■) and *Lactococcus lactis* ssp. *cremoris* 205 (□), during ripening and storage of experimental buttermilk.

ssp. *cremoris* strains used to acidify milk in studies of multiple-strain cultures were unable to utilize citrate, which was verified by enzymatic analyses of single-strain milk cultures. Commonly, no detectable amounts of diacetyl, but variable amounts of acetoin (0 to 40 ppm), were produced during fermentation by *Leu. mesenteroides* ssp. *cremoris* 91404 under the acidic conditions that were created by growth of *Lc. lactis* ssp. *cremoris* in the multiple-strain cultures. The lack of diacetyl production may be explained by directing the citrate metabolism to other products or,

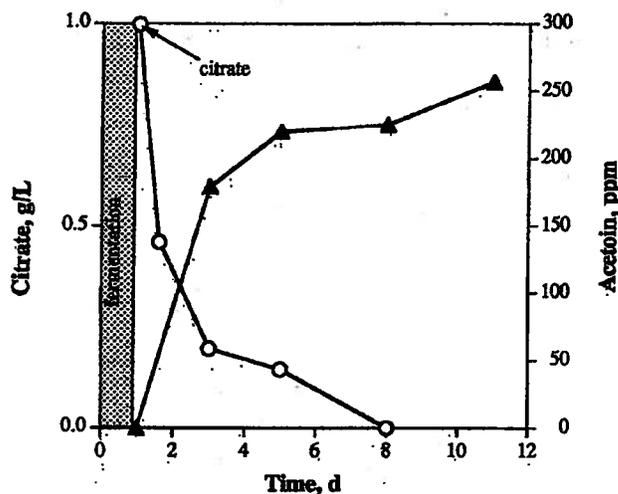
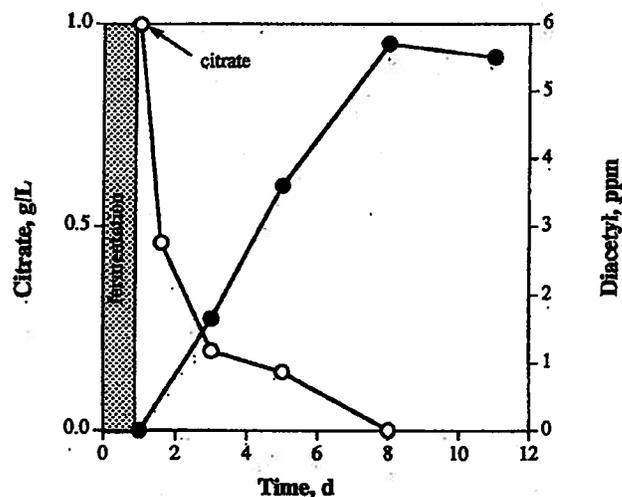


Figure 5. Citrate utilization (○) and production of diacetyl (●) and acetoin (▲) during storage of experimental buttermilk after fortification with sodium citrate. Starter cultures: *Leuconostoc mesenteroides* ssp. *cremoris* 91404 and *Lactococcus lactis* ssp. *cremoris* 205 and 352.

TABLE 2. Acidity (pH), GLC analyses, and comments on sensory characteristics of experimental buttermilks after 4 d of refrigeration.

Sample ¹	pH	Acetaldehyde	(ppm)			Diacetyl: acetaldehyde	Sensory comments
			Diacetyl	Acetoin	Ethanol		
A	4.6	0.9	3.4	179.3	174.2	3.8	Butter flavor, slightly lumpy
B	4.7	0.8	2.1	95.4	162.3	2.6	Buttery flavor, high gas
C	4.6	1.2	3.6	220.0	150.5	3.0	Nice flavor, thick, shiny
D	4.6	ND ²	0.9	206.0	102.2	...	Nice flavor, thick, shiny

¹Sample A, lowfat milk inoculated with *Leuconostoc mesenteroides* ssp. *cremoris* 91404 and *Lactococcus lactis* ssp. *cremoris* 205; B, low fat milk plus 0.1% citrate, inoculated with *Leu. mesenteroides* ssp. *cremoris* 91404 and *Lc. lactis* ssp. *cremoris* 205; C, lowfat milk inoculated with *Leu. mesenteroides* ssp. *cremoris* 91404, *Lc. lactis* ssp. *cremoris* 205 and 352; and D, nonfat milk plus 0.1% citrate inoculated with *Leu. mesenteroides* ssp. *cremoris* 91404, *Lc. lactis* ssp. *cremoris* 205, and *Lc. lactis* ssp. *cremoris* 352.

²Not detected.

as was found by Monnet et al. (13), by a rapid drop of redox potential at the beginning of the mixed-strain fermentation, resulting in absence of oxidative decarboxylation of ALA to diacetyl.

From the present study, the simple modification of the traditional procedure for making culture buttermilk involved fortification of ripened buttermilk with sodium citrate during coagulum breaking. The results presented in Figure 4 show that cultures were not actively growing during this storage period because of the low pH and low temperature. However, citrate utilization was evident, although it was much slower than during the ripening period. Citrate, added after growth ceased and after favorable acidic conditions developed, was expected to act as a precursor of diacetyl and acetoin, to stimulate ALA synthase by internal accumulation of pyruvate, and to stabilize the level of diacetyl in cultured buttermilk by retarding eventual diacetyl reductase activity.

Fortification of buttermilk with sodium citrate after ripening enhanced production of diacetyl and acetoin. Rapid uptake of citrate and its conversion to diacetyl and acetoin took place in all buttermilks that were supplemented with citrate after fermentation with *Leu. mesenteroides* ssp. *cremoris* 91404 and *Lc. lactis* ssp. *cremoris* strains (Figure 5). In our study, excess citrate from the second addition, low pH, sufficient numbers of active, nongrowing leuconostocs, incorporation of air by shaking during curd breaking, and cooling the buttermilks to 5°C had favorable effects on flavor development in experimental buttermilk during storage. Citrate uptake was stimulated by low pH because of the pH dependence of citrate permease and because a considerable fraction of the

citrate ($pK_a = 3.14, 4.77$ and 5.40) in buttermilk at pH 4.5 to 4.6 was present in the uncharged, acidic form, which could diffuse through the bacterial membrane (6). In addition to providing the precursor of

1. Select lowfat (1 to 1.5%) high quality milk.
2. Fortify to 9.0% SNF with NDM to improve body and texture.
3. Add 1 lb (454 g) of sodium citrate per 100 gal (384 L) of milk (optional).
4. Add salt at rate of 7 to 8 lb (3175 to 3628 g)/100 gal of milk.
5. Batch pasteurize the milk to 185°F (85°C) for 30 to 45 min.
6. Thaw two 70-ml cans of *Lactococcus lactis* ssp. *cremoris* (acid producer, preferably a ropy strain) and two 70-ml cans of *Leu. mesenteroides* ssp. *cremoris* 91404 (flavor producer) in cool chlorinated water.
7. Add all four cans to 300 to 1000 gal (1152 to 3840 L) of milk.
8. Agitate the milk slowly to thaw thoroughly and mix the cultures into the milk.
9. Incubate the inoculated milk at 72°F (22°C), without agitation, until a titrable acidity of 0.8 to 0.85% (pH 4.6 to 4.7) is reached (approximately 16 to 18 h).
10. Turn on the cooling water and gently agitate the coagulum to break it. Immediately add a previously prepared sodium citrate solution to a final level of 0.2% [908 g (2 lb) of sodium citrate per 100 gal of milk]. The sodium citrate solution was prepared by dissolving 2 lb (908 g) of sodium citrate in 0.5 gal (1.92 L) to 1 gal (3.84 L) of water in a Pyrex or stainless steel container. Autoclave the solution for 10 min at 250°F. Cool and add to cultured buttermilk using aseptic techniques.
11. Stir at slow speed until buttermilk is cooled to 40°F, package, and store cold (2 to 5°C).

Figure 6. The procedure for the manufacture of cultured buttermilk with improved flavor using *Leuconostoc mesenteroides* ssp. 91404 as diacetyl producer.

diacetyl under appropriate conditions, citrate was most likely involved in the induction of citrate lyase and ALA synthase (5). Fortification with precursor also provides a safety margin in preventing flavor loss by repressing diacetyl reductase. According to Hugenholz (5), high concentrations of acetoin in buttermilk may lower the rates of diacetyl reduction in buttermilk because of the higher affinity of diacetyl reductase for acetoin than for diacetyl together with noncompetitive inhibition of enzyme activity by acetoin. Cooling of cultured products to refrigeration temperature also arrests the destruction of diacetyl by retarding diacetyl reductase activity. Although diacetyl reduction was not expected to present a major problem in our experiments, considering the low diacetyl reductase activity of the strain 91404, these aspects of citrate metabolism need to be considered because a variety of starters are used in buttermilk production and because contamination with psychrotrophs, which have high diacetyl reductase activity, may occur in commercial practice (22).

Characteristics of Experimental Buttermilk

Manufacture of experimental buttermilk under different conditions revealed that simple modifications in the traditional manufacturing procedure, involving starter composition and delayed citrate fortification, would yield a refreshing product with clean, aromatic, thick, and carbonated properties. Results of CMC analyses and sensory evaluation of the four experimental buttermilks are shown in Table 2. All samples had a delicate buttery flavor. Buttermilks made with *Leu. mesenteroides* ssp. *cremoris* 91404 and *Lc. lactis* ssp. *cremoris* 205 (A and B) had a more distinct buttery flavor and were more carbonated than buttermilks C and D. However, fortification of milk with citrate prior to pasteurization did not affect production and subsequent perception of flavor determinants (sample B vs. sample A). Incorporation of rony *Lc. lactis* ssp. *cremoris* strain 352 in the starter resulted in texture improvement. Buttermilks C and D had thick, viscous, and shiny bodies and very smooth mouthfeel. The flavor of buttermilks C and D was very good, but different from A and B. High quality buttermilk D was made from nonfat milk and could not be distinguished from buttermilk made from lowfat (2%) milk with the same starter culture. *Leu. mesenteroides* ssp. *cremoris* 91404 provided a nice flavor, and rony *Lc. lactis* ssp. *cremoris* 352 provided excellent body for the buttermilk D. Because we could not find any fat-free buttermilk on the market, this

product could be interesting for consumers concerned about fat content of dairy products.

Protocol for Manufacturing Flavorful Buttermilk

Fortification of ripened buttermilk with sodium citrate was commercially used on an experimental basis (Umpqua Dairy, Roseburg, OR) with excellent results. The procedure for production of buttermilk that was slightly aromatic, clean, thick, shiny, and containing carbon dioxide is presented in Figure 6.

CONCLUSIONS

The traditional method of manufacturing cultured buttermilk (milk pasteurization, cooling, inoculation of milk with starter culture, incubation, cooling and curd breaking, packaging, and marketing of cold product) was found to be inadequate to produce a product with good flavor (diacetyl). By using *Leu. mesenteroides* ssp. *cremoris* strain 91404 as flavor producer in combination with a lactococcal acid producer and adding 0.2% sodium citrate at breaking after incubation followed by cooling, the newly added citrate was maximally converted to diacetyl. Sodium citrate solution [previously dissolved in about 0.5 gal (2 L) of water 2 lb (908 g) per 100 gal (384 L) of milk] should be autoclaved or at least pasteurized.

ACKNOWLEDGMENTS

We thank Maysoon Salama for confirming the identity of they *Lc. lactis* ssp. *cremoris* strains used in this study by applying a subspecies-specific rRNA probe in the whole-cell dot blot hybridization procedure.

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**Attachment C - GMA Comments on OSHA Draft Standard for Occupational
Exposure to Diacetyl and Food Flavorings Containing Diacetyl**



TO: Charles Schroeder
Small Entity Representative, SBREFA Panel for Diacetyl

FROM: Nancy J. Rachman, Ph.D.,
Senior Director of Science Policy, Chemical Safety
GMA

DATE: May 26, 2009

SUBJECT: OSHA Draft Standard for Occupational Exposure to Diacetyl and Food
Flavorings containing Diacetyl, OSHA Docket ID: OSHA-2008-0046 –
Comments of GMA¹

This preliminary analysis is designed to identify and explore some of the issues and concerns raised by OSHA's draft Standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl and associated materials.

I. Introduction

OSHA has initiated this rulemaking based on an initial determination that a comprehensive occupational safety and health standard is necessary to protect employees from the adverse health effects associated with flavorings containing diacetyl. Both reported animal studies (primarily Morgan et al. 2008) and a soon-to-be published epidemiology report (Lockey et al. 2008) indicate that high airborne exposures to diacetyl generated from flavorings containing high concentrations of diacetyl have been associated with a significant risk of harm to the human respiratory system and have caused significant harm to the respiratory systems of test animals. What remains to be determined are the exposure levels of concern, the bulk

¹ The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

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diacetyl concentrations of concern, and where those exposures or bulk concentrations are likely to occur.

The occurrence of the cluster of lung obstruction cases among workers at microwave popcorn plants identified in the year 2000, and the initial absence of a responsible regulatory response, have led to a situation in which the political demand for action on this issue is ahead of the science needed to responsibly develop an appropriate standard. This situation is clear from a review of the Technical and Economic Feasibility Analysis for Proposed OSHA Standard for Diacetyl and Acetoin (TEFA), and the Preliminary Initial Regulatory Flexibility Analysis (PIRFA) distributed to the Small Entity Representatives (SERs), which acknowledge the inadequacy of the exposure and toxicology data currently in OSHA's possession. Both documents state:

Given the unique challenges that OSHA has encountered in investigating and evaluating these hazards, the Agency is considering traditional and non-traditional means of regulating employee exposures.

OSHA has never attempted to, and should not attempt to adopt a substance-specific standard on the basis of the limited and inadequate data currently in its possession. In situations where the data are inadequate to establish a permissible exposure limit (PEL), the appropriate regulatory approach, from both a legal and public policy perspective, is to rely on the enforcement of OSHA's Personal Protective Equipment standards, including its Respiratory Protection Standard, and the General Duty Clause, combined with education and outreach, to provide interim protection to workers while the necessary airborne exposure and toxicology data are being developed.

By no means, however, are we suggesting that OSHA abandon this effort. As OSHA is aware, a critically important report on an epidemiological study of the association between exposure to diacetyl and lung function in workers at four microwave popcorn plants is expected to be published in July of this year. Even more significant to this rulemaking is the wealth of information in the data base of airborne exposure monitoring and medical monitoring gathered in connection with that study. Our understanding is that OSHA is in the process of arranging for access to that data base. In addition, we understand that NTP has completed two 90-day animal studies on exposure to airborne diacetyl and the analyses are underway.

Based on the information available to us at this time, it appears that the data bases assembled in connection with the Lockey et al. (2008) study and the Morgan et al. (2008) study could be utilized to develop a useful 8-hour-time weighted average (TWA) occupational exposure limit (OEL) for diacetyl and flavorings containing diacetyl. In the absence of other data, it might even be appropriate for OSHA to adopt an interim PEL based on those two data bases. Given our understanding that the two NTP studies have been completed, and that there is a much greater awareness of the potential workplace significance of diacetyl exposures, we believe the prudent course of action is to await the analyses from the NTP studies. If OSHA elects to proceed without waiting for the analyses of the NTP studies, we believe it should limit the application of the rule to the two sectors where a significant risk from exposure to diacetyl and flavorings containing diacetyl has been established -- flavor manufacturers that manufacture

flavors containing diacetyl and microwave popcorn manufacturers that continue to use flavorings with high concentrations of diacetyl.

According to the TEFA, there are approximately one million employees working at approximately 23,000 food industry establishments “where diacetyl exposures are possible.” In other words, there are approximately 23,000 establishments manufacturing or handling products that may or may not contain diacetyl, which may or may not produce exposures having any health significance. Of those 23,000 establishments, slightly over one-half (50.4%) employ fewer than 10 employees, another 16.4% employ 10 to 19 workers, and only 10% employ 100 or more workers. It seems likely that, if a rule similar to the draft rule was adopted, it would have a more significant impact on small business than any rule, other than the ergonomics standard, adopted by OSHA since the SBREFA process was established.

If one further considers the potential impact of the application of the draft rule to almost 2 million “cooks” and their places of employment (see p. 69 of PIRFA), as well as the wine, beer and dairy industries (see p. 68 of PIRFA) whose ingredients and/or products may contain naturally-occurring diacetyl, one quickly concludes that a far more refined analysis of the exposures and related scope issue is required. OSHA must identify those tasks or activities, if any, in sectors beyond flavor manufacture and microwave popcorn manufacture with high concentrations of diacetyl, and possibly high temperatures, where there is truly a significant risk of harm requiring the imposition of the burdensome requirements of a comprehensive OSHA health standard.

II. Principles Governing the Overall Approach to the Regulation of Diacetyl

A. The Basic Legal Criteria For An Occupational Safety and Health Standard Addressing Workplace Exposure To A Toxic Material Are Provided In Sections 3(8), 6(b)(5) and 6(f) Of The Occupational Safety And Health Act (OSH Act)

1. Section 3(8) of the Occupational Safety and Health Act (OSH Act) defines an occupational safety and health standard as:

A standard which requires conditions, or the adoption or use of one or more means, methods, operations, or processes, reasonably necessary or appropriate to provide safe and healthful employment and places of employment.

Section 6(b) of the OSH Act provides that:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of

standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility [emphasis added] of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Further, Section 6(f) of the OSH Act provides that:

The determinations of the Secretary shall be conclusive if supported by substantial evidence [emphasis added] in the record considered as a whole.

2. Based on the foregoing, OSHA is authorized to adopt a health standard, pursuant to Sections 3(8) and 6(b) of the OSH Act, to address those identified workplace hazards that are shown to pose a significant risk of harm – sometimes referred to a material impairment of health or functional capacity. Generally, to sustain a standard on judicial review as being reasonably necessary and appropriate, OSHA must demonstrate the following:
 - a) Current workplace exposure levels to the identified hazards pose a significant risk of harm to the workers who would be covered by the standard;²
 - b) The proposed requirements would significantly or materially reduce the workplace risk to workers exposed to those identified hazards;
 - c) The proposed requirements are technically and economically feasible and within the bounds of what are reasonable for each industrial sector;
 - d) The proposed requirements are the most cost-effective approach for achieving the reduction in risk by those identified hazards;
 - e) For health standards dealing solely with harmful physical agents, the standard must, to the extent feasible and within reasonable bounds, reduce workplace exposures to a level below that which presents a significant risk of material impairment of health or functional capacity to employees.

² *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 615 (1980) (Benzene) (vacating the benzene standard).

B. Limit Regulation to Establishments Posing a Significant Risk of Harm

As noted above, as a threshold matter, OSHA may regulate exposure to diacetyl under a substance-specific standard only to the extent that it establishes the existence of a significant risk of harm – a material impairment of health or functional capacity – at current exposure levels in the industries and portions of the establishments that would be subject to the rule.

A significant risk of harm has been established only for the manufacture of concentrated flavorings containing diacetyl and the manufacture of microwave popcorn with flavorings containing relatively high concentrations of diacetyl. OSHA has not established that exposure to diacetyl poses a significant risk of harm for the entire food manufacturing industry or any particular sectors of that industry. The reported occurrences of a few isolated cases of lung obstruction in other industrial sectors (or in a consumer who apparently chose to deeply inhale bags of freshly popped popcorn on a frequent basis) does not establish a significant risk of harm for approximately one million employees in 23,000 establishments manufacturing or handling products that may or may not contain diacetyl, at concentrations that may or may not produce exposures having any health significance.

ERG's analysis (in the TEFA) indicates that the final product of the flavoring manufacturer, which generally has a diacetyl concentration below 1%, is the incoming raw material (flavoring) for the receiving food manufacturer. ERG found that the incoming flavor is quickly diluted by a factor of 100 to 1000 at the beginning of the typical food manufacturing process, which strongly suggests that the small concentration of diacetyl that is generally present further downstream would be insignificant from the standpoint of worker health and safety.

The scope of a standard should only include those sectors in which a significant risk of harm has been established. It would not make any sense, and is beyond OSHA's authority, to require every employer in the food industry that may use an ingredient containing added diacetyl, much less natural diacetyl, to initiate exposure monitoring to prove there are no exposure levels above the action level, much less the threshold trigger level -- both initially and with each new flavor or flavor reformulation.

C. OSHA May Not Impose Regulatory Burdens Beyond Those Necessary To Address Significant Risks, Or Which Are Infeasible

1. To the extent OSHA establishes that a particular task or activity poses a significant risk of harm, OSHA must limit its regulation of that task or activity to the most cost-effective approach that will control the risk, subject to feasibility constraints.

2. To the extent that a standard is justified, a comprehensive health standard based on a PEL would be most the cost-effective approach for regulating workplace exposures to diacetyl.
 - a) Under a PEL-based approach, employers could review all feasible measures and select the most cost-effective measures that would achieve the PEL based on site-specific conditions, subject to the constraints of a hierarchy of controls provision.
 - b) The employer could choose between various engineering controls and work practices where required to achieve the PEL. The non-PEL approach would inappropriately mandate engineering controls where work practices would be more cost-effective. The non-PEL approach would inappropriately mandate work practices (e.g., setting up regulated areas and operating pursuant to the requirements governing regulated areas) where exposures are so low that no regulated area is needed.
3. An OSHA mandate to follow a non-PEL alternative would be invalid because it would effectively impose a 0.03 ppm PEL (8-hour TWA) or 0.2 ppm (STEL) – the threshold coverage trigger – and impose burdens far beyond those reasonably necessary and appropriate to control a significant risk. An employer would be required to establish a regulated area, install engineering and administrative controls, enforce the use of respiratory protection, etc. where the employer cannot demonstrate that “all employee exposures” to a flavoring containing diacetyl, throughout the facility, do not exceed an airborne concentration of diacetyl in excess of 0.03 ppm (8-hour TWA) or a 0.2 ppm (15-minute STEL). As written, the non PEL-based standard would require an employer to implement those controls where an employee is exposed at 0.2 ppm for 15 minutes while performing a task just once per year. The employer would incur significant expense for a very intermittent task at a level where OSHA has not established that a significant risk exists.
 - a) At the time it was developed, the apparent rationale for developing a non PEL-based standard was as follows:
 - (1) Diacetyl posed a potentially significant risk of harm at some unknown dose(s) (combinations of concentration and time of exposure),
 - (2) OSHA did not know what levels/doses were hazardous, and
 - (3) Since there was no level/dose known to be “safe”, exposures had to be reduced to the lowest feasible level

through the implementation of engineering and administrative controls, and then to zero through the use of respirators, subject only to a triggering level that is not based on significant risk of material impairment.

- b) We believe this is the same basic rationale that Federal OSHA attempted to rely on, and that the U.S. Supreme Court squarely rejected in Benzene in finding a Federal OSHA standard for workplace exposure to benzene (a known human carcinogen) to be invalid.³

In Benzene, industry groups challenged a final OSHA rule, adopted under Section 6(b)(5) of the OSH Act, which would have reduced the OSHA PEL for benzene from 10 ppm to 1 ppm. The following excerpts from the Supreme Court's decision⁴ illustrate the principle in issue:

The Agency made no finding that ... any ... empirical evidence, or any opinion testimony demonstrated that exposure to benzene at or below the 10 ppm level had ever in fact caused leukemia.

....

In the end OSHA's rationale for lowering the permissible exposure limit to 1 ppm was based, not on any finding that leukemia has ever been caused by exposure to 10 ppm of benzene and that it will *not* be caused by exposure to 1 ppm, but rather on a series of assumptions indicating that some leukemias might result from exposure to 10 ppm and that the number of cases might be reduced by reducing the exposure level to 1 ppm. In reaching that result, the Agency first unequivocally concluded that benzene is a human carcinogen. Second, it concluded that industry had failed to prove that there is a safe threshold level of exposure to benzene below which no excess leukemia cases would occur. [Emphasis added.]

....

Third, the Agency applied its standard policy with respect to carcinogens, concluding that, in

³ Industrial Union Dept., AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 100 S.Ct. 2844 (1980).

⁴ The Court's decision was based on a plurality of four Justices and later endorsed by a majority of the Justices in American Textile Mfrs. Inst. Inc. v. Donovan, 452 U.S. 490, 101 S.Ct. 2478 (1981) ("Cotton Dust").

the absence of definitive proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer.

....

Fourth, the Agency reiterated its view of the Act, stating that it was required by § 6(b)(5) to set the standard either at the level that has been demonstrated to be safe or at the lowest level feasible, whichever is higher. If no safe level is established, as in this case, the Secretary's interpretation of the statute automatically leads to the selection of an exposure limit that is the lowest feasible.

....

In the absence of a clear mandate in the Act, it is unreasonable to assume that Congress intended to give the Secretary the unprecedented power over American industry that would result from the Government's view of §§ 3(8) and 6(b)(5), coupled with OSHA's cancer policy. Expert testimony that a substance is probably a human carcinogen--either because it has caused cancer in animals or because individuals have contracted cancer following extremely high exposures--would justify the conclusion that the substance poses some risk of serious harm no matter how minute the exposure and no matter how many experts testified that they regarded the risk as insignificant. That conclusion would in turn justify pervasive regulation limited only by the constraint of feasibility. In light of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit.

- c) The courts have also upheld the determination by OSHA that "a standard is technologically infeasible if it cannot be achieved in a typical facility without reliance on respiratory protection in more than a few, isolated operations," United Steelworkers of America v. Marshall, 647 F.2d 1189, 1272 (D.C. Cir. 1980), [or in an excessive portion of the affected worker population]. Public

Citizen v. OSHA , (3rd Cir. 2009). This is the case even if the Agency has determined that employees remain exposed to a significant risk of harm. That policy determination is based on a finding that the harm resulting from widespread use of respiratory protection outweighs the harm posed by exposure to the chemical in issue. That policy was explicitly relied upon by OSHA in setting the PEL for hexavalent chromium at 5 ug/m³ rather than a lower level that could be achieved by greatly expanded use of respirators. While the situation is unclear, it appears there is a significant possibility that this draft rule would violate that well-established policy.

- d) As stated, an OSHA mandate to follow a non-PEL alternative would be invalid. OSHA would impermissibly force compliance with requirements where no significant risk of harm was ever shown to exist or where any significant risk has already been eliminated. The Agency should derive a PEL based on an adequate data set and adopt a PEL-based standard to control occupational exposure to diacetyl, subject to the following alternative.
4. To the extent that a standard is justified, OSHA should offer a non-PEL based alternative to the PEL-based standard for those employers who find it to be more practical or cost-effective for their particular operations. Furthermore, OSHA should make it clear that the employer may use both approaches within a single facility, where practical. This hybrid method would allow an employer to follow the PEL-based approach in one area of the facility, and the non-PEL approach in others.
- a) For example, an employer might prefer to use the PEL-based approach where engineering or work practice controls adequately control exposures so that the employer would not be required to go to the expense of further isolating areas [per non-PEL Section (l)(i)] that do not need further isolation. An employer may also prefer to use the PEL-based approach where the task or activity does not result in exposures above the PEL for 30 or more days per year.

I. A PEL For Diacetyl, A Non-Cancer Respiratory Risk, Should Be Developed On Application of the Benchmark Dose (BMD) Methodology

A. The Reports and Data Bases From Recent Animal And Epidemiology Studies Appear to Provide A Sufficient Data Set For Establishing An Interim OEL For Diacetyl

- 1. Toxicology Excellence for Risk Assessment (TERA) performed an

independent assessment of the current health effects data for diacetyl and an executive summary of its assessment is attached to these comments.⁵ Based on that assessment, TERA determined that the most appropriate measure of the adverse effects of workplace exposure to diacetyl was the inflammation of the tracheobronchial region. Most importantly, TERA determined that a dose-response analysis tied to tracheobronchial inflammation could be developed -- based on a recent subchronic study in mice (Morgan et al., 2008) and supported by a recent cohort study (Lockey et al. 2008) -- and relied upon to develop an OEL for airborne exposure to diacetyl vapors.

2. According to TERA, “the data from these studies identify the same critical effect -- tracheobronchial inflammation -- and converge on a likely OEL range making confidence in establishing an OEL from the database medium to high.” TERA derived its suggested OEL – an 8-hour TWA of 0.2 ppm -- through the well recognized BMD Methodology, which relies on an extrapolation of the health effects from the toxicology data, and addresses the uncertainties of relying on that extrapolation through the application of uncertainty factors.
3. TERA concluded that the data are sufficient to derive an OEL for diacetyl, and that an OEL “developed from the existing database [including the complete data base from the Lockey et al. 2008 study] can be refined as new studies are completed.” The question then becomes how OSHA should proceed where the current data seem to support this suggested OEL, but the body of available data is far less robust than the body of human and animal data OSHA has traditionally assembled and relied on in setting an OSHA PEL.

B. Workplace Exposures To Airborne Diacetyl Are Most Appropriately Regulated By An 8-Hour Time-Weighted-Average (TWA), And Should Not Be Subject To A Short-Term Exposure Limit (STEL).

According to TERA, a study that evaluated and compared the effects of cumulative airborne exposures to peak airborne exposures in rodents, over the course of a day, demonstrated that cumulative exposure is better than peak concentration as a predictor of tracheobronchial inflammation effects (Hubbs et. al. 2008).⁶ TERA also concluded that the tracheobronchial region effects do not appear to progress significantly from subacute to subchronic durations of exposure (Morgan et. al. 2008) and that this finding is supported by the absence of duration of employment effect on pulmonary function testing (PFT) changes reported in the microwave popcorn workers (Lockey et al., 2008). Based on these

⁵ A Current Toxicological Review of Diacetyl : Considerations and Uncertainties for Occupational Risk Assessment.

⁶ Id.

findings, TERA concluded that an OEL based on an 8-hour TWA approach was appropriate and that there was insufficient data to establish a STEL.

C. **OSHA Health Standards Must be Based on the Best Available Evidence**

Without attempting to establish the bounds of the best available evidence for purposes of this rulemaking, we believe it is clear that the best available evidence would include the soon-to-be-released report and the underlying database from the Lockey et al. 2008 study, which we understand has been offered to OSHA, and the two recently completed NTP 90-day animal studies and any other NTP studies, which are under the control of a Federal Government agency cooperative in which NIOSH is a core member and OSHA serves on the NTP Executive Committee.

II. Application of the Basic Principles of the OSH Act to this Draft Regulatory Package

- A. The requirements of a rule must be reasonably necessary and appropriate to protect employees from significant risks.
- B. The burdensome, overlapping, belt and suspenders approach of the ancillary provisions of a traditional substance-specific standard employed by OSHA to address the significant residual risks of exposure from genotoxic carcinogens, such as hexavalent chromium, should not be applied to a chemical, such as diacetyl, for which there is no evidence of carcinogenicity and for which there is a threshold dose below which the exposure is insignificant.
 - 1. **Scope of Covered Chemicals:** There is no data to support the inclusion of acetoin in any PEL-based or non PEL-based standard of the type contemplated by OSHA, and no legal basis for requiring implementation of engineering and work practice controls that would effectively impose a PEL of approximately zero for acetoin.
 - 2. **Medical Surveillance:**
 - a) Requiring medical examinations, every six months, for any employee with exposures above the action level for 30 days or more per year is costly, burdensome and not supported by the literature. Rapid lung function degradation would only result from extreme exposures that would not be permitted by the rule. An employer in gross violation of a PEL is not going to comply with medical monitoring provisions. This misplaced approach of “catching” the lowest common denominator simply imposes

unnecessary costs on responsible employers with no increase in workplace safety. Again, this is a substance with a no effect level; there is no evidence of carcinogenicity.

- b) A PLHCP should be able to determine the required frequency of exams for each individual based on exposure conditions in the workplace and a medical evaluation of the individual.
- c) Exposure monitoring:
 - (i) Once exposure monitoring has demonstrated that any exposures above the action level are stable, there is no reason to require employers to go through the exercise of performing costly, periodic testing to confirm those levels.
 - (ii) The rule should not be designed to impose an economic cost on employers with exposures above the action level as a way of motivating them to try to find ways to reduce exposures so they are no longer subject to expensive exposure monitoring requirements. Again, this is a substance with a no effect level; there is no evidence of carcinogenicity.
 - (iii) There is a provision in the draft standard requiring additional monitoring where there has been any change in the production process, raw materials, equipment, personnel, work practices or control methods that may result in new or additional exposures or when the employer has any reason to believe that new or additional exposures have occurred. That provision would ensure that additional sampling is performed where exposure levels may change, thus avoiding unnecessary and duplicative sampling.
 - (iv) The estimated costs of exposure monitoring are significantly understated in the current SBREFA documents:
 - a. Labor costs for Industrial Hygiene services are underestimated. They appear to be based on sampling 2 workers per 8-hour shift, which underestimates the cost of a true monitoring scenario.
 - b. Time and costs for CIH oversight and review and report writing are underestimated.
 - c. Sample cost is underestimated. Consulting costs vary

across the country and employers in some locations may be disproportionately affected. Consultants are currently reporting costs of \$130 per sample for analysis.

- d. Costs for instrumentation and overhead, travel and expenses are not adequately accounted for. A contract industrial hygienist will require travel reimbursement, which is likely to run from \$500 to \$1000 per trip.
 - e. The cost estimate does not take into account the fact that the Industrial Hygienist will need an escort while on the premises, thus leading to additional "lost work time" of a worker. It is rare that contractors are left completely alone in a manufacturing facility often because of safety. In addition, the work required to complete this monitoring will, at various points in the process, likely require at least two technicians, particularly in a large facility.
 - f. The estimated times spent on record keeping and employee notification are extremely underestimated as the suggested time is 15 minutes per sample. Depending on the PEL, any explanation of values that exceed a PEL will likely require more than a 45 minute time period (which assumed 3 samples per employee to get an 8-hr TWA). Even when values do not exceed the PEL, exposure data will have to be taken from the final contractor report and translated back to a relevant record keeping form for the affected individuals. Furthermore, exposure data will have to be included in the training materials to walk the individuals through their monitoring results as they are presented.
 - g. Most small to medium size employers do not have the ability to solicit multiple labs and consultants to obtain the lowest possible cost and ensure adequate quality of service.
- (v) It is also a serious concern that OSHA the specification of a particular sampling method will discourage the development of new, more accurate and less costly sampling methods, which could only be approved by a follow-up rulemaking. More direct sampling methods utilizing canisters and media that support thermal desorption are showing promise to be more accurate and

more sensitive than the old, retooled methods contemplated by the draft rule.

- (vi) There should also be provisions for short-term sampling methods where employee tasks involving diacetyl last only a few minutes, once or twice a day. Full-shift TWA samples for these employees would be non-productive expenditure of time and resources.
 - (vii) The standard should include provisions for screening airborne levels of diacetyl using portable direct reading instruments such as FTIR, GC-FID and PID's. If these instruments are at least as sensitive as the proposed Silica Gel method and screening yields no detectable levels at the point of operation during tasks with diacetyl, then no further sampling should be required.
- d) **Clothing Requirements:** In the absence of gross clothing contamination, available data do not indicate that the presence of diacetyl on clothing worn at work, whether or not protective clothing, poses any harm to people in the home of an employee who wears or carries the work clothing home. Information from the first SERs conference call on May 19, 2009 indicated that no protective clothing (aside from gloves) is worn or required. The reference to "protective clothing" is also ambiguous where protective clothing is worn for reasons unrelated to diacetyl, but might have been splashed with a trace amount of diacetyl.
 - e) **Engineering controls:** The costs of engineering controls in the PIRFA and TEFA are significantly underestimated. The suggested cost structure does not adequately account for material costs (stainless steel), engineering costs (design, drawings, etc.), explosion venting and obtaining environmental permits (modified air permits).
 - f) **Regulated Areas:** There is a need to recognize these would sometimes be temporary classifications for infrequent activities.

III. To The Extent That A Standard Is Justified, Appropriate Exemptions Are Needed To Avoid Imposing Significant And Unnecessary Burdens

A. Threshold Trigger for Coverage:

- 1. The draft proposed standard would exempt a facility from coverage where "all" employee exposures are below a threshold trigger level (which the draft rule sets at 0.03 ppm as an 8-hour TWA or 0.2 ppm as a 15-minute STEL).

2. Consistent with the approach of OSHA's hexavalent chromium standard (which involved a genotoxic carcinogen), the exemption should be extended to any task, process or activity reliably determined to maintain exposures below the threshold trigger level rather than the all or nothing approach reflected in the draft. We are not aware of any reason for limiting this exemption to situations where no task, process or activity would have exposure levels above the threshold trigger.

B. Bulk Concentration Exemption:

1. In developing its draft standard for diacetyl, Cal-OSHA determined, presumably based on toxicological considerations, that it would exclude flavors containing less than 1% diacetyl, and the TEFA appears to support that exemption.
 - a. That approach is also consistent with the approach of the OSHA Hazard Communication Standard (HCS), which does not require the disclosure of diacetyl levels below 1% unless the chemical manufacturer has evidence that diacetyl could be released at concentrations that could pose a risk to employees.
 - b. In its guidance on the application of the HCS to Food Flavors Containing Diacetyl (FFCD), OSHA states:

Chemical manufacturers and importers of food flavorings containing one percent or more diacetyl must convey information in the health effects section of an FFCD MSDS regarding the human health effects; i.e., that NIOSH has reported that employees exposed to butter flavorings containing diacetyl are at risk of developing occupational lung diseases and that in one instance, similar illnesses have been found among employees producing butter and vanilla flavorings containing diacetyl. Finally, these MSDSs must convey that contact with liquid or vapors can cause irritation to the skin, eyes, nose, and throat.

Chemical manufacturers and importers of any food flavoring containing one percent or more diacetyl must convey in the health effects section of the FFCD MSDS the hazard information regarding diacetyl from the animal studies previously discussed. They must also consider other available health effects information for all components greater than one percent, convey that information on the FFCD MSDS, and include appropriate hazard warnings on the labels.

2. As clearly stated during the first SERs conference call on May 19, 2009, there are also serious underlying hazard communication issues facing purchasers of flavors. Few flavor manufacturers currently disclose all potentially hazardous flavoring chemicals on MSDS. A review of current MSDS reveals that many flavor companies list serious hazards linked to the ingredients in their products, such as serious lung hazards and cancer, without disclosing the name of the chemical(s) posing that/those hazard(s). Some of our members have received MSDS for flavors in which the hazardous ingredients section has up to one-half dozen "trade secret" entries to let the purchaser know there are up to one-half dozen unnamed hazardous ingredients. Some flavor manufacturers will disclose chemicals upon request. Some flavor manufacturers will disclose chemicals only after signing confidentiality agreements prepared and/or reviewed by legal counsel. This process is very time consuming and resource intensive, especially with formulations changing on an ongoing basis. In addition to being resource intensive, at times it is likely to be very difficult to protect employees from unknown chemicals.

IV. Conclusion

The occurrence of the cluster of lung obstruction cases among workers at microwave popcorn plants identified in the year 2000, and the initial absence of a responsible regulatory response, have led to a situation in which the political demand for action on this issue is ahead of the science needed to responsibly develop an appropriate standard. The science is beginning to catch up, but the data currently in OSHA's hands is inadequate to support the adoption of a comprehensive standard of the type contemplated by the draft distributed to the SERs. The databases underlying the Morgan et al. 2008 and Lockey 2008 et al. studies appear adequate to formulate a useful OEL, but we believe OSHA should wait for the analyses of the completed NTP studies.

If OSHA should elect to proceed with rulemaking without waiting for the analyses of the NTP studies, we believe it should adopt an interim rule applicable only to the two industrial sectors for which the current data appear to establish a significant risk of harm from exposure to diacetyl and flavorings containing diacetyl. They are concentrated flavor compounding and the manufacture of microwave popcorn with flavoring containing high concentrations of diacetyl. Thank you for your consideration of these comments.

Attachment: Executive Summary from TERA's *Current Toxicological Review of Diacetyl: Considerations and Uncertainties for Occupational Risk Assessment, 5.15.2009*

Attachment D – Report “A Current Toxicological Review of Diacetyl: Considerations and Uncertainties for Occupations Risk Assessment”

**Attachment D – Report “A Current Toxicological Review of Diacetyl:
Considerations and Uncertainties for Occupations Risk Assessment”**

**A Current Toxicological Review of Diacetyl:
Considerations and Uncertainties for
Occupational Risk Assessment**

Developed by:

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May 26, 2009

A Current Toxicological Review of Diacetyl: Considerations and Uncertainties for Occupational Risk Assessment

Executive Summary

As knowledge about an occupational exposure risk matures there is a transition from a hazard-based risk management approach to the use of a health-based occupational exposure limit (OEL). This transition requires data that support concentration-response analyses. The health effects data for diacetyl were critically evaluated and key issues, uncertainties, and future research directions related to the occupational risk assessment needs were identified. Overall the data are sufficient to derive an OEL for diacetyl.

Examination of the health effects literature led to the consideration of several possible health effects as the basis for developing an OEL. Potential adverse effects and the conclusions regarding their use as the basis for identifying a point of departure for developing an OEL are as follows:

- Upper respiratory tract (e.g., nasal) irritation/inflammation. Acute and subchronic studies in rodents indicate that the upper respiratory tract is a significant target for the effects of diacetyl vapor exposure. The nasal inflammation and histopathology findings generally occurred at lower concentrations and shorter exposure durations than effects in more distal portions of the respiratory tract in rats and mice. However, rodents are obligate nose breathers and have very different nasal morphology than humans. Moreover, the existing case reports in workers provide very inconsistent reports of nasal irritation, suggesting that this is not a clear critical effect in humans. In addition, there is no reliable concentration-response information for evaluation of such effects in humans. Due to these considerations, rodent nasal inflammation is not the most appropriate choice as the point of departure for OEL development.
- Tracheobronchial irritation/inflammation. A subchronic inhalation study in mice (Morgan et al., 2008) is available that provides concentration-response information for sensitive indicators of inflammation of the tracheobronchial region (mild peribronchial lymphocytic inflammation). This finding is consistent with the qualitative evidence of tracheobronchial effects such as cough and breathing symptoms in several case series (e.g., Rose et al., 2007), as well as more rigorous functional measures such as decreased performance in pulmonary function tests in a cohort study (Lockey et al., 2007). The animal and human data are concordant and the animal data provide adequate concentration-response information to support OEL development. The findings in rodents demonstrate that over the course of a single exposure day cumulative exposure is better than peak concentration as a predictor of adverse tracheobronchial effects (Hubbs et al. 2008). The implication of this for developing full-shift time weighted average (TWA) versus a short-term exposure limits (STEL) is discussed below. The tracheobronchial region effects do not appear to progress significantly from subacute to subchronic durations of exposure (Morgan et al., 2008). Consistent with this finding, there was no impact of duration of employment on pulmonary function testing (PFT) changes reported in the microwave

popcorn workers (Lockey et al., 2007). These data suggest that an OEL based on an 8-hr time-weighted average (TWA) approach extrapolated from subchronic exposure data is appropriate for this endpoint.

- Fibrotic Diseases of the bronchial region (e.g., bronchiolitis obliterans). The only available longer-term inhalation study in animals is the subchronic study in mice discussed in the previous bullet (Morgan et al., 2008). No evidence of fibrotic disease was reported in that study following exposure to vapor concentrations that resulted in marked inflammatory and histopathology effects. Moreover, the results of Hubbs et al. (2008) in rats shows increasing severity of effects more distally in the respiratory tract with increasing cumulative daily dose. This result suggests that for cumulative vapor exposures the tracheobronchial effects associated with mild irritation will occur at concentrations below those that are associated with severe effects (including fibrosis). Thus, preventing exposures that generate mild tracheobronchial irritation (and initial symptoms) would be expected to protect against fibrotic disease for cumulative exposures. In contrast, the same study (Morgan et al., 2008) found that aspiration of diacetyl aerosols (presumably generating large local doses in distal portions of the tracheobronchial region) generated a rapid fibrotic response in mice. This finding in mice is supportive of the conclusion that diacetyl might contribute to bronchiolitis obliterans in workers. However, in considering the data related to bronchiolitis obliterans in food flavoring or microwave popcorn industries, there are significant uncertainties regarding the diagnosis as well as in determining the appropriate measure of dose and exposure scenario (role of peak versus cumulative exposures as well as role of vapor versus particulate exposures). The absence of a correlative finding in mice following inhalation exposure, as well as the unavailability of concentration-response data related to the human case reports, limits the use of the findings from the human case reports as a quantitative basis for OEL development. Due to the potential role of peak exposures, the traditional use of excursion limits as a supplement to a TWA-based OEL for control of very high peaks exposures might further mitigate the potential for a fibrotic effect.
- Systemic target organ effects. The available longer-term inhalation studies were limited to evaluations of the respiratory tract. Oral dosing studies can provide qualitative hazard information regarding the potential for extrapulmonary effects. In a subchronic oral dosing study in rats (Colley et al., 1969), the only effects were observed at high doses (540 mg/kg-day), and were related to inflammation of the gastrointestinal tract, generalized inflammation (increased leukocyte count) and decreased body weight. Studies in rats and hamsters conducted by FDA (1973) did not identify any developmental effects. These studies suggest that the portal of entry is the primary target site for diacetyl, indicating that an OEL based on respiratory tract effects would be protective of systemic effects from inhalation exposure.
- Other effects. No data regarding potential respiratory sensitization effects from inhalation were identified. The results from a recent mouse local lymph node assay (Anderson et al., 2007) suggest that diacetyl is a potential skin sensitizer following

dermal application. This finding is consistent with the biochemical properties (ability to bind to amino acid residues) of diacetyl. Although the data are limited to a single assay, such information informs the assignment of hazard notations, and it might be prudent to include a notation (DSEN) until additional data are available.

A key consideration in developing an OEL is the appropriate dose-metric for the effects of concern. For diacetyl, this translates to the question of whether toxicity is driven by peak or cumulative exposure (or both). Hubbs et al. (2008) conducted a series of studies in rats to address this question, by comparing the histopathology effects of comparable TWA concentrations, resulting from either continuous exposure or a series of 15-minute pulses. They found that, for a given TWA, toxicity of the two exposure regimes was comparable, supporting the conclusion that the TWA is the primary determinant of toxicity for short exposures. However, as noted in the context of uncertainty factors (discussed below), little to no progression was seen between 6 and 12 weeks of exposure in a mouse study (Morgan et al., 2008), indicating that exposure concentration, rather than cumulative exposure, dominates toxicity at longer exposure durations. Conversely, peak exposures might be expected to play some role at very high concentrations that lead to altered kinetics of uptake and distribution in the nose. However, there is no current quantitative basis to determine at what concentrations peak exposure plays a role, and therefore what the appropriate concentration is for a short-term exposure limit (STEL). Alternatively, hybrid computational fluid dynamic (CFD)-physiologically based pharmacokinetic (PBPK) modeling, such as done by Morris and Hubbs (2009), could be used to address the issue. Overall, it is reasonable to conclude that regular high peak exposures that generate a significant daily cumulative dose are a concern for inducing tracheobronchial inflammation. However there are not adequate concentration-response data to develop a quantitative exposure limit for infrequent short-term exposures apart from evaluating the resulting cumulative daily exposure. Thus, to be prudent, control of high exposure excursions using generally accepted industrial hygiene practices is appropriate.

The hazard characterization and evaluation of potential endpoints and dose metrics suggests that a concentration-response analysis could be developed for TWA exposure to diacetyl vapors based on tracheobronchial inflammation in the subchronic study in mice (Morgan et al., 2008) and supported by the cohort study by Lockey et al. (2007). The results of Morgan et al. (2008) suggest that exposures as low as 25 ppm increased the incidence of peribronchial lymphocytic proliferation, which was the most sensitive, sustained tracheobronchial effect that increased in severity and incidence in a treatment-related manner. More severe involvement of the peribronchial epithelium, extending to the peribronchiolar epithelium, also occurred at the highest concentration of 100 ppm. The degenerative epithelial changes as well as measures of overall toxicity (decreased body weight) identify 100 ppm as a clear lowest-observed-adverse-effect-level (LOAEL) for this study. The discrimination of the transition point from a No-Observed-Adverse-Effect-Level (NOAEL) to a LOAEL is difficult and depends on the degree to which the minimal to mild lymphocytic inflammation would be considered adverse (i.e., result in functional impairment or affect the ability of the animals to respond to further exposure).

The concentration response data were adjusted to human equivalent exposures using EPA methods (U.S. EPA, 1994) and refined by the computational fluid dynamics model developed for

diacetyl for rats and humans (Morris and Hubbs, 2009). In brief, the concentrations used in the subchronic mouse study were converted to a TWA equivalent exposure for 8 hours per day and 5 days per week to derive a duration-adjusted concentration. The regional gas dose ratio (RGDR) for the tracheobronchial region was calculated using the EPA default equations for a category 1 (reactive) gas based on species-specific minute volumes and regional surface areas, without accounting for the effect of removal of diacetyl from the airstream (scrubbing) in the upper respiratory tract (URT). This latter consideration of URT scrubbing was addressed using the ratio of the relative concentration of diacetyl exiting the trachea modeled for the rat and human exposed to 100 ppm diacetyl (Morris and Hubbs 2009). At 100 ppm, Morris and Hubbs (2009) reported that the concentration exiting the trachea was 61 ppm in rats; in humans the concentration was 79 ppm for nose breathing and 96 ppm for mouth breathing (average 87.5% penetration). The human value was based on the average of concentration predictions for mouth and nose breathing. Thus, the adjustment to the human equivalent concentration calculated using the EPA default equations was the ratio of the percent penetration, or $0.61/0.875 = 0.70$. Although the modeling was available for rats and not mice, such data were considered a better estimate of potential URT uptake differences between humans and rodents than the default equations used in the EPA model.

The concentration response was determined using benchmark concentration (BMC) modeling (U.S. EPA 2000) to estimate a concentration (the BMC_{10}) associated with a 10% extra risk of peribronchial lymphocytic inflammation (of minimal severity or greater) and a 95% lower confidence bound concentration estimate (the $BMCL_{10}$). The predicted BMC_{10} and $BMCL_{10}$ were 33 mg/m^3 (9 ppm) and 9 mg/m^3 (2 ppm), respectively. This $BMCL_{10}$ of 2 ppm for sensitive tracheobronchial effects in mice is similar to the approximate cut point for observed pulmonary function decrements reported by Lockey et al. (2007) in their analysis of workers in four different plants, providing greater confidence in the relevance of the effect level derived from the toxicology data.

The typical practice in developing OEL recommendations is to identify an effect level or concentration for the most sensitive relevant adverse effect as a "point of departure" and then apply factors to address uncertainties in extrapolation from the identified effect levels. For this evaluation, mild tracheobronchial irritation (peribronchial lymphocytic inflammation) identified in a subchronic mouse study (Morgan et al., 2008) is the basis for the point of departure. Key areas of uncertainty typically considered in such analyses are as follows:

- Interspecies differences (UF_A). This factor accounts for toxicokinetic and toxicodynamic differences between the test species and the average human. In light of the application of dosimetry adjustments to address kinetic differences (see above), the remaining consideration is the magnitude of toxicodynamic differences. A central starting point with regard to toxicodynamic differences is whether the effect seen in animals is representative of the types of effects of concern in humans. As discussed in greater detail above, the tracheobronchial effects (including inflammation, cytotoxicity, and fibrotic effects) seen in rodents are considered relevant to humans, and the toxicodynamic responses in the tracheobronchial region of mice are reasonably concordant with those of humans in qualitative terms. Although the data are not adequate for quantitative evaluation of the toxicodynamic differences, a factor of 3 for differences in

toxicodynamics is generally considered appropriate for extrapolation from animal data. For assessments based on human data a factor of 1 is appropriate. In this case, a factor of 3 is used to extrapolate from the effect level in animals, in the absence of sufficient data to derive a chemical specific adjustment for toxicodynamic considerations.

- Human variability (UF_H). This factor addresses the need to extrapolate from the average human response to cover potential sensitive individuals. Current occupational risk assessment practice reflects the perspective that health-based exposure guidance should protect the majority of the worker population, but not necessarily hypersensitive individuals. For example, this perspective is reflected in the description of the ACGIH TLV[®] or AIHA WEEL as protecting “nearly all workers.” Similarly, OSHA PELs are typically based on weighing risk management considerations that result in some residual risk, reflecting this general approach/concept. A priori, one might expect that smoking would contribute to sensitivity. However, epidemiology data (Rose et al., 2007) suggest that both smoking and diacetyl exposure generate effects consistent with tracheobronchial toxicity, but that the sensitivity of smokers to the effects of diacetyl exposure does not differ markedly from that of nonsmokers. Genetic variability that can contribute to airway reactivity and asthma and that determines differences in lung fibrotic diseases may also result in individual sensitivity (reviewed in Grutters and du Bois, 2005), but the impacts of such variability is a common consideration for respiratory toxicants and is difficult to quantify. Some of these genetic factors would be more relevant for consideration of potential hypersensitive individuals. Finally, it is unclear whether diacetyl would be a cause of asthma or increase symptoms in asthmatic individuals. An increased prevalence of asthma was reported in food flavoring production workers exposed to diacetyl (Rose et al., 2007). However, the reason for this increase has not been adequately evaluated in human populations.

Occupational assessments apply to only a subset of the population; thus a factor of 3 is typically applied to account for variability in human for assessments based on animal studies. When extrapolating from a human study the need for a factor depends on the relevance and representativeness of the studied population to the intent of the OEL. A factor of 1 would be appropriate when extrapolating from a robust epidemiology study of a diverse worker population as was completed by Lockey et al. (2007). Based on the effects of diacetyl, there is no reason to expect that the default approach is not adequate and a factor of 3 is used to account for human variability when extrapolating from the effect level from the mouse subchronic study (Morgan et al., 2008).

- Extrapolation from a LOAEL (UF_L). A factor of 1 is appropriate for extrapolation from a NOAEL, a threshold estimate from human data, or a $BMCL_{10}$. The $BMCL_{10}$ is a surrogate that is comparable, on average, to NOAELs from animal studies and provides a lower bound (health protective) estimate on the threshold for an increased incidence of tracheobronchial effects. Although the BMC_{10} is an estimate of the concentration resulting in a 10% response (not a 0% response) in the animal study, statistical analyses of study sensitivity and the power of typical study designs have found that the $BMCL_{10}$ corresponds on average to the NOAEL determined for that study. Note, however, that this calculation is specific to the modeled study data, and does not take into account

interspecies differences or other considerations addressed by the uncertainty factors discussed here, and so the percentage of risk in a human population cannot generally be determined directly from the BMCL₁₀ in an animal study.

- Extrapolation from a shorter-term study (UF_S). This factor addresses the possibility that with longer-term exposure the effective concentration might decrease. In the absence of a chronic study the selection of this factor depends on evidence for effect progression. The absence of increased severity of the tracheobronchial effects following exposure for 6 versus 12 weeks (Morgan et al., 2008) indicates there is little effect progression with repeated exposures. This finding is consistent with the results of Lockey et al. (2007) who found no progression of effects with exposure duration in a prospective study design. These data suggest that a factor of 1 is appropriate for extrapolation from the subchronic study in mice to address the potential effects of chronic exposure.
- Other deficiencies in the database (UF_D). This factor addresses the concern that with the addition of new data a more sensitive effect would be identified. The data are compelling that the respiratory tract is the most sensitive target for diacetyl inhalation exposure. When data for the critical target and sensitive (or most relevant) species are available, a factor of 1 is considered appropriate, and so is recommended here. It is noteworthy, that there are ongoing robust inhalation studies in mice and rats being conducted by the National Toxicology Program (NTP, 2009). There is no reason to expect that these studies will yield results dramatically different from those reported by Morgan et al. (2008). However, the results of such studies would add to the robustness of the overall database (particularly in providing a longer-term study in a second species), and should be considered in modification of the OEL derivation when available.

The development of an OEL recommendation includes identifying potential adverse effects, analyzing the concentration response profiles for the sensitive effects to estimate a point of departure, and applying uncertainty factors to account for uncertainties in extrapolation. The data for diacetyl are sufficient to complete this process. Based on the current data an OEL can be derived for diacetyl vapor based on the tracheobronchial region effects in mice reported by Morgan et al. (2008) as follows:

Point of Departure: BMCL₁₀ of 2 ppm for mild peribronchial inflammation

Composite UF: 10

OEL Recommendation: 0.2 ppm vapor as an 8-hr TWA, with a DSEN notation

This OEL derived from the mouse inhalation study is consistent with the concentration-response for decrements in pulmonary function test performance reported by Lockey et al. (2007) in four microwave popcorn plants after accounting for additional uncertainties related to potential human variability in response and the consideration that the average exposure duration in the cohorts was less than a full working lifetime.

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Appendix D

Preliminary Initial Regulatory Flexibility Analysis (PIRFA) and Draft Proposed Standard for Diacetyl and Food Flavorings Containing Diacetyl

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**PRELIMINARY INITIAL REGULATORY FLEXIBILITY ANALYSIS
OF THE DRAFT PROPOSED STANDARD FOR OCCUPATIONAL EXPOSURE
TO DIACETYL AND FOOD FLAVORINGS CONTAINING DIACETYL**

Office of Regulatory Analysis
Directorate of Evaluation and Analysis
Occupational Safety and Health Administration
U.S. Department of Labor
April 20, 2009

Introduction

OSHA has initiated rulemaking that could lead to a comprehensive health standard to address potential occupational hazards associated with exposure to diacetyl and food flavorings containing diacetyl. The proposed rule should ensure that the regulatory requirements are effective in reducing potential risks and do not impose any unnecessary burdens on employers. To that end, OSHA will invite public comment on the proposal together with a preliminary analysis of its impact and will base any final rule on the best available evidence in the entire rulemaking record.

OSHA also will develop an Initial Regulatory Flexibility Analysis (IRFA) to accompany the proposal that describes the potential impacts of the proposal on small businesses. As noted in the Regulatory Flexibility Act (5 U.S.C. 601 et. seq.), an IRFA must contain the following elements:

- 1) a description of the reasons why action by the Agency is being considered;
- 2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- 3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- 4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- 5) an identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule; and
- 6) a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities.

In addition to the information and comments solicited from all interested parties in response to the proposal and its accompanying documents and analyses, OSHA has a particular interest in identifying and responding at an early stage in the rulemaking to concerns of potentially affected small businesses and other small entities. Thus, as part of this rulemaking, prior to the publication of the proposal, OSHA is convening a Small Business Advocacy Review Panel (SBARP) in accordance with Section 609 of Title 5 of

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the United States Code. The SBARP process enables OSHA, with the assistance of the Chief Counsel for Advocacy of the Small Business Administration, and with the assistance of the Office of Information and Regulatory Affairs in the Office of Management and Budget, to obtain advice and recommendations from affected small entities about the potential impacts of the proposal.

This Preliminary Initial Regulatory Flexibility Analysis (PIRFA) has been prepared to aid in the SBARP process. The IRFA for the proposal will discuss the Panel's recommendations and OSHA's responses to those recommendations. The next section of this PIRFA provides a summary of the proposal. The remaining sections respond to the requirements of the Regulatory Flexibility Act. OSHA emphasizes the preliminary nature of the preliminary draft standard and analyses included in this document. At this preliminary stage, it should be noted that there are numerous uncertainties in the preliminary health risk and economic analyses. The uncertainties with respect to health risks are noted and discussed in the Risk section of the PIRFA. Uncertainties with respect to the economic analysis are discussed in the appropriate section, with Table 9 summarizing some of the uncertainties with respect to potential costs. OSHA, through the SBARP process and other steps throughout the rulemaking, will be soliciting comment and additional data and will continue to refine its analyses to fully address these uncertainties.

Summary of the Draft Proposed Standard for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

Introduction

OSHA has initiated rulemaking to protect employees from the adverse health effects associated with flavorings containing diacetyl. Given the unique challenges that OSHA has encountered in investigating and evaluating these hazards, the Agency is considering traditional and non-traditional means of regulating employee exposures. A traditional approach would include a permissible exposure limit (PEL) for diacetyl while a non-traditional approach could rely exclusively on process-specific requirements for engineering controls, exposure monitoring, exposure control planning, and respiratory protection to reduce exposure to flavorings containing this chemical.

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In an approach consistent with the majority of the Agency's previous standards that regulate chemical hazards, OSHA is considering setting a PEL for diacetyl. A number of occupational investigations found adverse respiratory effects from exposure to flavorings containing diacetyl during their manufacture and during their use in the production of microwave popcorn. The Agency is considering several PEL options based on diacetyl exposures associated with the elevated occurrence of respiratory disease in these studies. Data from investigations that are currently underway may also assist the Agency in selecting appropriate PELs.

A standard containing a PEL would be performance-oriented and allow employers to determine the appropriate methods to reduce and maintain employee exposures below the PEL. As in previous standards regulating chemical hazards, a PEL-based rule would require that employers implement engineering controls as a primary means of reducing exposure. A PEL-based standard would also include provisions for exposure monitoring, medical surveillance, personal protective equipment (PPE), hygiene areas and practices, recordkeeping, housekeeping, hazard communication, and prohibited practices.

The Agency is also considering a regulatory approach that would not include PELs, and would instead require specific control measures for operations and processes found to be associated with the occurrence of flavoring-related lung disease. Such a standard would require the implementation of engineering and work practice controls that are known to decrease exposure to diacetyl and other volatile flavoring chemicals. This approach is supported by the reduced diacetyl exposures and lower prevalence of respiratory effects among employees following implementation of engineering and work practice controls at a microwave popcorn facility. The California Division of Occupational Safety and Health (Cal/OSHA) is currently considering a similar, process-driven rule as a means of regulating exposures to flavorings. In regulating safety hazards, as opposed to health hazards, OSHA typically relies on specified engineering and work practice controls rather than a performance oriented approach. Thus, the development of a process-driven standard would not be novel for the Agency.

There are advantages associated with each of the approaches under consideration. A process-driven standard would require a sound industrial hygiene program that specifies control methods and work practices recommended by the National Institute of Occupational Safety and Health (NIOSH) and shown to be effective at reducing

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exposures. A PEL-based standard allows greater flexibility in the methods used to achieve exposures below the PEL and may be less likely to impose costly engineering controls where they may not be needed.

OSHA has normally used a PEL-based approach for health standards because, in general, it is the most cost-effective method of protecting employees in the sense that it results in the lowest costs for limiting exposures to any given level in most situations. Two factors account for the cost effectiveness of the PEL approach. First, a PEL-based approach assures that all employees above a given exposure level are subject to controls, while exposures below that level are not required to be controlled. Under a non-PEL approach, specified engineering controls would be used to reduce employee exposures only for those processes found to be associated with the occurrence of flavoring-related lung disease. This type of approach may miss some employees whose exposures would warrant controls if the process where they work is not one of the identified processes subject to the rule. Also, requiring controls based on the type of process rather than the level of exposure may result in a requirement for controls in some situations in which exposures do not represent a significant risk to employees. Additionally, a PEL-based approach allows employers to select the most effective and least costly ways of achieving a PEL, while the non-PEL approach requires all employers to implement a specified set of controls in all affected workplaces.

The relative cost of the two alternate approaches for small businesses depends on the specific requirements of each approach and the current exposure and control situation in the workplace. For example, a non-PEL approach may impose higher costs than a PEL approach if a firm uses diacetyl in a limited way and already has other controls in place so that no exposures occur above a given PEL. Such firms may incur programmatic costs they would not otherwise, or be required to install additional controls. On the other hand, a PEL approach may impose greater costs than a non-PEL approach if more extensive controls are necessary than would be required under the non-PEL approach. More generally a PEL-based approach would be much less expensive than a non-PEL approach if few exposures exceed the PEL, and a non-PEL approach may be less expensive (but also less protective) if requirements for engineering and other controls are not as extensive as would be necessary to achieve a given PEL. In the discussion of the provisions of these two approaches that follows, OSHA has attempted

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to identify the situations in which the cost-effectiveness of those provisions may differ.

OSHA welcomes comments from the small business representatives on the merits of the two approaches described above as well as any reasonable alternative approaches to addressing occupational exposure to diacetyl and food flavorings containing diacetyl. OSHA is also interested in obtaining information describing processes where flavoring containing diacetyl are used as well as any information regarding employee exposures and methods used to control those exposures. Of particular interest are work settings where flavorings containing diacetyl are used in the manufacture of foods. Such information will help the Agency to better define and refine approaches currently under consideration, to describe potential impacts, as well as to identify other alternatives that might better realize the goal of reducing the health risks associated with exposures to flavorings containing diacetyl.

The following discussion describes the types of work settings/facilities that would be covered under both the PEL and non-PEL approaches and outlines the different provisions that would apply for each approach. OSHA has developed two alternate draft regulatory texts as a side-by-side comparison document to help readers better understand the differences between these two distinct approaches and thus be able to provide better comment.

Under both the PEL and the non-PEL alternatives, switching to flavorings that do not contain diacetyl would move an employer out of the scope of the standard, and the employer would not be required to do anything more. However, as discussed in the Alternatives section of this PIRFA, OSHA is concerned with the possible hazards of some substances included in flavor formulations other than diacetyl. As a result, OSHA is considering possible alternatives that might cover flavorings containing diacetyl substitutes and other compounds in butter and related flavorings if they are found to contribute to flavorings-related lung disease. Adoption of such an alternative would mean that substitution would not necessarily remove the employer from the scope of a flavorings standard. In any case, those considering substitution as a mechanism for avoiding this regulation should make inquiries concerning the substitutes used and carefully consider the possible hazards associated with such substitutes.

I. Scope and Application

The scope of both PEL and non-PEL approaches may be restricted to food and flavoring industries and establishments. Specifically, both approaches would probably apply to occupational exposures to flavorings containing diacetyl in the following settings:

- Industries and establishments that manufacture flavorings; and
- Industries and establishments that manufacture food products.

One important reason for focusing the scope of the draft proposed standard on these industries is that the Agency has the best information about exposures, processes, and costs in these settings, and these are the settings where adverse respiratory effects have been observed.

Additionally, in a standard that is process-driven rather than PEL-based, the Agency would need information about specific exposure scenarios to impose effective engineering and work practice controls. For these reasons, “industries and establishments that manufacture flavorings” is not intended to cover cooks in restaurant and cafeteria kitchens who make their own flavorings, as little is known about this category of exposures. Similarly, the “manufacture of food” is not intended to cover cooks or food handlers in restaurants or institutions such as hospitals and schools.

The Agency’s definition of flavorings containing diacetyl would reflect the Food and Drug Administration’s definition of *flavoring agents or adjuvants*, which are defined as “substances added to impart or help impart a taste or aroma in food.” The Agency is considering whether “taste” should encompass substances used to impart a texture.

Pure diacetyl would fall within this definition, when used to impart or help impart a taste or aroma in food. Thus defined, “flavorings containing diacetyl” refers to the same set of substances as “diacetyl.” However, the Agency is using the slightly longer phrase, “flavorings containing diacetyl,” in reference to the intended scope of the section, which limits the section to industries and establishments that manufacture flavorings or food products. The term “flavorings containing diacetyl” would include items such as “butter starter distillate,” which is listed as a separate flavor by FDA, and contains mostly water, but may contain as much as 5% diacetyl, and in which diacetyl is the primary flavor component.

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A mixture containing diacetyl, produced to provide fragrance to a non-food product, would not be considered a *flavoring containing diacetyl*. (See the Alternatives section for discussion of an alternative that would include fragrance mixtures in the scope of the draft proposed standard.)

Although diacetyl occurs naturally in a range of foods, naturally occurring diacetyl, like the synthetic equivalents, would fall within the scope of this section only if used in the manufacture of flavorings, or if it constitutes part of a flavoring used in manufacturing food items.

Both PEL and non-PEL approaches might include a provision exempting any employer that is able to demonstrate that employee exposures to diacetyl will not exceed a threshold airborne concentration (hereinafter “the scope threshold”) under any expected conditions of use. In the context of a PEL or non-PEL approach, the scope threshold provision will ideally exempt a category of exposures that are well below levels that have been associated with adverse effects. The Agency has provisionally chosen a scope threshold for diacetyl of 0.03 ppm for an eight-hour time weighed average (TWA). Until recently, this air concentration represented the reliable quantitation limit (RQL) using OSHA's analytical methods. Eight hour TWAs below 0.03 ppm have not been associated with adverse health effects, with the exception of one investigation at a microwave popcorn plant where peak exposures reached approximately 80 ppm, and where environmental conditions of high humidity may have biased the NIOSH analytical method that was used to measure diacetyl. OSHA's new more sensitive analytical methods, which the Agency has validated, have RQLs of approximately 0.001 ppm for analytical Method 1012 and 0.01 ppm for analytical Method 1013 for an eight-hour TWA. The Agency may choose a scope threshold below 0.03 ppm, if evidence indicates that a lower threshold is warranted.

II. Permissible Exposure Limits

The Agency is considering a range of potential PELs for diacetyl. These values are based on OSHA's initial analysis of the information that is available concerning the health effects associated with exposure to flavorings containing diacetyl. In the section entitled, “Reasons Why Action by the Agency is Being Considered,” the Agency provides a preliminary description of the available data.

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Based on the existing data describing health outcomes associated with diacetyl and flavorings containing diacetyl, OSHA is preliminarily considering the following PELs:

- The employer shall ensure that no employee is exposed to an airborne concentration of diacetyl in excess of the PEL of (0.05, 0.1, 0.5, or 1.0) ppm as an 8-hour TWA or a Short-Term Exposure Limit (STEL) of (0.2, 0.5, 2.0, or 4.0) ppm (during a 15 minute period).

OSHA is considering short-term exposure levels as well as 8-hour TWAs, because evidence suggests that both cumulative and peak exposures increase risk for adverse respiratory effects.

At the low end of the range stated above, a PEL of 0.05 ppm as an 8-hour TWA describes a level below which there is little evidence that exposures cause adverse health effects. Until recently, a 15-minute STEL of 0.2 ppm is believed to be the lowest short-term exposure level at which diacetyl could be reliably measured by the analytical methods. The new more sensitive analytical methods 1012 and 1013 have RQLs well below 0.2 ppm for a short-term sample collected over 15 minutes. OSHA may consider a STEL below 0.2 ppm, if evidence indicates that a lower limit is warranted.

At the high end of the range above, a PEL of 1.0 ppm as an 8-hour TWA and a 15-minute STEL of 4.0 ppm are likely to be associated with respiratory impairment. However, it is possible that these levels will prove to be the lowest that are both technologically and economically feasible. PELs and STELs between the high and low end of the specified range might also prove appropriate, when risk and feasibility analyses are refined.

III. Exposure Assessment

a. PEL Approach

A PEL approach would require exposure assessment similar to that required under other OSHA standards regulating chemical hazards. Thus, 8-hour TWA and 15-minute short-term sampling would be required for each employee exposed to flavorings containing diacetyl. Additional monitoring would be required at specified frequencies depending on the level of employee exposure. Employers would be required to notify employees when sampling indicates that the PEL has been exceeded, and would be

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required to notify employees of corrective actions taken. Employers would be required to ensure that employees and their representatives have the opportunity to observe exposure monitoring. Additionally, employers would be allowed to use representative sampling or objective data to evaluate similar employee exposures.

b. Non-PEL Approach

Exposure assessment would also be required under the non-PEL approach. Despite the absence of an exposure limit, exposure assessment comprises a potentially important aspect of a process-driven standard. Initial monitoring would identify sources of exposure within the workplace and assist the employer in selecting exposure control methods. Ongoing monitoring would allow the employer to determine whether the engineering controls remain effective in controlling exposures. Employers might be required to conduct additional exposure assessments when methods of production, processing, equipment, or practice change in ways that are likely to increase exposure, and when employees are diagnosed with flavoring-related disease. As with a PEL-approach, employers would be allowed to use representative sampling or objective data to evaluate similar employee exposures. As in a PEL approach, provisions for employee notification and observation of monitoring would be included. Requirements for TWA and short-term monitoring, and accuracy of measurement method, would be the same in PEL and non-PEL approaches.

IV. Exposure Control Plan

a. PEL Approach

A PEL-based standard would not require a written exposure control plan, though the other provisions in the PEL-based standard would include many of the obligations that the components of a written exposure control plan is designed to cover. Nonetheless, with respect to the obligation to create a written control plan, a PEL approach would be less burdensome, as it would omit this requirement.

b. Non-PEL Approach

A non-PEL approach would require employers covered under the standard to create a written exposure control plan. An exposure control plan would need to describe:

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- Work operations and sources of emission where exposure to flavorings containing diacetyl occur or are likely to occur (as identified through the required exposure assessment);
- Regulated areas, and methods of demarcation;
- Engineering and work practice controls already in use;
- The effectiveness of engineering and work practice controls in use;
- A leak prevention, detection, and repair procedure;
- A timeline for engineering and work practice controls yet to be implemented;
- The required personal protective equipment, including respirators, and the work areas in which the use of such equipment is required;
- The employee exposure monitoring program, as required by the exposure assessment section;
- Procedures for clean up; and
- Emergency procedures.

The Agency believes that a written control plan will be more appropriate and beneficial in a non-PEL approach than in a PEL approach. First, compliance with the exposure control plan under the non-PEL approach, especially the central engineering and work practice control requirements, will require sophisticated planning and ongoing review. OSHA believes that written documentation will help to ensure that all the required elements of the exposure control plan have been implemented fully and are working effectively. Second, it will be important for employers to gather ongoing feedback concerning the functioning of central engineering controls and the levels of exposure among employees to determine whether additional measures or changes in the plan are necessary. A written exposure control plan will encourage frequent systematic assessment of the plan, which will generate important feedback information. OSHA welcomes comments and suggestions on the exposure control plan requirements and whether the Agency should include the same provisions in a PEL approach standard.

V. Regulated Areas

The designation of regulated areas is a relatively simple and efficient

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administrative method of isolating employees from activities or processes that generate exposures to toxic chemicals. Regulated areas are meant to demarcate areas where significant exposure is likely and the use of PPE is required.

a. PEL Approach

A PEL approach would establish regulated areas wherever employees' exposure could reasonably be expected to exceed the PEL. Demarcation of the boundaries would be required to alert employees of the hazard, and access would be limited to persons authorized and required to be present in the area. Designated representatives would also be allowed to enter to observe monitoring procedures.

b. Non-PEL Approach

A non-PEL approach would establish regulated areas by operation. For example, regulated areas might be required when employees pour, weigh, mix, or bag flavorings containing diacetyl, and when they engage in processes that generate exposures similar to those that occur during pouring, weighing, mixing, transferring, spraying, and bagging. Although provisions describing demarcation and access to regulated areas would be largely the same under PEL and non-PEL approaches, it is not clear how the boundaries of regulated areas should be defined in a process-driven approach. This question is less important in facilities where separate rooms for pouring, weighing, mixing, and bagging are practicable. Since the physical isolation of regulated areas may not always be feasible, the Agency welcomes feedback and suggestions on how to define the boundaries of regulated areas in a non-PEL approach.

A non-PEL approach may require greater use of regulated areas than a PEL approach. The difference between the extent to which the regulated areas are required under the PEL and non-PEL approach will be dependent upon the actual level of the PEL. At present, the extent of this difference is hard to determine, for two reasons. First, the Agency is considering a range of PELs. Second, the Agency needs more detailed exposure profiles for operations involving pouring, weighing, mixing, transferring, spraying, and bagging flavorings containing diacetyl in various food and flavor manufacturing work environments. The Agency seeks comment on the relative utility and practicality of regulated area requirements in the PEL and non-PEL approaches.

VI. Methods of Compliance

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a. PEL Approach

A PEL approach would generally require that employers use engineering and work practice controls to reduce and maintain employee exposures at or below the PEL to the extent feasible. Employers would be allowed to demonstrate instances in which engineering and work practice controls would not be feasible. In such cases, employers would be required to reduce employee exposures to the lowest achievable levels, and to also implement respiratory protection for exposed employees. Employers would be exempted from requirements for engineering and work practice controls upon demonstration that a task or process would not result in employee exposure above the PEL for 30 or more days per year. In such cases, employers would still be obligated to require that employees wear respirators when exposed above the PEL. While OSHA prefers the use of engineering controls to control employee exposures, the Agency recognizes the burden this may place on employers who use such substances very infrequently and has thus included this provision for consideration.

b. Non-PEL Approach

A non-PEL approach would require specific, process-related engineering and work practice controls in areas where flavorings containing diacetyl are mixed, produced, or added to food. The Agency is defining the term “produce” to encompass operations such as weighing, pouring, bagging, transferring, spraying, or performing other similar operations in the manufacture of flavorings or food.

The specified controls in a non-PEL approach would be similar to the interventions that proved effective at the sentinel microwave popcorn plant where butter flavorings were initially identified as a hazard. For example, where flavorings containing diacetyl are mixed or produced, employers might be required to isolate mixing or production rooms using solid barriers, and to provide ventilation at specific performance standards. Local exhaust ventilation hoods around mixing, compounding, and quality control operations would be required, and temperature requirements for production, storage, and cleaning operations might be imposed. Additional requirements might also be incorporated, including accepted industrial hygiene specifications for engineering controls.

In contrast to the relatively flexible and performance-oriented methods of compliance that would be required in a PEL approach, the non-PEL approach would

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impose specification requirements for the use of isolation, ventilation, and negative pressure, which may potentially impose a greater burden on employers.

VII. Respiratory Protection

a. PEL Approach

A PEL approach would obligate employers to require that employees use respiratory protection during periods when engineering and work practice controls have not yet been installed and in work operations where engineering and work practice controls are not feasible or not sufficient to reduce exposures to or below the PEL. Additionally, employers would be required to ensure that employees use respirators in emergencies and in work operations where the employer has elected not to implement engineering and work practice controls, because employees are exposed above the PEL for fewer than thirty days per year.

b. Non-PEL Approach

As in a PEL approach, a non-PEL approach would require respiratory protection during periods necessary to install engineering and work practice controls, during work operations for which engineering and work practice controls are not feasible, and during emergencies. Additionally, a non-PEL approach would require respiratory protection for employees performing specific work operations. For example, employers may be required to provide and ensure that employees use respiratory protection when pouring, weighing, mixing, or bagging flavorings containing diacetyl, and during work operations that generate similar exposures. Respiratory protection would also be required during emergency clean-up.

Furthermore, under the non-PEL approach, respiratory protection would consist of at least a full-face air purifying respirator with combination organic vapor and particular cartridges, whereas, under the PEL approach, the respirator would be selected according to the Assigned Protection Factor (APF) table in 29 CFR 1910.134.

With respect to respiratory protection, the non-PEL approach may be more burdensome than the PEL approach, since employees in all of the specified work operations would be required to wear respirators. Under the non-PEL approach, employees in certain specified operations will be required to wear respirators while working in areas where engineering controls are present. In contrast, under the PEL

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approach, respirators will not be required if engineering controls reduce exposures to below the PEL. The Agency welcomes feedback concerning the use of respirators in conjunction with engineering controls.

VIII. Protective Work Clothing and Equipment

Both PEL and non-PEL approaches would include provisions, similar to those in other health standards, describing requirements for the use, maintenance, removal, and storage of protective work clothing and equipment. Thus, when skin or eye contact with diacetyl is likely, both PEL and non-PEL approaches would require that employers provide PPE, at no cost to the employee, and would require that employers ensure that employees use such equipment. This provision is included based on several investigations that have revealed increased prevalence of skin irritation among employees exposed to flavorings containing diacetyl. Both approaches would also contain specific provisions governing the removal, storage, transport, cleaning, repair, and replacement of personal protective equipment.

IX. Hygiene Areas and Practices

Both PEL and non-PEL approaches would include provisions, similar to those in other health standards, describing hygiene areas and practices. Thus, where protective clothing and equipment are required, the employer will be obligated to provide and maintain, according to certain standards, change rooms, washing facilities, and eating, drinking, and smoking areas.

X. Hazard Communication and Training

PEL and non-PEL approaches to hazard communication and training would generally be the same. In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, both approaches would require that employers train employees sufficiently to ensure that they are familiar with the standard and the employer's medical surveillance program. In a standard requiring a written exposure control plan, an employer would also be required to ensure that employees are familiar with the exposure control plan.

XI. Medical Surveillance

Both the PEL and non-PEL approaches would require that employers make surveillance available at no cost to all employees who are exposed to flavorings containing diacetyl above the action level for 30 days or more each year. While the Agency anticipates that PEL and non-PEL approaches to medical surveillance may be largely the same, the group of employees covered by the provisions may differ. A non-PEL approach may obligate employers to provide surveillance to a potentially larger set of employees, including all employees working in areas where flavorings containing diacetyl are mixed, produced, or added to foods, and all employees working in maintenance, quality control, or laboratory environments. Medical surveillance may be appropriate for a broad set of employees, given the severity of lung damage that some exposed employees have suffered, the rapidity with which some employees have developed bronchiolitis obliterans, and the lack of an exposure level limit where delineations in risk can be better defined.

Under both PEL and non-PEL approaches, employers would also be required to make medical surveillance available at no cost to any employee who:

- Experiences signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl
- Is exposed in an emergency.

Both PEL and non-PEL approaches would require that medical examination be provided at the following times:

- Before the time of initial assignment of the employee;
- Every six months, or more frequently if deemed necessary by the physician or other licensed health care professional (PLHCP);
- At the termination of employment;
- Whenever an employee shows signs or symptoms associated with exposure to diacetyl;
- Within 30 days of an emergency involving flavorings containing diacetyl; and
- Within 30 days after an employee who works in a similar area or process is diagnosed with flavoring-related lung disease.

Both PEL and non-PEL approaches might contain provisions allowing for the

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termination or reduction in frequency of medical surveillance for employees in a particular job or location, if an employer is able to demonstrate that:

- Employees working in that particular job or location have no measurable exposure to diacetyl; and
- Three consecutive rounds of medical surveillance at 6-month intervals have not revealed changes in spirometry or new cases of flavoring-related disease.

Both PEL and non-PEL approaches would require that a medical examination consist of the following (at a minimum):

- A medical and work history, with emphasis on past, present, and potential exposure to flavorings containing diacetyl;
- A physical examination with emphasis on the respiratory system, eyes, and the integumentary system;
- Completion of the respiratory questionnaire; and
- Spirometry administered by individuals who have completed a training course in spirometry that is certified by NIOSH.

Both the PEL and non-PEL approaches would contain similar provisions describing equipment standards, information that must be provided to the PLHCP, and requirements for the PLHCP's written opinion.

Finally, both approaches would require that the PLHCP refer the employee to a pulmonary specialist in the event of abnormal spirometry or other clinical findings associated with exposure to flavorings containing diacetyl. Both approaches would require the employer to provide and pay for any additional medical services recommended by the PLHCP or the medical specialist. In summary, although most of the content of PEL and non-PEL approaches to medical surveillance would be similar, a non-PEL approach would likely obligate employers to cover a larger set of employees.

XII. Housekeeping

Housekeeping obligations would be the same under PEL and non-PEL approaches. These provisions would require employers to maintain all surfaces as free as practicable of flavorings containing diacetyl, and create a program for detecting leaks, spills, and discharges, as required under the exposure control plan provisions. Employers

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would also be obligated to prevent reentry of flavorings containing diacetyl into the work environment during the disposal of waste items.

XIII. Recordkeeping

Both PEL and non-PEL approaches would include provisions, similar to those in other health standards, requiring that employers maintain records of air monitoring that is conducted to comply with the requirements of the standard, and obligating employers to maintain records of historical monitoring data and objective data, when used to determine levels of exposure to diacetyl. Employers would also be obligated to maintain records of medical surveillance for each employee covered under the medical surveillance provisions of the standard.

XIV. Prohibited Practices

Both the PEL and non-PEL approaches contain requirements prohibiting certain workplace practices, including:

- Cleaning or removing flavorings containing diacetyl with compressed air, dry sweeping, or vacuums that are not equipped with high efficiency particulate air (HEPA) filters;
- Leaving uncovered containers of flavorings containing diacetyl when not in use; and
- Discharging onto the floor wastewater or cleaning solvent.

XV. Dates

The timetable on which employers would be obligated to implement the requirements of a standard would be nearly identical in PEL and non-PEL approaches. In a PEL approach, the standard would become effective within 30 days after publication in the Federal Register. Within 60 days after the effective date, employers would be required to implement provisions describing exposure assessment, hazard communication, housekeeping, recordkeeping, and prohibited practices. Within 90 days after the effective date, employers would be required to implement requirements relating to respiratory protection, protective work clothing and equipment, regulated areas, and medical surveillance. Within two years after the effective date, engineering and work practice controls would be required.

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In a non-PEL approach, the only difference would be an additional provision requiring that the written exposure control plan provisions be implemented within sixty days of the effective date.

Reasons Why Action by the Agency is Being Considered

In the past decade, higher-than-expected levels of respiratory disease have been documented among employees who work with butter flavorings. Investigations at microwave popcorn and flavoring manufacturing facilities have revealed elevated prevalence of obstructive and restrictive losses in pulmonary function, asthma, chronic bronchitis, chronic cough, shortness of breath, and wheezing. Cumulative exposure to diacetyl, the predominant volatile organic chemical in butter flavorings, has been associated with an elevated prevalence of obstructive lung disease. To protect employees who are exposed to diacetyl and food flavorings containing diacetyl, the Agency has initiated rulemaking.

What follows in this PIRFA is a description of the findings that OSHA must make to establish the need for a new standard. Next, the PIRFA presents a brief summary of the health effects of diacetyl and food flavorings containing diacetyl. Finally, the PIRFA describes OSHA's preliminary assessment of the risk associated with exposure to diacetyl and flavorings containing diacetyl.

FINDINGS THE AGENCY MUST MAKE TO ESTABLISH THE NEED FOR A STANDARD

To establish the need for an occupational safety and health standard, OSHA must evaluate the available health and safety data and determine whether or not employees suffer material impairment of their health or functional capacity as a result of being exposed to a particular safety or health hazard. For health standards regulating toxic materials and harmful physical agents, the Occupational Safety and Health Act (OSH Act) directs OSHA to set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even when such an employee has regular exposure to the hazard dealt with by such standard for the period of his working life" (Section 6(b) (5) of the OSH Act). The Supreme Court, in reviewing previous OSHA standards, has also directed the Agency to make a determination that significant risks are

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present and can be eliminated or lessened by a change in practices before promulgating any health or safety standard (*Industrial Union Dept. v. American Petroleum Inst.*, 448 U.S. 607, 655 (1980)). The Court also stated that, while OSHA’s significant risk determination must be supported by substantial evidence, this requirement “is not a mathematical straitjacket,” and that “the Agency has no duty to calculate the exact probability of harm.” *Id.* Indeed, the Agency “is not required to support the finding that significant risk exists with anything approaching scientific certainty” (448 U.S. at 656).

The first step in making material impairment and risk determinations requires the Agency to examine a broad array of scientific data to evaluate the overall weight of the evidence with regard to the specific hazard of interest. In the next step, the Agency develops quantitative estimates that characterize the risk of material impairment among exposed employees over a working lifetime. Although the Agency has often relied on quantitative dose-response modeling to develop risk estimates for several chemical carcinogens (e.g. hexavalent chromium, methylene chloride, 1,3-butadiene), the Agency successfully demonstrated significant risk from occupational exposure to the hepatitis B virus as part of the bloodborne pathogen rulemaking in the absence of sophisticated models of risk (56 FR 64023-64038).

HEALTH EFFECTS

a. Health Outcomes Associated with Occupational Exposure to Flavorings

The 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. (Parmet, 2002). 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 into and out of the lung. Obstruction is typically fixed, meaning that pulmonary function test 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 (Akpinar-Elci, 2004). At least three employees with flavoring-related bronchiolitis obliterans have died (Egilman, 2007).

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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.

In addition to airway obstruction and bronchiolitis obliterans, some studies suggest that exposure to butter flavorings may be associated with a range of other respiratory disorders and symptoms, including restrictive lung function loss and asthma (NIOSH, 2006). Exposed employees have also experienced irritation of the eyes, skin, nose, and throat (Akpınar-Elci, 2004).

b. Findings from Health Effect Studies

There have been a number of occupational investigations and case reports that document an excess occurrence of obstructive airway disease among employees who are exposed to an airborne mixture of butter flavoring chemicals, including diacetyl. The studies include investigations of several microwave popcorn production plants, flavor manufacturing facilities, and a diacetyl production plant. There are also inhalation studies in rodents exposed to diacetyl and vapors of a butter flavoring mixture. The key findings from the studies are summarized below. A more detailed background document is available in the public docket (Docket No. OSHA-2008-0046) that describes the evidence in more detail.

Following diagnoses of bronchiolitis obliterans among former production employees at the Missouri microwave popcorn plant, NIOSH evaluated the medical condition of current employees at that plant and found more than three times the expected

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, obstructive losses in lung function. These losses are often "fixed," meaning that spirometry test results do not improve following bronchodilator treatment.

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rate of obstructive lung disease (Kreiss, 2002). The frequency and extent of the airway obstruction was greatest among employees with the highest exposures to the butter flavoring vapors. NIOSH investigated five additional microwave popcorn plants that confirmed and extended its initial findings (Kanwal, 2006). The prevalence of airways 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. Six employees engaged in these job operations at four 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.

Another industry for which cases of flavoring-related airway disease have been reported is food flavor manufacturing. Two cases of fixed airways obstruction compatible with bronchiolitis obliterans were reported at a small company that manufactured butter flavorings and other flavorings for the baking industry (NIOSH, 1986). Five cases of severe respiratory disease consistent with bronchiolitis obliterans were uncovered during ongoing medical surveillance at a large flavoring manufacturing plant (Lockey, 2002). Seven employees with severe obstructive lung disease were identified among four flavoring manufacturing establishments in California (CDC, 2007). The nine cases cited above worked in jobs in which they regularly handled, blended, or packaged flavorings, including butter flavorings, during their production. The available air monitoring data indicate that the concentrations of diacetyl in the air during the blending and packaging operations are comparable to the concentrations found in the mixing areas of microwave popcorn plants (NIOSH, 2007).

Four cases of obstructive airway disease compatible with bronchiolitis obliterans were found among employees that worked in the production of diacetyl at a Dutch chemical plant (Van Rooy, 2007). Another butter flavoring chemical, acetoin, was also manufactured as a co-product during the same production process. Unlike in microwave popcorn and flavoring manufacture facilities, these employees were exposed to a more limited number of chemical agents, principally diacetyl and acetoin.

A single six-hour inhalation of butter flavoring vapors consisting of diacetyl, acetoin, and other volatile chemicals caused injury over a large portion of the respiratory

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tract of rats (Hubbs, 2002). The butter flavoring concentrations used in the study were comparable to the levels measured inside the butter flavoring tanks at microwave popcorn plants. Inhalation of comparable concentrations of pure diacetyl caused injury to the nose and upper respiratory tract of rats but the damage was not as extensive as found following inhalation of the butter flavoring mixture (Hubbs, 2008). This suggests that other butter flavoring components in addition to diacetyl may contribute to the flavoring-induced airway damage. Repeated six hour inhalations of pure diacetyl vapor for up to 12 weeks primarily damaged the upper airways in mice but also affected the lower airways under certain conditions of exposure (Morgan, 2008). Liquid diacetyl caused significant damage to the lower airways when administered by a non-physiological technique (i.e. oropharyngeal aspiration) that forced the chemical into the pulmonary region of the lung. The authors concluded that “these results, collectively, indicate that clinically relevant diacetyl exposures result in a pattern of injury that replicates features of bronchiolitis obliterans.”

These findings indicate that diacetyl vapor is primarily absorbed in the nose and the upper respiratory tract of rodents following inhalation, and does not as readily reach the lower airways where bronchiolitis obliterans occurs in humans. The reason may be that rodent species are obligate nose breathers with highly developed nasal passages able to efficiently remove diacetyl and other water-soluble vapors from the airstream before reaching the lower airways. However, diacetyl would be expected to penetrate further into the respiratory tract of humans following inhalation, especially during mouth breathing. The potential for inhaled diacetyl and other butter flavoring chemicals to reach and damage lower airways in employees will need to be further investigated and evaluated.

c. Diacetyl as an Etiological and Marker Agent

Butter 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, both as a marker of flavoring exposure, and as a suspected etiological agent in part because diacetyl has been a predominant volatile organic chemical found in butter flavorings.. Diacetyl was used as a marker for exposure to

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flavoring mixtures in investigations of popcorn and flavoring facilities. In this context, a marker is one or more component substances that is measured to represent exposure to a complex mixture of concern. The marker should have a reasonably strong association with the health impairment, be as specific as possible, and be reliably measurable. OSHA has, in the past, relied on a set of marker substances when establishing exposures to a complex mixture that represent a risk of material health impairment (41 FR 46742, Occupational Exposure to Coke Oven Emissions).

Diacetyl has received serious consideration as an independent etiological agent in the development of respiratory disease. 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. 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 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. Although acetoin has also been found in butter flavorings containing diacetyl, diacetyl is more volatile than acetoin and has been found in higher concentrations than acetoin in most of the popcorn processing and flavoring work environments surveyed thus far (Kreiss 2007). OSHA will continue to examine the roles of diacetyl, acetoin, and other components of butter flavoring mixtures as etiological agents and marker compounds when further data become available. Some butter flavorings used in microwave popcorn are undergoing significant reformulation away from diacetyl. As the Agency learns more about the replacement compounds, they will also be evaluated as potential etiological agents or marker compounds.

RISK

OSHA is currently evaluating the available data to characterize the relationship between respiratory impairment and exposure to diacetyl and flavorings containing

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diacetyl. Occupational studies of microwave popcorn production and food flavor manufacturing plants that are discussed later in this section indicate that brief periods of high exposure as well as prolonged, full shift exposure to lower levels of flavoring compounds can lead to obstructive airway disease. Respiratory disease has been observed among mixing and blending operators who were exposed to high concentrations of diacetyl during specific tasks such as pouring, transferring, bagging, and cleaning operations (Kanwal, 2006; NIOSH, 2007). High cumulative and average full-shift exposures have also been documented among mixing operators at microwave popcorn plants. Respiratory disease has also been observed among quality control technicians in microwave popcorn plants who were exposed to brief, high concentrations of butter flavorings during and shortly following popping corn in microwave ovens (NIOSH, 2006). In many cases, these short-term excursions represented the majority of the full-shift personal exposures. Additionally, respiratory disease has been observed among microwave popcorn packaging operators who were exposed to lower, steady, prolonged air concentrations of butter flavoring compounds over the entire work shift (Kanwal, 2006).

The following subsection offers a very preliminary discussion of the risk associated with different levels of exposure to flavorings containing diacetyl. Salient epidemiological data are organized within the framework of three exposure categories, which are subject to change as the Agency continues its analysis, and as information characterizing the relationship between exposure and impairment continues to emerge. Additionally, this subsection presents evidence that control measures can lower airborne exposures to flavorings containing diacetyl and reduce the occurrence of flavoring-related respiratory disease.

a. High-Exposure Category

A number of data sets indicate that job operations that result in exposure to diacetyl equal to and above 0.5 ppm as a TWA or involve routine exposures to short-term exposure levels of 1 ppm or more while engaged in specific tasks lead to an elevated risk of airway obstruction and respiratory symptoms. Prior to installation of controls, production employees at the Missouri microwave popcorn plant investigated by NIOSH had an almost four-fold higher prevalence of airway obstruction and respiratory symptoms than the national reference population (Kreiss et al., 2002). There were nine

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cases of severe respiratory disease consistent with bronchiolitis obliterans among mixers and packaging line operators that started work at the plant prior to 2000 (Akpinar-Elci, 2004). Average mixing and packaging area diacetyl levels were 38 and 1.7 ppm, respectively (NIOSH, 1/2006; 8/2001). Five of six quality control employees surveyed at the Missouri microwave popcorn plant had airway obstruction. These employees popped roughly 100 bags per 8-hour shift. Mean diacetyl air levels were 0.5 ppm in the breathing zone of the employee, with short-term exposure levels averaging around 2 ppm during the task of dumping freshly popped corn into containers. Similar short-term exposure levels for diacetyl were measured in the residence of a consumer with obstructive-airway disease consistent with bronchiolitis obliterans who popped multiple bags of microwave popcorn daily for several years (Rose, 7/2007).

Employees with 12 months or more of mixing experience at four other microwave popcorn plants also had elevated prevalence of airway obstruction and respiratory symptoms when compared to employees with less than 12 months of mixing experience (Kanwal et al., 2006). Eighty percent of the airway obstruction was fixed (i.e. no improvement with bronchodilator treatment) and several employees had severe loss of pulmonary function. Average breathing zone concentrations of diacetyl in the mixing areas of these plants were 0.6 to 1.2 ppm (NIOSH, 5/2003, 10/2003, 12/2004). Real-time breathing zone measurements during and following pouring butter flavoring into heated oil indicated short-term diacetyl levels averaged approximately 4 to 40 ppm over a 10 to 30 minute period.

Aggregated data for packaging line employees at three other microwave popcorn plants demonstrated an elevated prevalence of fixed airway obstruction (Kanwal et al., 2006). Three packaging line employees from one of the plants suffered losses in lung function and had clinical findings consistent with bronchiolitis obliterans. Like the Missouri plant, the packaging lines were adjacent to improperly sealed mixing tanks. Average diacetyl levels in packaging areas that were not isolated from the tanks of butter flavoring were 0.5 to 0.6 ppm (NIOSH, 5/2003, 10/2003).

Respiratory symptoms were common among production employees who routinely made powdered flavors, including diacetyl-containing flavorings, at a Commerce, CA flavor manufacturing plant (NIOSH, 4/2007). Three cases of severe obstructive airway disease consistent with bronchiolitis obliterans were identified among powder production

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employees at this plant. Mean breathing zone diacetyl levels during the 1-2 hour productions of butter and vanilla flavored powders were near 10 ppm. Mean full-shift 8-hour TWA diacetyl levels among powder production employees were reported to be 0.22 ppm. This may under-represent exposure during the production of diacetyl-containing flavors since sampling occurred during shifts when flavored powder containing diacetyl were not being prepared.

Four cases of severe obstructive airway disease consistent with bronchiolitis obliterans were identified among process operators employed at a chemical plant in the Netherlands from 1960 to 2003 (Van Rooy, 2007). Diacetyl levels averaged 2.3 ppm (geometric mean) over 2 to 3 hours in production processing areas.

b. Low-Exposure Category

There is evidence to suggest that exposures to diacetyl at full-shift, TWA concentrations below 0.05 ppm and less than a 1 ppm short-term exposure level are not associated with an elevated prevalence of airway obstruction and respiratory symptoms. There was not an elevated prevalence of airway obstruction among packaging line employees at three microwave popcorn plants where the packaging areas were isolated from the mixing tanks (Kanwal et al., 2006). Average breathing zone levels in the packaging areas were 0.002 to 0.02 ppm for diacetyl (NIOSH, 7/2003; 12/2004). While there were a few employees with obstructed airways among non-production employees at the Missouri microwave popcorn plant, there was no evidence of fixed airway obstruction among these employees. This contrasts with the considerably elevated prevalence of fixed obstructive airway disease among production employees at the same plant. Diacetyl levels in the non-production areas such as warehouse, bag printing, and administrative areas averaged 0.03 ppm (NIOSH, 2001).

NIOSH discovered cases of fixed airways obstruction among mixers whose full-shift personal sampling for diacetyl averaged 0.02 ppm TWA. However, the mixers were also exposed to very high short-term concentrations in the breathing zone over several minutes while pouring liquid butter flavoring into solutions of heated oil. Additionally, the air measurements from this plant may have been collected under conditions of high relative humidity. NIOSH's method for measuring diacetyl is currently being reevaluated to determine the extent to which exposure may be underestimated under different

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conditions of high relative humidity. Thus, at present, there is little or no evidence to suggest that exposure to levels of diacetyl below an eight hour TWA of 0.05 ppm is associated with an elevated prevalence of adverse health effects.

c. Intermediate-Exposure Category

The association between respiratory impairment and exposures to diacetyl air concentrations at or above 0.05 but less than 0.5 ppm TWA and less than a 1 ppm short-term exposure level is not as clear from the limited amount of data. Employees who had ever worked in the quality control area of one microwave popcorn plant had a higher observed prevalence of airway obstruction compared with employees who had never worked in the quality control area (NIOSH, 10/2003). Mean personal full shift TWA diacetyl was 0.06 ppm. The employees were repeatedly exposed to estimated short-term excursions of diacetyl that may have been as high as 0.46 ppm while opening and dumping bags of heated popcorn into a container. There was no significant change in the prevalence of airway obstruction among packaging area employees at the Missouri microwave popcorn plant who were hired following implementation of a series of exposure-reduction steps described below (NIOSH, 2006). Average diacetyl levels averaged 0.11 ppm in the packaging area during the intervention period.

OSHA is continuing to evaluate data from other facilities that NIOSH investigated to better characterize the risk associated with exposures in this category.

d. Reduction in Exposure and Disease Following Implementation of Controls

In the study mentioned above, NIOSH evaluated exposure to diacetyl from the use of butter flavorings at the Missouri microwave popcorn production plant during and following implementation of engineering controls (NIOSH, 2006). Plant employees received regular medical surveys during this time. Improvements in general ventilation of the mixing area, installation of local exhaust ventilation, and reduced mixing tank temperatures effectively lowered average diacetyl concentrations in the mixing area from 38 ppm to around 0.5 ppm. The ventilation controls in the mixing area also reduced average diacetyl at the packaging lines from 2 ppm to around 0.1 ppm. Installation of mixing tank enclosures that isolated packaging lines from the mixing operations further dropped average air concentrations of diacetyl in the packing area to below 0.01 ppm.

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Installation of engineering controls that provided additional ventilation in the quality control laboratory reduced average diacetyl concentrations from 0.5 ppm to below 0.1 ppm. Peak exposures were also lower in all production areas after controls were installed.

Results from the medical surveillance program at the Missouri plant demonstrated that production employees hired after engineering controls were installed had lower prevalences of respiratory symptoms and airway obstruction than production employees hired prior to the implementation of controls. Seven percent of employees hired post-implementation had declines in pulmonary function between the first and last spirometry test compared with 22 percent of pre-implementation hires. These findings suggest that installation of controls not only lowered air levels in the plant but may have also reduced the incidence of flavor-related airway disease. Some mixers hired prior to the introduction of respiratory protection and installation of local exhaust ventilation at the mixing tanks had continued loss of pulmonary function after installation of controls and subsequent reduction in exposure.

e. Limitations and Uncertainties

OSHA's assessment of risk is primarily restricted by the limited amount of data available to characterize the relationship between adverse health outcomes and exposure to diacetyl and flavorings containing diacetyl. This is particularly the case with regard to low and intermediate categories of exposure.

Some uncertainty is introduced by the design of the studies on which this assessment relies. Cross-sectional analyses may have failed to capture employees who previously developed obstructive airways disease and subsequently left employment. Thus, these studies may underestimate the relationship between flavorings and disease.

Existing methods of exposure measurement may also complicate the risk assessments. The NIOSH method, which was used to determine air levels in most of the cited studies, may underestimate diacetyl levels under conditions of high humidity. Moreover, the exposure data are based on air-monitoring samples that were collected over several days; these measurements may not accurately reflect the exposure levels that existed in previous months and years.

Most of the currently available data are from studies of microwave popcorn

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production that routinely used liquid butter flavor or plated butter flavoring powders in a manner that probably generated regular exposures to airborne vapor concentrations of volatile chemicals within the plant. The risk of flavoring-related obstructive airway disease among employees exposed in facilities that use flavorings containing diacetyl on a less frequent basis will also need to be evaluated as further data become available. Future risk assessments may also need to address processes that use spray-dried, encapsulated flavoring powders, in which employees may be exposed to substantial amounts of airborne particulate diacetyl and other flavoring chemicals, rather than vapors.

OSHA plans to reexamine the limitations and sources of uncertainty as more data become available. Further research is underway at NIOSH and other organizations. As information emerges regarding health effects and exposure characteristics of diacetyl and flavorings containing diacetyl, OSHA will refine its evaluation of risk accordingly.

Benefits

Benefits from the draft proposed standard are based on estimates of the prevalence of obstructed airway cases among the at-risk population in the affected food, flavor, and popcorn industries, as discussed in the Risk section. The prevalence estimates associated with the various exposure categories in Table 1 were derived from the data sets described in the previous section and are more fully explained in a background document available in the public docket. The occurrence of airway obstruction and severe airway obstruction was determined from measurements of obstructive lung function in exposed employees. Severe cases were considered to be employees that had experienced 50 percent or greater loss in pulmonary function (i.e. FEV1). The exposure distribution for diacetyl allocates at-risk employees according to four exposure ranges: high task (short-term exposure levels equal to or greater than 5.0 ppm), high exposure (TWA exposures equal to or greater than 0.5 ppm and/or short-term exposure levels equal to 1.0 ppm or greater but less than 5.0 ppm), middle exposure (TWA exposures equal to or greater than 0.05 ppm but less than 0.5 ppm and short-term exposure levels less than 1.0 ppm), and low exposure (TWA exposures less than 0.05 ppm and short-term exposure levels less than 1.0 ppm). See Table 1. Estimates of averted cases assume that the standard is sufficiently effective in reducing exposures such that after promulgation

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no employees remain in the high task range and that half of the employees in the high and medium exposure ranges in the baseline case have exposures post standard that are, respectively, one exposure range lower.² (See Tables 2a and 2b)

² Note that the algorithm to estimate the benefits of the standard first shifts all employees from the high task to the high exposure range and then shifts half of the employees in the high exposure and medium exposure ranges one exposure range lower.

Table 1. Excess Prevalence* of Adverse Health Effects by Exposure Level

Exposure Level	Airway Obstruction		Severe Airway Obstruction	
	Low Excess Prevalence Estimate	High Excess Prevalence Estimates	Low Excess Prevalence Estimate	High Excess Prevalence Estimates
Low exposure range (<.05 ppm)	0.0%	4.5%	0.0%	0.0%
Middle exposure range (=>.05 and <0.5 ppm)	1.0%	10.2%	0.0%	0.0%
High exposure range (=>0.5 ppm and/or short-term exposure level =>1.0 ppm and <5.0 ppm)	6.0%	77.8%	0.3%	2.2%
High task (=>5.0 ppm short-term exposure level)	6.0%	77.8%	2.2%	37.5%

* observed prevalence minus background

Table 2A. Baseline Distribution of At-Risk Employees by Exposure Range

		Distribution of At-Risk Employees			
		Low Exposure Range	Medium Exposure Range	High Exposure Range [a]	High Task Range [b]
Sector					
Food	Mixing and Blending Occupations	59.0%	32.0%	6.8%	2.3%
	Cooking and Baking Occupations	100.0%	0.0%	0.0%	0.0%
Flavor	All At-Risk Employees	10.0%	10.0%	60.0%	20.0%
Popcorn	All At-Risk Employees	60.0%	30.0%	7.5%	2.5%

[a] Includes employees with short-term exposure levels >1.0 ppm and <=5.0 ppm.

[b] Includes employees with short-term exposure levels >5.0 ppm.

Table 2B. Post Standard Distribution of At-Risk Employees by Exposure Range [a]

		Low Exposure Range	Medium Exposure Range	High Exposure Range [b]	High Task Range [c]
		Sector			
Food	Mixing and Blending Occupations	75.0%	20.5%	4.5%	0.0%
	Cooking and Baking Occupations	100.0%	0.0%	0.0%	0.0%
Flavor	All At-Risk Employees	15.0%	45.0%	40.0%	0.0%
Popcorn	All At-Risk Employees	75.0%	20.0%	5.0%	0.0%

[a] Assumes no employees in the "high task" range and that half of the employees in the baseline high and medium exposures ranges are each moved one exposure range lower.

[b] Includes employees with short-term exposure levels >1.0 ppm and <=5.0 ppm.

[c] Includes employees with short-term exposure levels >5.0 ppm.

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The Agency has further assumed that the incidence rate for flavoring-related obstructive airway disease is somewhere between 1 and 0.371 times the prevalence rate. An incidence of 1 assumes that employees contracting the illness leave after one year on the job. An incidence rate of .371 reflects the average turnover rate in nondurable manufacturing in the 2007 BLS JOLTS survey; this presumes that the illness does not accelerate their departure. This approach suggests a range of between 100 and 3,168 total cases prevented annually by the standard, and between 19 and 830 severe cases prevented annually by the standard. (A more detailed discussion of this analysis is provided in the ERG Benefits Memo, 2008.)

The Agency estimates that an appropriate monetary value for the less severe cases of flavoring-related obstructive airway disease would be similar to that for chronic bronchitis. In EPA's recent rulemaking on Ozone [EPA, 2008], chronic bronchitis cases were valued at approximately \$460,000 in 2008 dollars.³ Severe obstructive airway disease, by contrast, involves a sizable loss of pulmonary function leading, in many cases, to permanent disability and, in some cases, death. Therefore, the Agency is tentatively valuing these cases at three times the value for chronic bronchitis, or \$1.5 million per case. This approach suggests the value of all cases avoided by the standard are between \$66 million and \$2.3 billion annually. (These benefits estimates correspond to the exposure assumptions described as the base case cost scenario below. Fewer exposures result in both lower benefits and lower costs.)

Objective of and Legal Basis for the Draft Proposed Standard

The objective of the draft proposed standard is to reduce the number of illnesses occurring among employees exposed to diacetyl and flavoring containing diacetyl in general industry. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment,

³ EPA estimated the value at \$410,000 in 1990 dollars and \$500,000 in 2020 dollars, based on a constant assumed income growth rate.

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respirators, training, medical surveillance, and other protective measures to perform their jobs safely.

The legal basis for the standard is the responsibility given the U.S. Department of Labor through the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act authorizes the Secretary of Labor to promulgate occupational safety and health standards as necessary “to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.” 29 USC 651(b).

Description and Estimate of Affected Small Entities

Uncertainties

At this time, OSHA has incomplete information on exposure to diacetyl in industry, particularly in food processing, other than microwave popcorn. While the Agency believes that all of the industries listed in this analysis are likely to be affected by the draft proposed standard to some degree, the extent of the effect is unknown. In many sectors, the Agency is confident some firms use flavoring containing diacetyl, but is uncertain how common the use of such flavoring is. At the time the economic analysis for this PIRFA was prepared, the Agency had exposure data only from popcorn plants in the food processing industry, and had made only one site visit specifically to examine possible diacetyl exposure in the rest of food processing. For this reason, for cost purposes, the Agency has developed a range of estimates of the portion of establishments in the various industries that would be affected by the standard. In some industries, for example, bakeries, this range is as wide as 5 to 75 percent. In addition, the Agency has only recently become aware of the extensive role “butter starter distillate” plays in some industries, primarily the dairy industry, and is seeking additional information in this area. The Agency also has considerable uncertainty over the frequency with which diacetyl exposure would occur in a particular industry among the affected plants, the amount of time these plants would need to run the local exhaust ventilation, or what proportion of the processing lines would be affected. For the sake of simplicity, the Agency has not carried these ranges through the entire analysis, but it must be emphasized that these ranges reflect not the potentially wide range of alternatives a potential standard might

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incorporate, but the lack of information the Agency has at its disposal on the issue at the current time.

An additional uncertainty is the extent to which these cost estimates may be altered by the introduction of flavor formulations that substitute away from the use of diacetyl, either partially or entirely. Lowering the diacetyl content has the potential to lower the cost of complying with the standard, or removing establishments from the scope of the standard entirely. Moving to non-diacetyl formulations also has the same potential.

In examining the costs of the rule for the base case, OSHA has assumed that any facility within the scope of the standard will need a full set of engineering and other controls. In this sense, the costing is closer to that of a non-PEL standard than is likely to be the case under a PEL standard.

OSHA will be working continuously to reduce the range of uncertainty. The Agency plans a number of site visits. It will also be conducting many interviews, and possibly undertaking a survey, to better determine the use of diacetyl and flavorings containing diacetyl in the affected industries.

As with other aspects of the PIRFA, the Agency invites comment on all elements of the economic analysis where individuals have information to help inform the Agency's assessment of the potential effects of the draft standard.

A Profile of Affected Entities

The Small Business Regulatory Enforcement Fairness Act (SBREFA) requires that OSHA estimate the number of small businesses ("small entities") affected by the draft proposed standard. "Entity" describes a legal business entity or firm; an "establishment" describes a particular site of economic activity. U.S. Small Business Administration (SBA) size standards were collected from the table of Small Business Size Standards Matched to the North American Industry Classification System (2002) from SBA's Web Site. SBA size standards for the affected diacetyl-using industries are expressed in terms of employment (U.S. SBA 2002). For the NAICS industries affected by the draft proposed standard, there were three different size standards for small entities based on number of employees: entities with fewer than 500 employees, entities with fewer than 750 employees, and entities with fewer than 1,000 employees. The Agency

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relied on the most recent census data for its description of small entities in affected industries.

Criteria for small entities are presented in Tables 3A and 3B for each affected industry. Identification of affected industries and the number of affected small entities within each industry were developed in the analysis of technological feasibility. These tables also show the numbers, employment totals, revenues, and estimated profits for small entities. The tables also show the numbers of affected small entities in both the base case and the “low prevalence” case in which the prevalence of diacetyl use among food manufacturing entities is limited to no more than 5 percent of the total entities.

The Agency developed data on the total number of small entities in each affected industry in order to estimate the revenues and profits for affected firms, permitting estimates of the impact of estimated costs on revenues and before-tax profits. For industries in which SBA has defined small entities as those having fewer than 500 employees, the total number of entities was taken from the 2005 Statistics of U.S. Business (SUSB) from the U.S. Census Bureau. The SUSB does not provide data in a way that permits estimating the number of small entities with either 750 or 1,000 or fewer employees. For those industries with these SBA size criteria, OSHA included all the entities as reported by the Census Bureau. The vast majority of entities in the three industries would be classified as small by the SBA criteria if more disaggregated Census data were available.

Revenues for small entities were calculated as the sum of revenues for all size groups below the maximum SBA classification. Since revenue data by employment-size category for entities are only available in the 2002 SUBA, OSHA extrapolated total revenues for all employment size groups using 2002 revenue data and 2002 and 2005 annual payroll ratio, taken from 2002 and 2005 SUSB data. OSHA estimated total revenues for SBA-defined small entities by multiplying the total revenues with the percentage of annual payroll for this size group of SBA standards. The percentage of annual payroll for SBA-defined small entity size was computed from 2002 SBA firm size employment data. Revenues of small entities presented here represent 2005 information

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NAICS	Industry	Employment Size Standard (Fewer than)	Entities		Establishments		Employment	
			Small	Total	Small	Total	Small	Total
311111	Dog and Cat Food Manufacturing	500	158	176	167	244	5,938	16,070
311119	Other Animal Food Manufacturing	500	975	1,031	1,113	1,532	18,377	31,604
311225	Fats and Oils Refining and Blending	1,000	73	73	112	112	7,599	7,599
311230	Breakfast Cereal Manufacturing	1,000	44	44	65	65	12,893	12,893
311320	Chocolate and Confectionery Manufacturing from Cacao Beans	500	130	138	135	147	2,521	7,797
311330	Confectionery Manufacturing from Purchased Chocolate	500	978	997	1,007	1,051	16,519	30,921
311340	Nonchocolate Confectionery Manufacturing	500	423	447	436	477	9,237	21,389
311411	Frozen Fruit, Juice, and Vegetable Manufacturing	500	135	158	150	244	10,163	35,402
311412	Frozen Specialty Food Manufacturing	500	328	375	336	437	13,883	54,471
311421	Fruit and Vegetable Canning	500	534	591	557	739	17,017	47,600
311422	Specialty Canning	1,000	110	110	123	123	13,274	13,274
311423	Dried and Dehydrated Food Manufacturing	500	129	146	147	181	6,055	13,017
311511	Fluid Milk Manufacturing	500	235	288	243	498	12,780	56,193
311512	Creamery Butter Manufacturing	500	18	26	18	28	506	1,442
311513	Cheese Manufacturing	500	338	370	354	495	13,892	41,188
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	500	118	145	133	200	4,262	13,933
311520	Ice Cream and Frozen Dessert Manufacturing	500	304	333	309	375	5,952	19,531
311711	Seafood Canning	500	115	121	119	136	2,998	4,261
311712	Fresh and Frozen Seafood Processing	500	482	504	512	581	18,848	33,423
311811	Retail Bakeries	500	6,218	6,236	6,394	6,446	57,668	60,075
311812	Commercial Bakeries	500	2,063	2,147	2,108	2,502	50,902	146,557
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	500	198	222	202	257	10,221	22,085
311821	Cookie and Cracker Manufacturing	750	294	294	348	348	32,295	32,295

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NAICS	Industry	Employment Size Standard (Fewer than)	Entities		Establishments		Employment	
			Small	Total	Small	Total	Small	Total
311822	Flour Mixes and Dough Manufacturing from Purchased Flour	500	166	190	176	231	4,496	12,940
311830	Tortilla Manufacturing	500	301	307	313	337	8,253	13,964
311911	Roasted Nuts and Peanut Butter Manufacturing	500	135	153	140	177	5,339	12,822
311919	Other Snack Food Manufacturing	500	260	280	276	346	8,722	28,772
311920	Coffee and Tea Manufacturing	500	275	294	279	311	6,200	12,351
311930	Flavoring Syrup and Concentrate Manufacturing	500	135	144	140	163	4,170	5,992
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing	500	239	259	254	302	6,072	14,897
311942	Spice and Extract Manufacturing	500	255	283	265	320	8,727	15,872
311991	Perishable Prepared Food Manufacturing	500	586	631	607	684	19,010	36,890
311999	All Other Miscellaneous Food Manufacturing	500	777	818	827	912	21,698	34,627
312111	Soft Drink Manufacturing	500	234	281	242	507	10,772	60,104
312120	Breweries	500	346	353	352	381	7,677	26,265
312130	Wineries	500	1,535	1,551	1,559	1,637	19,458	28,772
312140	Distilleries	750	59	59	74	74	5,461	5,461

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Table 3B – Characteristics of Small Businesses—Financial Characteristics and Range of Number of Entities Estimated to be Actually Affected by the Draft Proposed Standard

NAICS	Industry	Employment Size Standard (Fewer than)	Revenues (\$1,000)				Profit Rate	Revenues per entity (Small) (\$1000)	Revenues per employee (total)	Profit per entity (\$1000)	Number of Affected Small Entities – Base Case	Number of Affected Small Entities - Low Case [a]
			Small Business (2002)	Small Business (2005)	Total (2002)	Total (2005)						
311111	Dog and Cat Food Manufacturing	500	\$1,691,455	\$2,589,948	\$9,894,674	\$12,645,956	5.27%	\$16,392	\$786,929	\$863	79	8
311119	Other Animal Food Manufacturing	500	\$8,486,533	\$8,760,608	\$19,196,816	\$18,756,934	5.27%	\$8,985	\$593,499	\$473	49	49
311225	Fats and Oils Refining and Blending	1,000	\$6,275,014	\$7,573,488	\$6,275,014	\$7,573,488	5.27%	\$103,746	\$996,643	\$5,462	18	4
311230	Breakfast Cereal Manufacturing	1,000	\$9,405,412	\$10,648,742	\$9,405,412	\$10,648,742	5.27%	\$242,017	\$825,932	\$12,742	2	2
311320	Chocolate and Confectionery Manufacturing from Cacao Beans	500	\$639,315	\$974,649	\$3,951,877	\$3,761,151	5.38%	\$7,497	\$482,384	\$404	98	7
311330	Confectionery Manufacturing from Purchased Chocolate	500	\$1,931,426	\$1,993,023	\$8,975,142	\$9,249,104	5.38%	\$2,038	\$299,120	\$110	734	49
311340	Nonchocolate Confectionery Manufacturing	500	\$1,907,616	\$1,801,661	\$5,642,216	\$5,732,521	5.38%	\$4,259	\$268,013	\$229	317	21
311411	Frozen Fruit, Juice, and Vegetable Manufacturing	500	\$2,080,119	\$2,585,346	\$9,490,329	\$10,062,595	5.09%	\$19,151	\$284,238	\$975	20	7
311412	Frozen Specialty Food Manufacturing	500	\$2,217,001	\$2,693,989	\$12,003,320	\$15,531,181	5.09%	\$8,213	\$285,128	\$418	16	16
311421	Fruit and Vegetable Canning	500	\$5,317,017	\$5,007,580	\$18,976,193	\$19,029,749	5.09%	\$9,377	\$399,785	\$477	80	27
311422	Specialty Canning	1,000	\$9,135,795	\$9,011,323	\$9,135,795	\$9,011,323	5.09%	\$81,921	\$678,870	\$4,169	17	6
311423	Dried and Dehydrated Food Manufacturing	500	\$1,549,845	\$2,318,241	\$3,941,503	\$4,427,207	5.09%	\$17,971	\$340,110	\$915	6	6
311511	Fluid Milk Manufacturing	500	\$4,549,345	\$4,713,609	\$25,566,516	\$27,901,172	2.09%	\$20,058	\$496,524	\$419	35	12
311512	Creamery Butter	500	\$609,955	\$448,051	\$1,361,251	\$1,395,948	2.09%	\$24,892	\$968,064	\$520	1	1

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Table 3B – Characteristics of Small Businesses—Financial Characteristics and Range of Number of Entities Estimated to be Actually Affected by the Draft Proposed Standard

NAICS	Industry	Employment Size Standard (Fewer than)	Revenues (\$1,000)				Profit Rate	Revenues per entity (Small) (\$1000)	Revenues per employee (total)	Profit per entity (\$1000)	Number of Affected Small Entities – Base Case	Number of Affected Small Entities - Low Case [a]
			Small Business (2002)	Small Business (2005)	Total (2002)	Total (2005)						
	Manufacturing											
311513	Cheese Manufacturing	500	\$6,069,174	\$7,071,813	\$21,853,334	\$26,245,224	2.09%	\$20,923	\$637,206	\$437	169	17
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	500	\$1,697,557	\$2,041,950	\$9,678,570	\$10,078,527	2.09%	\$17,305	\$723,357	\$361	59	6
311520	Ice Cream and Frozen Dessert Manufacturing	500	\$1,294,059	\$1,172,745	\$7,076,979	\$7,926,343	2.09%	\$3,858	\$405,834	\$81	152	15
311711	Seafood Canning	500	\$671,540	\$670,841	\$1,178,688	\$1,420,284	2.44%	\$5,833	\$333,322	\$142	6	6
311712	Fresh and Frozen Seafood Processing	500	\$4,533,692	\$4,312,378	\$7,668,467	\$8,154,776	2.44%	\$8,947	\$243,987	\$218	24	24
311811	Retail Bakeries	500	\$2,979,396	\$2,969,811	\$3,267,038	\$3,287,633	11.68%	\$478	\$54,725	\$56	4,664	311
311812	Commercial Bakeries	500	\$5,252,544	\$5,227,209	\$23,991,833	\$24,293,919	11.68%	\$2,534	\$165,764	\$296	1,547	103
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	500	\$1,190,336	\$1,722,460	\$3,083,688	\$4,608,625	11.68%	\$8,699	\$208,677	\$1,016	149	10
311821	Cookie and Cracker Manufacturing	750	\$10,723,038	\$10,138,970	\$10,723,038	\$10,138,970	11.68%	\$34,486	\$313,949	\$4,028	147	15
311822	Flour Mixes and Dough Manufacturing from Purchased Flour	500	\$980,258	\$1,051,233	\$5,959,367	\$4,833,886	11.68%	\$6,333	\$373,562	\$740	8	8
311830	Tortilla Manufacturing	500	\$600,377	\$716,149	\$1,465,053	\$1,760,567	11.68%	\$2,379	\$126,079	\$278	15	15
311911	Roasted Nuts and Peanut Butter Manufacturing	500	\$1,211,334	\$1,529,791	\$4,261,567	\$5,720,807	3.81%	\$11,332	\$446,171	\$432	7	7
311919	Other Snack Food Manufacturing	500	\$1,644,392	\$1,641,896	\$12,406,099	\$11,570,394	3.81%	\$6,315	\$402,141	\$241	195	13
311920	Coffee and Tea Manufacturing	500	\$1,511,241	\$1,710,740	\$5,443,286	\$6,124,929	3.81%	\$6,221	\$495,906	\$237	41	14
311930	Flavoring Syrup and Concentrate Manufacturing	500	\$1,138,818	\$2,019,450	\$8,701,902	\$11,699,376	3.81%	\$14,959	\$1,952,499	\$570	49	39

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Table 3B – Characteristics of Small Businesses—Financial Characteristics and Range of Number of Entities Estimated to be Actually Affected by the Draft Proposed Standard

NAICS	Industry	Employment Size Standard (Fewer than)	Revenues (\$1,000)				Profit Rate	Revenues per entity (Small) (\$1000)	Revenues per employee (total)	Profit per entity (\$1000)	Number of Affected Small Entities – Base Case	Number of Affected Small Entities - Low Case [a]
			Small Business (2002)	Small Business (2005)	Total (2002)	Total (2005)						
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing	500	\$1,985,709	\$2,059,206	\$5,910,332	\$6,608,133	3.81%	\$8,616	\$443,588	\$328	12	12
311942	Spice and Extract Manufacturing	500	\$1,955,602	\$2,513,487	\$5,139,042	\$6,609,460	3.81%	\$9,857	\$416,423	\$375	42	42
311991	Perishable Prepared Food Manufacturing	500	\$1,968,488	\$2,748,152	\$3,933,290	\$6,292,320	3.81%	\$4,690	\$170,570	\$179	29	29
311999	All Other Miscellaneous Food Manufacturing	500	\$4,612,635	\$5,976,346	\$10,668,572	\$11,118,721	3.81%	\$7,692	\$321,100	\$293	174	102
312111	Soft Drink Manufacturing	500	\$4,073,977	\$3,510,637	\$33,116,813	\$34,478,047	7.13%	\$15,003	\$573,640	\$1,069	12	12
312120	Breweries	500	\$1,568,980	\$1,785,574	\$18,659,524	\$17,207,668	12.67%	\$5,161	\$655,156	\$654	17	17
312130	Wineries	500	\$3,830,825	\$5,031,473	\$9,717,671	\$11,091,956	6.56%	\$3,278	\$385,512	\$215	77	77
312140	Distilleries	750	\$4,547,608	\$4,284,275	\$4,547,608	\$4,284,275	6.56%	\$72,615	\$784,522	\$4,762	9	3
[a] Prevalence of diacetyl use assumed to be less than or equal to 5.0% among food entities.												

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and, presumably, for most affected industries, are somewhat lower in most cases than today, if only due to general price increases from inflation. Economic impacts will then be somewhat overstated when costs, which are current estimates, are compared to revenues and profits (which are derived from revenues).

OSHA estimated profits from ratios of net income to total receipts as reported for 2004 by the U.S. Internal Revenue Service, *Corporation Source Book*. Profit data for some industries are not available at disaggregated levels; therefore profit rates at more highly aggregated levels are used instead.

The cost estimates presented in the PIRFA are preliminary. In most cases, when the Agency (or its contractor) had uncertainty about the appropriateness or effectiveness of engineering controls, it opted for the most extensive—and therefore most costly--control. The Agency will revise its cost estimates as it collects information from site visits, feedback from the SBREFA panel, and later information gathering efforts. Similarly, when there was uncertainty about the number of small entity employers who had already installed needed engineering controls or program elements such as exposure monitoring or medical surveillance, the Agency chose to assume in most cases that few or no employers had done so. (Details of the assumptions and estimated costs for each affected sector can be found in ERG, 2008.) As a result, the Agency believes that the estimated impacts in Tables 4 and 5, as well as aggregated costs (presented in Tables 7 and 9 below), are likely to be overestimates of final costs and economic impacts.

As a preliminary method of estimating the significance of the economic impacts on affected entities, OSHA compared, for each industry, the average costs of compliance for affected small entities with average small entity revenue and profits. This analysis, which OSHA terms a screening analysis, is a simple calculation of the costs as percentage of profits and as a percentage of revenues. It is not a prediction that revenues will increase by this percentage or that profits will fall by this percentage. Instead, this is a screening analysis for the potential significance of the economic impacts. OSHA has not yet done a full economic feasibility analysis, which would analyze the likelihood of severe impacts on profits. In general, the issue of whether a fall in profits will actually occur as a result of incurring these costs is dependent on whether prices can be increased without such major losses in revenue that few if any firms in a class remain viable.

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The preliminary screening analysis is presented in Table 4. The Agency also estimated costs and conducted a screening analysis for very small employers (those with fewer than 20 employees). Estimating the number of these very small employers and their revenues and profits was performed in the same manner as for SBA-defined small entities. Compliance costs as percentage of revenue and profits for the very small employers are presented in Table 5.

For the base case scenario, average costs as a percent of revenues for small entities range from 0.03 percent (breakfast cereal manufacturing) to 2.56 percent (retail bakeries). Table 4 also shows the “low” scenario in which utilization of ventilation (i.e., the time equipment is operated) is limited to 20 percent among flavor establishments and 50 percent of popcorn manufacturers, and capital costs for controls are constrained to 50 percent of the base levels. Under this scenario, average costs as a percent of revenues range from 0.02 percent to 1.41 percent. Under either of these two scenarios, only small entities in the retail bakery industry incur compliance costs in excess of 1.0 percent of revenues.

Costs as a percentage of before-tax profits range from 0.52 (breakfast cereal manufacturing) to 21.94 percent (retail bakeries) in the base case and from 0.32 percent to 12.08 percent in the low scenario. Altogether, in the base case, 13 industries have profit impacts in excess of 5.0 percent. In the low case, this number drops to 8, half of which barely exceed 5%.

Table 5 illustrates costs as percentage of revenues and profits for the very small size-class of entities, ones with fewer than 20 employees. Average compliance costs as a percent of revenues range from 0.21 percent (butter manufacturers) to 2.98 percent (retail bakeries) in the base case scenario and from 0.10 percent to 1.63 percent under the low cost scenario. Altogether, costs as a percent of revenues among very small entities exceeds 1.0 percent in 14 industries under the base case scenario and in 5 industries under the low cost scenario case.

For the smallest entities, costs as a percent of profit ranges from 5.81 percent (frozen fruit, juice, and vegetable manufacturing) to 43.8 percent (non-chocolate confectionary manufacturing) under the base case and from 2.88 percent to 20.93 percent under the low cost scenario. All of the very small entities had profit impacts in excess of 5.0 percent in the base case and in all but 11 industries in the low scenario case.

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This analysis has not examined potential secondary effects of the draft proposed standard. For example, firms that deal with diacetyl only occasionally may opt to cease those operations. This would tend to lower the cost of the draft proposed standard, as capital costs of controls would be required of fewer employers. In addition, substitution to non-diacetyl flavoring substances holds the potential to significantly lower the cost of the draft proposed standard.

Table 4 – Screening Analysis for Potential Economic Impacts, Entities Covered under SBREFA

NAICS	Industry	Low Case [a]			Base Case		
		Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits	Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
311111	Dog and Cat Food Manufacturing	\$8,130	0.05%	0.94%	\$14,479	0.09%	1.68%
311119	Other Animal Food Manufacturing	\$6,507	0.07%	1.38%	\$12,679	0.14%	2.68%
311225	Fats and Oils Refining and Blending	\$32,570	0.03%	0.60%	\$66,157	0.06%	1.21%
311230	Breakfast Cereal Manufacturing	\$40,249	0.02%	0.32%	\$66,613	0.03%	0.52%
311320	Chocolate and Confectionery Manufacturing from Cacao Beans	\$7,179	0.10%	1.78%	\$13,131	0.18%	3.25%
311330	Confectionery Manufacturing from Purchased Chocolate	\$8,751	0.43%	7.98%	\$16,981	0.83%	15.48%
311340	Nonchocolate Confectionery Manufacturing	\$9,115	0.21%	3.98%	\$17,128	0.40%	7.47%
311411	Frozen Fruit, Juice, and Vegetable Manufacturing	\$9,793	0.05%	1.00%	\$16,471	0.09%	1.69%
311412	Frozen Specialty Food Manufacturing	\$9,901	0.12%	2.37%	\$18,386	0.22%	4.40%
311421	Fruit and Vegetable Canning	\$7,017	0.07%	1.47%	\$12,647	0.13%	2.65%
311422	Specialty Canning	\$24,876	0.03%	0.60%	\$41,530	0.05%	1.00%
311423	Dried and Dehydrated Food Manufacturing	\$10,170	0.06%	1.11%	\$18,323	0.10%	2.00%

Table 4 – Screening Analysis for Potential Economic Impacts, Entities Covered under SBREFA

NAICS	Industry	Low Case [a]			Base Case		
		Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits	Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
311511	Fluid Milk Manufacturing	\$7,078	0.04%	1.69%	\$12,699	0.06%	3.03%
311512	Creamery Butter Manufacturing	\$6,519	0.03%	1.25%	\$12,336	0.05%	2.37%
311513	Cheese Manufacturing	\$8,079	0.04%	1.85%	\$14,638	0.07%	3.35%
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	\$6,669	0.04%	1.85%	\$12,309	0.07%	3.41%
311520	Ice Cream and Frozen Dessert Manufacturing	\$4,769	0.12%	5.92%	\$8,703	0.23%	10.81%
311711	Seafood Canning	\$7,171	0.12%	5.03%	\$14,990	0.26%	10.52%
311712	Fresh and Frozen Seafood Processing	\$7,845	0.09%	3.59%	\$16,109	0.18%	7.37%
311811	Retail Bakeries	\$6,740	1.41%	12.08%	\$12,239	2.56%	21.94%
311812	Commercial Bakeries	\$8,655	0.34%	2.92%	\$13,235	0.52%	4.47%
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	\$21,685	0.25%	2.13%	\$37,255	0.43%	3.67%
311821	Cookie and Cracker Manufacturing	\$43,441	0.13%	1.08%	\$70,572	0.20%	1.75%
311822	Flour Mixes and Dough Manufacturing from Purchased Flour	\$9,215	0.15%	1.25%	\$14,746	0.23%	1.99%
311830	Tortilla Manufacturing	\$11,926	0.50%	4.29%	\$19,258	0.81%	6.93%
311911	Roasted Nuts and Peanut Butter Manufacturing	\$9,112	0.08%	2.11%	\$16,011	0.14%	3.71%
311919	Other Snack Food Manufacturing	\$9,721	0.15%	4.04%	\$18,499	0.29%	7.69%

Table 4 – Screening Analysis for Potential Economic Impacts, Entities Covered under SBREFA

NAICS	Industry	Low Case [a]			Base Case		
		Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits	Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
311920	Coffee and Tea Manufacturing	\$10,243	0.16%	4.32%	\$20,439	0.33%	8.63%
311930	Flavoring Syrup and Concentrate Manufacturing	\$61,982	0.41%	10.88%	\$76,139	0.51%	13.36%
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing	\$6,664	0.08%	2.03%	\$11,970	0.14%	3.65%
311942	Spice and Extract Manufacturing	\$53,049	0.54%	14.13%	\$66,408	0.67%	17.69%
311991	Perishable Prepared Food Manufacturing	\$8,988	0.19%	5.03%	\$16,062	0.34%	8.99%
311999	All Other Miscellaneous Food Manufacturing	\$32,548	0.42%	11.11%	\$41,611	0.54%	14.20%
312111	Soft Drink Manufacturing	\$3,827	0.03%	0.36%	\$8,158	0.05%	0.76%
312120	Breweries	\$2,923	0.06%	0.45%	\$6,148	0.12%	0.94%
312130	Wineries	\$4,296	0.13%	2.00%	\$9,272	0.28%	4.31%
312140	Distilleries	\$15,431	0.02%	0.32%	\$32,994	0.05%	0.69%

[a] Utilization of ventilation equipment limited to 20% among flavor establishments and 50% for food and popcorn establishments and engineering control costs assumed to be 50% of base-case levels.

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Table 5 - Screening Analysis for Potential Economic Impacts on Entities With Fewer Than 20 Employees

NAICS	Industry	Number of Entities with <20 Employees	Average Revenues per Entity	Profit Rate	Number of Affected Entities with Fewer Than 20 Employees	Low Case [a]			Base Case		
						Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits	Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
311111	Dog and Cat Food Manufacturing	100	\$2,318,250	5.3%	50	\$4,369	0.19%	3.58%	\$8,699	0.38%	7.13%
311119	Other Animal Food Manufacturing	706	\$2,748,548	5.3%	35	\$5,217	0.19%	3.61%	\$10,361	0.38%	7.16%
311225	Fats and Oils Refining and Blending	36	\$2,609,985	5.3%	9	\$6,085	0.23%	4.43%	\$13,045	0.50%	9.49%
311230	Breakfast Cereal Manufacturing	17	\$2,046,060	5.3%	1	\$4,344	0.21%	4.03%	\$8,481	0.41%	7.87%
311320	Chocolate and Confectionery Manufacturing from Cacao Beans	101	\$946,372	5.4%	76	\$5,859	0.62%	11.50%	\$11,975	1.27%	23.50%
311330	Confectionery Manufacturing from Purchased Chocolate	781	\$589,152	5.4%	586	\$6,652	1.13%	20.97%	\$13,883	2.36%	43.77%
311340	Nonchocolate Confectionery Manufacturing	328	\$539,425	5.4%	246	\$6,078	1.13%	20.93%	\$12,721	2.36%	43.80%
311411	Frozen Fruit, Juice, and Vegetable Manufacturing	59	\$2,964,255	5.1%	9	\$4,347	0.15%	2.88%	\$8,760	0.30%	5.81%
311412	Frozen Specialty Food Manufacturing	169	\$1,136,173	5.1%	8	\$7,394	0.65%	12.79%	\$15,886	1.40%	27.47%
311421	Fruit and Vegetable Canning	339	\$1,484,062	5.1%	51	\$3,981	0.27%	5.27%	\$8,028	0.54%	10.63%
311422	Specialty Canning	61	\$1,517,933	5.1%	9	\$3,902	0.26%	5.05%	\$7,778	0.51%	10.07%
311423	Dried and Dehydrated Food Manufacturing	62	\$1,584,793	5.1%	3	\$3,788	0.24%	4.70%	\$7,617	0.48%	9.44%
311511	Fluid Milk Manufacturing	113	\$1,670,901	2.1%	17	\$3,828	0.23%	10.98%	\$7,748	0.46%	22.22%
311512	Creamery Butter Manufacturing	12	\$4,043,925	2.1%	1	\$4,054	0.10%	4.80%	\$8,374	0.21%	9.92%
311513	Cheese Manufacturing	181	\$2,574,753	2.1%	91	\$4,583	0.18%	8.53%	\$9,274	0.36%	17.26%
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing	65	\$1,885,104	2.1%	33	\$5,551	0.29%	14.11%	\$11,347	0.60%	28.84%
311520	Ice Cream and Frozen Dessert Manufacturing	226	\$1,062,805	2.1%	113	\$3,687	0.35%	16.62%	\$7,452	0.70%	33.59%
311711	Seafood Canning	82	\$1,579,084	2.4%	4	\$3,276	0.21%	8.50%	\$6,938	0.44%	17.99%
311712	Fresh and Frozen Seafood Processing	285	\$2,156,845	2.4%	14	\$3,455	0.16%	6.56%	\$7,337	0.34%	13.93%
311811	Retail Bakeries	5496	\$283,498	11.7%	4,122	\$4,614	1.63%	13.93%	\$8,455	2.98%	25.54%
311812	Commercial Bakeries	1449	\$501,845	11.7%	1,087	\$4,777	0.95%	8.15%	\$8,706	1.73%	14.85%

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Table 5 - Screening Analysis for Potential Economic Impacts on Entities With Fewer Than 20 Employees

NAICS	Industry	Number of Entities with <20 Employees	Average Revenues per Entity	Profit Rate	Number of Affected Entities with Fewer Than 20 Employees	Low Case [a]			Base Case		
						Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits	Compliance Costs per Small Entity	Compliance Costs as a % of Revenues	Compliance Costs as a % of Profits
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing	91	\$877,835	11.7%	68	\$7,036	0.80%	6.86%	\$14,183	1.62%	13.83%
311821	Cookie and Cracker Manufacturing	184	\$873,544	11.7%	92	\$6,974	0.80%	6.84%	\$14,031	1.61%	13.75%
311822	Flour Mixes and Dough Manufacturing from Purchased Flour	100	\$1,371,202	11.7%	5	\$5,329	0.39%	3.33%	\$9,865	0.72%	6.16%
311830	Tortilla Manufacturing	193	\$385,463	11.7%	10	\$4,537	1.18%	10.08%	\$8,274	2.15%	18.38%
311911	Roasted Nuts and Peanut Butter Manufacturing	76	\$1,511,614	3.8%	4	\$3,910	0.26%	6.79%	\$7,717	0.51%	13.40%
311919	Other Snack Food Manufacturing	161	\$1,639,849	3.8%	121	\$6,594	0.40%	10.56%	\$13,856	0.84%	22.19%
311920	Coffee and Tea Manufacturing	202	\$1,962,181	3.8%	30	\$6,120	0.31%	8.19%	\$13,041	0.66%	17.45%
311930	Flavoring Syrup and Concentrate Manufacturing	82	\$2,796,180	3.8%	25	\$22,685	0.81%	21.30%	\$30,077	1.08%	28.24%
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing	157	\$1,790,535	3.8%	8	\$3,976	0.22%	5.83%	\$7,873	0.44%	11.55%
311942	Spice and Extract Manufacturing	151	\$1,877,736	3.8%	20	\$28,259	1.50%	39.51%	\$37,405	1.99%	52.30%
311991	Perishable Prepared Food Manufacturing	365	\$814,963	3.8%	18	\$4,463	0.55%	14.38%	\$8,880	1.09%	28.61%
311999	All Other Miscellaneous Food Manufacturing	523	\$1,697,572	3.8%	101	\$16,479	0.97%	25.49%	\$22,561	1.33%	34.89%
312111	Soft Drink Manufacturing	118	\$1,796,976	7.1%	6	\$3,798	0.21%	2.97%	\$8,246	0.46%	6.44%
312120	Breweries	181	\$836,092	12.7%	9	\$3,135	0.37%	2.96%	\$6,687	0.80%	6.31%
312130	Wineries	336	\$557,634	6.6%	17	\$3,018	0.54%	8.25%	\$6,477	1.16%	17.71%
312140	Distilleries	251	\$1,051,602	6.6%	38	\$2,542	0.24%	3.69%	\$5,403	0.51%	7.84%

[a] Utilization of ventilation equipment limited to 20% among flavor establishments and 50% for food and popcorn establishments and engineering control costs assumed to be 50% of base-case levels.

Summary of Reporting, Recordkeeping, and Other Compliance Requirements

OSHA has estimated costs resulting from the draft proposed standard, using the non-PEL option as the base, in the areas of engineering controls, exposure assessment, written control plans, health screening, regulated areas, hygiene facilities, training, housekeeping, and respirators in all affected industries. OSHA has not included costs or benefits for protective clothing, housekeeping, or hygiene areas and practices, all of which are currently required (29 CFR 1910.22, 1910.132, 1910.141). A summary of the employee time unit cost assumptions used in the cost analysis is presented in Table 6.

Table 6. Time Requirements for the Draft Proposed Standard

Section	Requirement	Time	Employee Type
Exposure Assessment	Recordkeeping and employee notification	15 minutes per sample	Manager
	Employee productivity loss while sampling equipment attached	30 minutes per 8-hour sample	Employee
	Time for IH to monitor employees	8 hours per two employees monitored	Industrial Hygienist
Medical surveillance	Employee time for examination and spirometry tests (includes travel)	60 minutes	Employee
	Initial work history/health and respiratory questionnaire	45 minutes	Employee
	Recordkeeping for medical tests and examinations	15 minutes per employee tested	Clerical employee
	Perform Medical Exam	30 minutes	Physician
Training	Time spent in training sessions	30 minutes	Employee
Respirators	Time spent in respirator training sessions	2 hours	Employee (respirator users only)
Regulated areas	Time to identify and establish regulated areas	1 to 16 hours, depending on establishment size	Manager (first year only)
	Time to administer regulated areas	4 to 32 hours per year, depending on establishment size	Supervisor

Table 6. Time Requirements for the Draft Proposed Standard

Section	Requirement	Time	Employee Type
Exposure control plan	Time to develop and revise plan	3 to 25 hours to develop plan, depending on establishment size	Manager (first year only)
	Time to administer and update plan	3 to 48 hours to administer and update plan, depending on establishment size	Manager

OSHA estimated the cost of complying with the provisions in the draft proposed standard for small entities in each affected industry. These were based on a detailed report of affected industries in the cost economic impact chapters of the contractor report. The total costs of an industry depend on the number of affected entities in the industry and the level of current compliance with provisions in the draft proposed standard. The following sections describe the cost methodology for the provisions in the draft proposed standard. (Details of the program cost methodology can be found in ERG, 2008.)

Engineering Controls

The Agency’s preliminary analysis of technological feasibility identified, for each process in each affected industry, the engineering controls that were appropriate to assure effective control of major emissions sources. Work practices are also part of the controls that can be considered in meeting a PEL. The Agency then estimated the costs of engineering controls, based on support provided by its contractor and engineering experts. The engineering controls necessary for entities in the affected industry are discussed in the technological feasibility section, as well as in the cost analysis section, of the detailed report accompanying this document in the docket [ERG, 2008]. OSHA developed estimates of the potential ventilation costs to control diacetyl emissions in flavoring and food operations (including popcorn facilities). These estimates reflect the best judgment regarding the most applicable probable set of ventilation controls. The specification of ventilation enhancements presents a challenge due to the need to create widely applicable, generic ventilation fixes without plant-by-plant information on facility configurations. In practice, ventilation designs could be used in widely varying combinations and sizes. The design of the ventilation system itself could also vary widely. The cost estimates, therefore, are intended to reflect a possible combination of

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ventilation enhancements, but these are by no means the only method to achieve the exposure controls required. The various ventilation hoods were characterized largely based on their design in the American Council of Government Industrial Hygienists Industrial Ventilation manual, or based on combinations of designs presented there. Thus, they represent standard industrial ventilation improvements that reduce potential exposures by drawing particulates or fumes away from employees, or by enclosing and exhausting process emissions.

OSHA also forecast representative operating costs in flavoring and food plants for the exhaust system, the replacement air system, and the pollution control equipment using \$2.50 per cfm as a representative average. Finally, OSHA developed costs for other controls, in addition to ventilation, such as covers for mixing tanks, buckets with lids, and closed transfer systems to help reduce potential exposures.

OSHA defined basic sets of controls for a medium-sized flavoring, food, or popcorn facilities (20 to 99 employees). Because establishment-specific information about ventilation requirements is lacking, OSHA extrapolated the medium plant's needs to large (100 and more employees), small (10 to 19 employees), and very small (fewer than 10 employees) establishments. Large facilities are assumed to require twice as many controls as the medium case, small flavoring facilities are judged to require one-half as many controls, and very small establishments are assumed to need 10 percent of the specified controls.

Program Costs

OSHA's draft proposed standard includes requirements for exposure monitoring, medical surveillance, training, respirator use, regulated areas, and an exposure control plan. OSHA has developed compliance costs for each of these requirements based primarily on the non-PEL versions of the draft proposed standard. Given the preliminary nature of the draft standard, however, these costs will likely change as more details of the program requirements become available.⁴

The estimates of compliance cost for these program requirements depend on the estimated numbers of establishments that manufacture or use diacetyl-containing flavorings and the associated number of at-risk employees at those establishments. Several of the cost elements also depend on the opportunity cost of time requirements. OSHA valued the time of at-risk

⁴ ERG based its cost estimates on the January 8, 2008 draft of the draft proposed standard.

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employees based on average hourly wage rate for production occupations in the food industry. Other cost estimates depend on the average hourly wage for safety and health specialists and for clerical occupations. In each case, the wage was adjusted upward to account for fringe benefits.⁵

Estimated annualized costs for small entities of the draft proposed standard's various provisions are presented in Table 7. Table 8 lists many of the unit costs that appear throughout the analysis. Table 9 shows the costs of engineering controls and program costs by affected industry sector.

Exposure Monitoring: The requirements for exposure monitoring, detailed in the non-PEL approach of the draft proposed standard used for costing purposes, specify initial monitoring of at-risk employees by affected establishments. The draft proposed standard also requires additional monitoring whenever production process changes occur. To estimate compliance costs, however, OSHA assumed that employers would conduct initial exposure monitoring for diacetyl, and that full-shift samples would be collected for one-fourth of all at-risk employees. OSHA also assumed that additional samples for one-tenth of the employees would be required each year due to changes in production processes. These estimates are based on the professional judgment and experience of OSHA staff.

At the time OSHA prepared the economic analysis for this PIRFA, sampling methods to obtain an 8-hour sample required the collection of four 2-hour samples. (OSHA's current sampling methods require only three samples: two 3-hour samples and one 2-hour sample. OSHA expects and cost differences between the two methods to be minor.) Costs for sample analysis vary, but the median of the price quotes obtained from several laboratories was \$90 per sample. In addition to the samples, the analysis of a blank sample is also needed for comparison purposes. (It should be noted that this economic analysis is based on the ERG report, which assumed lab analysis for acetoin also. Therefore, these costs are overstated in this regard, by approximately \$4 million annually for small employers). Monitoring unit costs also include the cost of a consulting IH technician and the value of lost employee productivity and the time for recording the monitoring results. Table 8 shows the assumptions and cost parameters for the monitoring costs and the resultant annualized cost per employee of cost (over a ten-year time

⁵ ERG used wage data from the BLS Occupational Employment Statistics Survey (BLS, 2006) and benefits ratios as reported by the BLS (BLS, 2007).

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horizon) of \$38 for the initial monitoring and \$108 per year for monitoring necessitated by process changes. Annualized costs for routine monitoring of at-risk employees would rise to \$540 if semi-annual monitoring were required.

As shown in the program cost summary table below (Table 7), these assumptions for the base case scenario result in aggregate annualized compliance costs of \$12.1 million for small entities. These costs reflect the assumed compliance rates shown in Table 10 below.

Medical Surveillance: The draft proposed standard requirements for medical surveillance specify that each at-risk employee would require an initial checkup including the completion of a work history and respiratory questionnaire. These employees need an initial medical exam and spirometry test and subsequent checkups and tests at least every six months. Employees also must have a checkup and spirometry test upon leaving their job, if they have not had one within six months of termination. Checkup and test costs were based on typical provider quotes and include the opportunity cost for the time required to travel to and from the test site and for recordkeeping of employee health information.

These assumptions, as presented in Table 8, when annualized over a ten-year time horizon result in annualized costs of \$416 per employee. When combined with an estimate of average job turnover and incorporating the additional cost of termination examinations, OSHA estimated the adjusted employee medical surveillance costs at \$514 per employee. Based on these assumptions and the assumed compliance rates, aggregate annualized compliance costs for small entities for medical surveillance in the draft proposed standard total \$42.4 million.

Respirators: The draft proposed standard will require respirator use by at-risk employees under certain conditions, including when engineering and work practice controls are infeasible. Table 10 shows the assumed compliance rates for the respirator use requirements.

OSHA estimated the costs for respirators assuming that 25 percent of the at-risk employees would regularly need to use full-face air-purifying respirators. This judgment implicitly assumes that one quarter of planned engineering controls would not be fully adequate to control exposures. To the extent this is not the case, this may be an overestimate. OSHA judged that the respirators would require both an organic vapor cartridge and a particulate filter. Table 8 shows the respirator assumptions and cost parameters. In addition to the cost of the

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equipment and filters, the costs include expenses for training, fit testing, and for respirator cleaning. Assuming a two-year life for the respirator, OSHA estimates annualized unit costs per respirator user of \$637.57. On an aggregate basis (and assuming use by 25 percent of at-risk employees), annualized compliance costs for small entities would total \$16.3 million for respirator use.

Training: The draft proposed standard requires employee training to achieve familiarity with the standard and with the employer's exposure control and medical surveillance plans. As detailed in Table 8, OSHA assumed that this training could be achieved through annual sessions lasting 30 minutes. Note that this time estimate describes the incremental training requirement imposed by this standard. The employer is already required to train workers under the existing Hazard Communication Standard.

Assuming a class size of four and a cost of \$2.00 per employee for training materials, annual training costs total \$17.69 per employee. Based on these unit costs and assumed compliance rates, annual training for all at-risk employees results in aggregate annualized training costs of \$1.4 million for small entities.

Regulated Areas: The draft proposed standard includes requirements for regulated areas (1) when employees pour, weigh, mix, spray, transfer, or bag flavorings containing diacetyl, (2) when employees engage in processes that generate exposures similar to those above, and (3) during emergency cleanup. OSHA developed costs for these requirements based on the assumption that each establishment would incur one-time costs to identify regulated areas and establish procedures to regulate access.

As shown in Table 8, OSHA assumed that this requirement would require between one and 16 hours of a safety and health specialist's time, depending on the size of the establishment. In addition, each establishment would incur some costs for hazard area marking, barriers, and similar items. Finally, some ongoing administrative time would be required to administer the regulated areas. Based on these assumptions, OSHA estimated annualized costs ranging from \$244 for very small establishments (fewer than 10 employees) to \$2,244 for large establishments (100 or more employees). On an aggregate basis, these unit costs result in annualized compliance costs for regulated areas of \$6.2 million for small entities. These estimates reflect the compliance

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rates shown in Table 10 below.

Exposure Control Plan: The non-PEL approach in the draft proposed standard requires employers to develop a written exposure control plan that identifies sources of diacetyl exposures and describes the processes and work practices where such exposures might occur. The plan must also document engineering and other controls intended to mitigate exposures, required personal protective equipment, and the exposure monitoring and the medical surveillance programs.

OSHA based its costs for this requirement on estimates of the amount of administrative time required to develop such a plan, valued at the average safety and health specialist wage. As shown in Table 8, time estimates are included for rule familiarization, program development, written program preparation, and program administration. Additional time is included to revise the plan for changes in production processes or other factors affecting potential exposures. The Agency is assuming that information on the appropriate controls in particular industries could be readily shared across establishments and will not require a substantial unique effort on the part of an individual establishment. While that information may not be available for all affected industries at the present time, the Agency believes a major benefit of the rulemaking, given an adequate phase-in, would be to ensure such information will be available to the appropriate parties by the time the requirement becomes effective. The time required for each employer depends on the size of the establishment, with annualized unit costs ranging from \$180 for very small establishments to \$1,956 for large establishments. On an aggregate basis, these unit costs of an exposure control plan result in aggregate annualized compliance costs of \$4.2 million for small entities. These costs would be somewhat higher if semi-annual review and revision were required, as under an alternative version of the draft proposed standard.

Compliance with Program Requirements: Table 10 shows the assumed compliance rates among establishments in the food, flavoring, and popcorn sectors, respectively. These rates imply no current compliance among food establishments, marginal compliance among flavoring establishments (10%), and more substantial compliance among popcorn facilities (50%). Further investigation is needed to verify the actual extent of compliance actions in the respective sectors. The Agency does not attribute costs to the draft proposed standard for activities that affected

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entities are already doing. To determine current compliance with program provisions in the draft proposed standard, the Agency relied on information from site visits and information supplied by employers in the industry.

Program Cost Summary: Table 7 summarizes the aggregated annualized compliance costs for small entities for each of the draft proposed standard's program requirements, while Table 9 shows the total program costs for each of the three industry groups covered by the draft proposed standard. Under that base case, the annual estimated total cost for all the program requirements is \$82.5 million, of which \$73.7 million will be incurred by food industry establishments and \$8.0 million and \$0.9 million incurred by flavoring and popcorn establishments, respectively. Medical surveillance is the most costly item, accounting for roughly 50 percent of the total program costs. The respirator requirement is also relatively costly, making up 19 percent of the total. Table 7 shows program costs under several alternative scenarios. When the prevalence of diacetyl use is assumed to be 5 percent or less among food manufacturing establishments (Scenario 1), program costs fall to \$17.1 million. Scenarios 2 and 3, which assume use of ventilation equipment and engineering controls at approximately 50 percent of the base case, leave program costs unchanged because the number of at-risk employees is not reduced under these scenarios.

Combined Control and Program Costs

Tables 7 and 9 show the combined costs for engineering controls and program requirements for the draft proposed standard. In the base case, compliance costs total \$297.3 million per year for the affected industries. Of this total, \$214.8 million is attributable to engineering costs. The overall total includes \$275.2 million per year for affected food industry establishments and \$20.3 million per year and \$1.8 million per year for flavoring and popcorn manufacturers, respectively. Under Scenario 1 where the prevalence of diacetyl use in food establishments is limited to 5 percent or less, total annualized compliance costs fall to \$56.8 million overall and to \$34.7 million for food manufacturing establishments. Assuming a lower rate of ventilation equipment utilization (Scenario 2) reduces engineering costs to \$179.1 million annually (compared to \$214.8 million annually in the base case) and total costs to \$216.7 million

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annually. Under Scenario 3, lower assumed capital costs for engineering controls (50 percent of the base case) result in engineering costs of \$113.9 million annually and total compliance costs of \$196.6 million annually. Finally, if all three scenarios are combined, overall compliance costs fall to \$37.9 million annually, of which engineering costs comprise \$20.8 million.

This cost estimate range represents the Agency's best effort to provide some boundary on the range of costs related to the rule. However, it also reflects the acute lack of data available at the present time. The Agency understands that costs could easily extend beyond either end of the range. For example, if it is the case that few facilities use diacetyl, and that the use is such that worker exposure does not rise above the limit of detection, then costs of the standard may be very low. On the other hand, if it turns out diacetyl exposures are nearly ubiquitous in the food processing sector and their control more complex than currently envisioned, the high end of the range could prove an underestimate. There is little exposure data available at the present time to document the frequency and extent of diacetyl exposures in the food processing sector beyond microwave popcorn.

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Table 7 - Provision by Provision Compliance Costs					
Cost Category	Base Case	Scenario 1: Exposure Factor ≤5.0% [a]	Scenario 2: Low Utilization of Ventilation Equipment [b]	Scenario 3: Low Engineering Control Costs [c]	Scenarios 1–3 Combined
Exposure Monitoring	\$12,071,079	\$2,162,166	\$12,071,079	\$12,071,079	\$2,162,166
Medical Surveillance	\$42,406,250	\$7,595,789	\$42,406,250	\$42,406,250	\$7,595,789
Respirators	\$16,309,106	\$5,525,438	\$16,309,106	\$16,309,106	\$5,525,438
Training	\$1,458,258	\$261,202	\$1,458,258	\$1,458,258	\$261,202
Regulated Areas	\$6,167,447	\$948,647	\$6,167,447	\$6,167,447	\$948,647
Exposure Control Plan	\$4,170,494	\$606,074	\$4,170,494	\$4,170,494	\$606,074
Total Program Costs	\$82,582,634	\$17,099,316	\$82,582,634	\$82,582,634	\$17,099,316
Engineering Costs	\$214,755,312	\$39,717,700	\$179,082,749	\$113,973,009	\$20,845,387
Total	\$297,337,946	\$56,817,015	\$261,665,383	\$196,555,643	\$37,944,703
[a] Prevalence of diacetyl use is assumed to be less than or equal to 5.0% of the food processing establishments in the industry sector.					
[b] Utilization of ventilation equipment limited to 20% of flavoring establishments and 50% for food processing and popcorn establishments.					
[c] Engineering control costs assumed to be 50% of base-case levels for food processing establishments.					
Note: Only Scenario 1 affects program costs, due to varying assumptions of the effective scope of the draft proposed standard. It does not, however, affect the per establishment cost. Alternately, Scenarios 2 and 3 affect per establishment costs for engineering controls only.					

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Table 8. Unit Costs

Cost Category	Cost	Comments/Assumptions
Exposure Assessment		
IH fees/8-hour PBZ sample	\$250	Consulting IH technician, daily rate \$500
Lab Fees and shipping cost	\$90	Per sample
Samples per 8-hour shift	3	New OSHA method allows for 3 hr samples
Fee for blank	\$90	1 blank for each set of samples
Employee productivity loss while pump is attached to employee.	0.5	Hours
Recordkeeping and employee notification by a manager per sample	0.25	Hours
Cost per 8-hr sample (PBZ)	\$1,080	Includes IH time, lab fees, and value of employee and management time
Medical Surveillance		
Spirometry test	\$100	
Checkup	\$80	
Work history/health and respiratory questionnaire	0.75	Hours; first year only
Employee time for test (includes travel)	1	Hours
Recordkeeping	0.25	Hours per employee tested
Initial examination cost per employee	\$223	Includes value of employee and clerical time.
Subsequent examination cost per employee	\$207	Includes value of employee and clerical time
Respirators		
Equipment Cost	\$238	Full-facepiece air purifying respirator
Equipment Service Life (years)	2	
Annualized Equipment Cost	\$131	
Accessory Cost	\$278	Includes filters
Accessory Service Life (years)	1	
Annualized Accessory Cost	\$278	
Total Annualized Equipment Costs	\$409	
Training Hours	2	Assumes two hours of training annually, with a class size of four.
Training Frequency (years)	1	
Annualized Training Cost	\$61	
Fit Test Cost	\$81	
Fit Test Frequency (years)	1	
Annualized Fit Test Cost	\$81	
Respirator Cleaning	\$87	
Total Annual Costs	\$638	
Training		
Class size	4	Employees
Training time per session	0.5	Hours
Materials	\$2	Per employee per session
Instructors	1	Per class
Recordkeeping	0.02	Hours per employee trained
Training frequency		

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Table 8. Unit Costs

Cost Category	Cost	Comments/Assumptions
Training cost per employee	\$17.69	
Regulated Areas		
Associated costs for hazard marking, etc	\$50 to \$600	Depends of the size of the establishment
Exposure Control Plan		
Rule familiarization	1	Hours, first year only.
Develop program	1 to 16	Hours, first year only. Depends on establishment size.
Written program	1 to 8	Hours, first year only. Depends on establishment size.
Administer Program	2 to 32	Hours, recurring. Depends on establishment size.
Revisions for process changes	1 to 16	Hours, recurring. Depends on establishment size.
Annualized cost of exposure control plan	\$133 to \$1,687	Depends on establishment size.

Table 9 - Costs by Sector

Sector	Engineering Costs	Program Costs	Total Compliance Costs
<u>Base Case</u>			
Food Manufacturers (except flavoring and popcorn manufacturers)	\$201,564,606	\$73,663,310	\$275,227,916
Diacetyl Flavoring Manufacturers	\$12,333,630	\$7,980,220	\$20,313,850
Butter Flavoring Microwave Popcorn Manufacturers	\$857,077	\$939,103	\$1,796,180
Total	\$214,755,312	\$82,582,634	\$297,337,946
<u>Scenario 1: Exposure Factor <=0.05</u>			
Food Manufacturers (except flavoring and popcorn manufacturers)	\$26,526,994	\$8,179,992	\$34,706,986
Diacetyl Flavoring Manufacturers	\$12,333,630	\$7,980,220	\$20,313,850
Butter Flavoring Microwave Popcorn Manufacturers	\$857,077	\$939,103	\$1,796,180
Total	\$39,717,700	\$17,099,316	\$56,817,015
<u>Scenario 2: Low Utilization of Ventilation Equipment</u>			
Food Manufacturers (except flavoring and popcorn manufacturers)	\$169,382,281	\$73,663,310	\$243,045,591
Diacetyl Flavoring Manufacturers	\$8,974,767	\$7,980,220	\$16,954,987
Butter Flavoring Microwave Popcorn Manufacturers	\$725,702	\$939,103	\$1,664,805
Total	\$179,082,749	\$82,582,634	\$261,665,383
<u>Scenario 3: Low Engineering Control Costs</u>			
Food Manufacturers (except flavoring and popcorn manufacturers)	\$100,782,303	\$73,663,310	\$174,445,613
Diacetyl Flavoring Manufacturers	\$12,333,630	\$7,980,220	\$20,313,850
Butter Flavoring Microwave Popcorn Manufacturers	\$857,077	\$939,103	\$1,796,180
Total	\$113,973,009	\$82,582,634	\$196,555,643
<u>Scenarios 1–3 Combined</u>			
Food Manufacturers (except flavoring and popcorn manufacturers)	\$11,144,919	\$8,179,992	\$19,324,911
Diacetyl Flavoring Manufacturers	\$8,974,767	\$7,980,220	\$16,954,987
Butter Flavoring Microwave Popcorn Manufacturers	\$725,702	\$939,103	\$1,664,805
Total	\$20,845,387	\$17,099,316	\$37,944,703

Requirement	Food Establishments	Flavor Establishments	Popcorn Establishments
Exposure Monitoring	0.0%	10.0%	50.0%
Medical Surveillance	0.0%	10.0%	50.0%
Respirator Use	0.0%	10.0%	50.0%
Regulated Area	0.0%	10.0%	50.0%
Training	0.0%	10.0%	50.0%
Exposure Control Plan	0.0%	10.0%	50.0%

Federal Rules that may Duplicate, Overlap or Conflict with the Draft Proposed Standard

The use of diacetyl as a food additive is regulated by the Food and Drug Administration (FDA). Diacetyl is currently listed by FDA as “generally recognized as safe” for consumption by the general public though there has been a petition asking for reconsideration of that designation. FDA regulations do not address occupational exposure to diacetyl. An OSHA occupational health standard would not in any way duplicate, overlap or conflict with the FDA jurisdiction on these issues. In this regard, not only diacetyl and flavoring using diacetyl, but many other foods, such as flour, can be safe to eat but can be occupational hazards when inhaled. Thus there is no direct connection between OSHA’s action under this draft proposed standard and FDA’s action under its mandates.

OSHA is currently undertaking a national emphasis program on occupational exposure to butter flavorings in popcorn, and is planning a national emphasis program for flavorings manufacturing. OSHA has also posted guidance on its website entitled

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[Recommended Preventative and Control Measures to Reduce the Risk of Obstructive Lung Disease Among Employees in the Microwave Popcorn Packaging Industry](#) and [Hazard Communication Guidance for Diacetyl and Food Flavorings Containing Diacetyl](#).

The draft proposed standard does not conflict with either of these existing enforcement or guidance efforts.

The State of California has also been concerned with diacetyl. In April 2006, in response to the identification of confirmed cases of bronchiolitis obliterans among food flavoring manufacturing employees, the California Division of Occupational Safety and Health (Cal/OSHA) initiated a special emphasis program called the Flavor Industry Safety and Health Evaluation Program (or FISHEP). The goal of this program is to evaluate California flavoring manufacturing plants using a mandatory consultation approach where participating companies agree to hire a provider or use consultants to (1) conduct an industrial hygiene survey of their plant by collecting exposure samples of diacetyl and other flavoring components, (2) conduct health screenings of exposed employees including spirometry tests, and (3) report their findings to Cal/OSHA and implement any recommendations for controlling exposures documented in these findings. If a company declines to participate or fulfill the requirements of the program, the company is then subject to a Cal/OSHA enforcement inspection and potential citations using Cal/OSHA's special order authority. Microwave popcorn plants were not included as a part of this program because there are no such plants in California.

In addition, Cal/OSHA has initiated rulemaking proceedings on diacetyl and other food flavorings. Specifically, in March 2007, Cal/OSHA held a public meeting of affected stakeholders at which it released a draft proposed regulatory text entitled "Occupational Exposure to Food Flavorings". The Cal/OSHA draft proposed standard covers not only the food flavoring manufacturing companies that are subject to the Cal/OSHA FISHEP, but other work sites where diacetyl in certain concentrations is heated or sprayed or work sites where obstructive lung disease has been identified. In July 2007, an advisory committee held its fifth and final meeting and discussed the California draft proposed standard. The State expects to have an official proposed standard for publication in the near future.

The OSH Act permits state standards that differ from standards promulgated by Federal OSHA provided the state "standards . . . are or will be at least as effective in

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providing safe and healthful employment and places of employment as the standards promulgated [by Federal OSHA] under section 6 which relate to the same issues, and which standards, when applicable to products which are distributed or used in interstate commerce, are required by compelling local conditions and do not unduly burden interstate commerce... .” (*See* 29 U.S.C. 667(c)(2).)

ALTERNATIVES

Alternative Approaches to the Rule as a Whole

This section considers very broad alternatives that would fundamentally change the structure of a possible standard or its application. Section 1 discussed one such pair of alternatives—PEL-based rule and a non-PEL rule. This section discusses the option of not having a regulation; the possible costs and small business impact implications of PEL v. non-PEL portions of the rules; and various options with respect to the scope of the rule.

No regulation: If the Agency determines that there is a significant risk of material impairment from occupational exposure to flavorings containing diacetyl that can be feasibly reduced, then the Agency will consider promulgation of a standard. If a standard is promulgated, then a comprehensive program will be necessary to address the occupational risks from flavorings containing diacetyl. If evidence demonstrates that there is no significant risk, then action would not be justified. The OSH Act indicates that development of a new standard is warranted when research, demonstrations, and experiments, and such other information as may be appropriate, such as feasibility of the standard, indicate that employees will suffer material impairment of health or functional capacity. (*See* 29 U.S.C. 655.) Moreover, the priority of establishing standards is under the discretion of the Secretary depending on the urgency of the need for mandatory safety and health standards for particular industries and work environments. A more detailed explanation of the Agency’s approach and justification for developing a health standard for flavorings containing diacetyl can be found above in the PIRFA in “Reasons Why Action by the Agency is Being Considered.”

PEL v. Non-PEL Approaches: The opening section outlined two fundamentally

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different approaches to the rule—one relying on a PEL, the traditional OSHA approach to health standards, and one not using a PEL. These approaches have somewhat different economic consequences. In terms of finding the most cost effective way of assuring employees are exposed at or below a given PEL, a PEL-based standard would be preferable. In the absence of a PEL, it is possible that in some facilities a variety of controls will be installed to protect employees who are exposed below the range of PELs being considered. In general, the relative costs and benefits of PEL and non-PEL approaches depend both on the exact description of the PEL and non-PEL approaches, and upon the exact circumstances of the affected employers.

In term of costs to small businesses, the total costs of a PEL and a non-PEL approach will depend on specific circumstances of which OSHA is still uncertain. A PEL approach will probably be less expensive and have less impact for a facility that can meet a PEL without use of extensive engineering controls or respiratory protection. Alternatively, a non-PEL approach may be less expensive for a facility that has high exposure rates that would be difficult to reduce using engineering and work practice controls below the level that a PEL might impose. The relative benefits of each approach depend on circumstances that OSHA has not determined. A PEL-based approach may leave more employees at risk than a non-PEL approach if there is significant risk below the PEL. The non-PEL approach would decrease that risk because it would probably cover more employees than a PEL-based approach. However, a PEL-based approach may leave fewer employees at risk if the non-PEL approach fails to recognize (and therefore fails to regulate) certain processes that generate harmful exposure.

Alternatives in the Scope and Application: In most OSHA health standards, the scope is defined as including any employer with employees having occupational exposure to the substance. In this case, however, OSHA has defined a more restricted scope in the PEL-based and non-PEL-based draft regulatory texts. The texts of the draft proposed standard have a scope including occupational exposures to flavorings containing diacetyl in industries and establishments that manufacture flavorings or foods. The reason for this restriction is two fold. First, the known cases of occupational lung illness are associated with employees exposed to food flavorings containing diacetyl. Second, OSHA has

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focused the draft proposed standard on the processes for which it has the best information. Waiting to regulate until the Agency has information on all the processes where diacetyl may be present would result in a delay of needed protection where evidence of risk exists.

Nevertheless, OSHA is aware of possible occupational exposures to diacetyl that do not involve food flavorings and is considering including employers with these exposures in the standard. These are:

- Employers processing foods in which diacetyl occurs naturally, such as dairy products, wine, and beer;
- Employers who use flavored oils or butter for cooking purposes; and
- Employers making fragrances, or adding fragrances to products.

Facilities processing foods in which diacetyl occurs naturally such as dairy products, wine and beer—Inclusion of foods with naturally occurring diacetyl would probably significantly increase the percentage of facilities affected, and would include the dairy products industry (NAICS 3115), breweries (NAICS 312120), and wineries (NAICS 312130). If all facilities in these sectors were affected, cost would increase by \$40 to \$50 million per year. (It should be noted that some establishments in each of these industries add extra diacetyl currently; hence their inclusion in the current version of the economic analysis. Diacetyl exposures from starter distillate are not considered “naturally occurring.”)

Facilities that use flavored oils or butter for cooking purposes: There have been some reports [SPI, 2008] suggesting that cooks using butter flavored oils may be exposed to significant levels of diacetyl. OSHA does not currently have any data concerning the extent to which butter flavored oils are used by cooks, what exposures occur if they do, or what kinds of controls would be appropriate for these exposures. As shown in Table 11, adding all cooks would potentially add several otherwise unaffected sectors that employ almost 2 million cooks in over 600,000 very small firms. OSHA has not developed a cost estimate for covering this sector.

TABLE 11
Estimated Number of Cooks and Establishments that Employ Them

Industry	NAICS code	# of cooks ¹	total # of firms ²	Firms with	
				<20 employees ²	<500 ²
Food service and drinking establishments	722	1,568,000	411,262	329,896	409,916
Elementary and secondary schools	6111	126,400	18,004	7,957	17,841
Traveler accommodations	7211	78,810	43,060	33,403	42,559
Nursing and residential care facilities	623	71,190	34,154	17,467	32,917
Other amusement and recreation industries	7139	35,580	62,355	51,358	61,991
General medical and surgical hospitals	6221	29,270	3,395	228	1,827
Gasoline stations	447	21,180	68,223	62,186	67,990
Grocery stores	445	14,540	118,360	106,989	117,900
Total		1,944,970	758,813	609,484	752,941

Sources:

¹ BLS Occupational Employment estimates, 2006

² SBA Office of Advocacy Data, 2005

Diacetyl in Additional Sectors: In the event that more information emerges about diacetyl exposure, including occupational exposure profiles describing a variety of industries, the Agency may consider regulating exposure to diacetyl in sectors beyond the

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manufacture of flavorings and food products.

Covering all occupational exposures: In the event that more information becomes available concerning the variety and extent of existing occupational exposures to diacetyl or flavorings containing diacetyl, the Agency may select a PEL that will apply to all occupational exposures to diacetyl or flavorings containing diacetyl.

Including Acetoin: Acetoin is a plausible contributor to flavoring-related lung disease, given its volatility, structural similarity to diacetyl, and presence in all of the work environments in which an elevated prevalence of respiratory disease has been noted. Acetoin and diacetyl are frequently generated during the same production processes, and diacetyl can be converted to acetoin at high temperatures, as well as through biological reactions. The National Toxicology Program is currently planning inhalational toxicology studies on acetoin as part of a testing nomination for artificial butter flavoring and its ingredients. (National Toxicology Program, 2007). If further research demonstrates that acetoin contributes to flavoring related lung disease, an alternative approach would include acetoin in the standard.

Including Compounds that Substitute for Diacetyl: Flavoring and food product manufacturers are exploring alternative substances to replace diacetyl in certain flavorings. Diacetyl trimer, diacetyl sulfite adducts, and acetyl proprionyl are possible replacement compounds with close structural similarity to diacetyl. Although less volatile, diacetyl derivatives, such as the trimer or sulfite adduct, may possibly convert to diacetyl during some manufacturing conditions or upon inhalation in the respiratory tract. Acetyl proprionyl is a α -diketone that bears a close structural resemblance to diacetyl. The α -diketone compounds are potentially airway-reactive and may pose a risk of respiratory tract injury in the workplace. If further research demonstrates these or other diacetyl derivatives and α -diketones contribute to flavoring-related lung disease, an alternative approach would include them in the standard.

Employers making fragrances, or adding fragrances to products: The production of fragrances is sometimes very similar to the production of flavorings, and may sometimes take place in the same facilities that produce flavorings. OSHA has found that some fragrances contain diacetyl, and that these fragrances may be used in the manufacture of scented candles (NAICS 339999), cosmetics (NAICS 326620), and air fresheners (NAICS 325612). OSHA has identified fragrance manufacturers in NAICS

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325199 (all other basic organic chemical manufacturing), but also in a variety of other NAICS codes. There is no NAICS code specifically for fragrance manufacturers. OSHA is uncertain how the inclusion of fragrances in the scope would increase the costs of the draft proposed standard, because of uncertainties about the extent of diacetyl use in this application and the extent to which there are substitutes for diacetyl.

Any industry with disease: Another alternative would be to include in the scope of the draft proposed standard industries in which diacetyl is used and in which there is evidence of bronchiolitis obliterans, or possibly fixed airway obstruction.

Alternative Provision for Exclusion from Scope: An alternative provision would exempt employers who only use flavorings containing diacetyl below a certain percent content. Such a provision would have the advantage from a small business viewpoint of excluding many employers without the need for demonstrating with objective data or through monitoring that an establishment was outside the scope of the standard. It has the disadvantage that it may exclude employees exposed to significant levels of diacetyl, given that OSHA does not yet have the ability to associate levels of diacetyl exposure with the percentage of diacetyl in materials being handled.

In the event that new information becomes available about the range of uses for, and exposures to, flavorings containing diacetyl, and about the reliability of analytical techniques for measuring airborne concentrations of diacetyl, the Agency may adjust the exclusion criteria in the draft proposed standard.

Alternatives for Specific Provisions

The remaining alternatives considered in this PIRFA are for specific provisions of the draft proposed standard.

Alternative Definitions for Flavoring-Related Lung Disease: Several alternative provisions provide varying definitions of “flavoring-related lung disease” and “flavoring-related skin disease.” These varying provisions are presented because the Agency is continuing to evaluate the range of clinical findings that may best serve as triggers for bringing employers under the scope of the draft proposed standard, in particular its

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exposure assessment and medical surveillance requirements. The Agency has not decided whether to define flavoring-related lung disease in the draft proposed standard, since the term has only recently been recognized as a medical condition, and the recognized clinical features of flavoring-related pathology may change as more information becomes available. In the definitions listed below, the first definition in the list would result in the least number of cases of flavor-related disease, and trigger the fewest additional expenses. The last definition in the list would result in the greatest number of cases of disease and trigger the greatest amount of additional expenses.

Alternate Definitions for Flavoring-Related Lung Disease:

I. Flavoring-Related Lung Disease:

a. Fixed obstruction:

1. FEV1/FVC below the lower limit of normal (National Health and Nutrition Examination Survey)

OR

2. Greater than 15% below employee's personal best FEV1

AND

3. No improvement with administration of bronchodilators

AND

- b. High Resolution Computed Tomography findings consistent with bronchiolitis obliterans

II. Flavoring-Related Lung Disease:

Either of the following new findings on spirometry:

- a. FEV1/FVC, FEV1, or FCV below the lower limit of normal;
FEV1 or FVC more than 15% below employee's personal best performance on these tests.

Alternative for Exposure Control Plan (ECP)

Frequency of ECP Evaluation: An alternative provision in the non-PEL approach would add the requirement that the exposure control plan must be reevaluated every six months, in addition to the text of the draft proposed standard, which only requires

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reevaluation of the exposure control plan when changes in processing may increase employee exposure, or when an employee is diagnosed with a flavoring-related lung disease. The alternative provision is included in recognition of the potential difficulty in ascertaining whether processes have changed in ways that may increase exposure, given that the composition of flavorings change frequently and that employers are not always aware of these changes. For example, an employer may not be aware of increases in the concentration of diacetyl in the flavorings that it purchases from a flavoring distributor, though higher concentrations would likely constitute a change in processing that would increase employee exposure. OSHA estimates that this alternative would increase the costs of this provision in the base case by 11.5 percent, resulting in an increase in costs of \$700,000 per year. This cost addition is relatively small because OSHA's base case cost estimate assumes full compliance with the draft proposed standard and thus costs for just changing the plan when conditions change would be minor.

ECP Phase-in: A second issue that OSHA is considering with respect to the exposure control plan is when it should first be required. Since a sound exposure control plan requires a good deal of work in the form of hazard assessment and in the form of engineering design, it may be difficult to develop an exposure control plan quickly. OSHA is therefore considering a longer time before the exposure control plan needs to be prepared or perhaps an exposure control plan that develops over time (initially simply a schedule for various activities, later details on planned controls, still later an actual plan making full use of experience with the fully implemented controls.)

ECP for PEL Approach: Finally, OSHA is considering an alternative that would require a written exposure control plan for the PEL approach. Although it creates a paperwork burden and it may introduce some redundancy in a PEL approach, a written exposure control plan organizes an employer's efforts and may stimulate more thorough understanding and planning concerning exposures.

Alternative for Regulated Areas

An alternative provision for the non-PEL approach would exempt employers from the regulated areas requirements if the employer can demonstrate through objective data or monitoring that the airborne concentration of diacetyl in the area in question is below the

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limit of detection of the measurement method. This would help to prevent employers from having to implement regulated areas in areas without any detectable levels of diacetyl. However, this exemption would not apply to any areas covered by the regulated areas requirements in which an employee works and experiences signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl.

Alternatives for Engineering Controls (EC)

EC Compliance Dates: While the draft proposed text for both the PEL and non-PEL approaches require the implementation of engineering controls and work practices within two years of the effective date, alternative provisions would allow employers less time. The first alternative provision would require that employers with 20 or more employees implement engineering controls and work practices within one year of the effective date, and that businesses with fewer than 20 employees implement engineering controls and work practices within two years of the effective date. The second alternative provision would require that employers with more than 20 employees implement engineering controls and work practices within six months of the effective date, and that businesses with fewer than 20 employees implement engineering controls and work practices within one year of the effective date. These alternative provisions are included in light of the potentially rapid onset and progression of flavoring-related lung disease. The alternative provisions provide businesses with fewer employees with a longer implementation period, in recognition of the relatively limited resources of small business owners. The third alternative would require that employers with fewer than 20 employees implement engineering controls within 4 years.

30-Day Trigger EC: Another alternative provision for both the PEL and non-PEL approaches would exempt from engineering control requirements those facilities where flavorings containing diacetyl are mixed, produced, or added to food for less than 30 days per year. Under this alternative, employers would be allowed to use respiratory protection and work practice controls instead of engineering controls for those areas and processes where engineering controls would otherwise be required. Such employers would be required to ensure that all employees wear respirators in all areas that would otherwise be subject to engineering control provisions. OSHA believes that this could result in major decreases in costs for many facilities that have limited use of diacetyl.

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Reliable Quantitation Limit Exemption: An alternative provision for the non-PEL approach would exempt employers from the engineering and work practice requirements in an area where flavorings containing diacetyl are mixed, produced, or added to food if the employer can demonstrate through objective data or monitoring that the combined airborne concentration of diacetyl in the area is below the reliable quantitation limit of the measurement method. This would help to prevent employers from having to implement engineering and work practice controls in areas without any detectable levels of diacetyl. However, this exemption would not apply to any areas in which an employee works and experiences signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl.

Alternatives for the Respiratory Protection Provision

An alternative provision for the non-PEL approach would exempt employers who implement the required engineering and work practice controls from respiratory protection requirements. The Agency is currently considering whether respiratory protection is needed where effective engineering and work practice controls are in place. This alternative would largely eliminate the costs associated with respiratory protection, estimated as \$16 million per year in the base case.

A second alternative provision for the non-PEL approach would exempt employers from the respiratory protections requirements when the airborne concentration of diacetyl is below the limit of detection of the measurement method.

A third alternative would allow the use of at least a half face air purifying respirator and goggles rather than requiring use of a full-face, air purifying respirator, if additional evidence demonstrates that a protection factor of ten afforded by a half-face respirator is adequate.

A fourth alternative would base the selection of respiratory protection on the limit of detection and the form of diacetyl being used in a process where respiratory protection would be required. This approach would require employers to ensure that employees conducting operations using powdered flavorings containing diacetyl use goggles in addition to a half-face respirator equipped with combination organic vapor/P100 cartridges where employee exposures are less than 10 times the level of detection (LOD). If employee exposures exceed this amount, the employers would be required to provide a

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full-face respirator equipped with combination organic vapor/P100 cartridges. For employees conducting operations using liquid flavorings containing diacetyl, the same principle would apply as described for powdered flavorings; however, employee exposures that yield results less than the LOD would not require the employee to use respiratory protection.

Alternative for Exposure Assessments (EA)

Frequency of EA: Alternative provisions for the non-PEL approach would require exposure assessment every six months or annually, in addition to the provisions in the draft proposed text which require exposure assessment when changes in production, process, control equipment, personnel, or work practice may increase employee exposure, or when an employee is diagnosed with a flavoring-related lung disease. The alternative provision is included in recognition of the potential difficulty in ascertaining whether processes have changed in ways that may increase exposure, given that the composition of flavorings change frequently and that employers are not always aware of these changes. This alternative would increase costs of exposure assessment by 342 percent—in the base case by \$41 million per year.

Exclude or Modify EA under non-PEL approach: As an alternative in the non-PEL approach, the Agency is considering removing or modifying exposure assessment provisions requiring the measurement of airborne diacetyl concentrations. OSHA standards have typically included exposure monitoring provisions to ensure that employees are not exposed to airborne chemical concentrations that exceed the PEL. In the non-PEL approach, exposure assessment provisions are included in the draft proposed standard to help employers determine which employees have the highest exposure to these compounds, identify where engineering controls might be needed, and evaluate the effectiveness of those controls. However, under the non-PEL approach, the draft proposed standard does not require employers to maintain exposures below specific airborne concentrations of diacetyl; therefore, exposure assessments may not be warranted.

Pre- and Post-Implementation Assessment of EC: Another alternative that the Agency is considering under the non-PEL approach is requiring that employers conduct exposure assessments before and after implementation of engineering controls. Such

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assessments would help employers determine the effectiveness of the controls and identify deficiencies that may still need to be corrected.

Alternatives for Hazard Communication for PEL and non-PEL approaches:

Provide Additional Information to Employees: An alternative provision would require the employer to obtain and make available to employees the concentration of diacetyl in all flavorings used in the workplace. The Agency is considering this provision because knowledge of diacetyl content in flavorings is likely to help ensure that adequate protection from exposure continues. For example, an additional exposure assessment is required whenever changes occur in production processes or raw materials. Knowing this information may better help the employer make these determinations. OSHA is aware that many flavorings manufacturer have good reasons to keep exact constituents secret, but is interested in determining if revealing diacetyl content alone would be problematic for manufacturers.

Retraining: An additional provision would require that retraining occur at fixed periods, such as annually. The current draft proposed standard requires that employers train employees with sufficient frequency to ensure that employee can demonstrate knowledge of hazards and the contents of the standard. Having a specified frequency would serve to further clarify employers' responsibilities for what constitutes a sufficient frequency of training. In our cost analysis OSHA assumes that training will be given annually even though retraining may not be required on an annual basis to ensure that employees continue to demonstrate knowledge of the standard, including the medical surveillance program. Training only new employees would reduce costs by 61 percent or, in the base case, by \$900,000 per year.

Alternative Provisions for Medical Surveillance for PEL and non-PEL approaches

Medical Surveillance for Past Exposure or Previous Diagnosis: An alternative provision would require that medical surveillance be offered to current employees who, in the past, mixed, produced, or added flavorings containing diacetyl to food. Another alternative would require that medical surveillance be offered to current employees

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previously diagnosed with flavoring-related lung disease, and employees that the PLHCP has identified as being at increased risk for flavoring-related lung disease. These provisions would capture a broader population of employees who were previously exposed and who potentially remain at risk for flavoring-related disease.

Reinstating Medical Surveillance: Another alternative provision would require employers to provide medical surveillance, regardless of whether conditions allowing decreased frequency or termination of surveillance are met, if new cases of flavoring-related lung disease occur. Similarly, meeting the conditions for termination or decreased frequency will not exempt an employer if changes in production, processing, control equipment, personnel, or practices occur that are likely to increase exposure.

It is difficult to estimate the exact effects of these alternatives on the costs of the draft proposed standard. OSHA examined the costs of two medical surveillance scenarios, in addition to the one in the non-PEL approach in the draft proposed standard. In the first of these analyses, OSHA examined the costs if all production employees were to receive medical surveillance. This would increase costs by 106 percent—over \$5 million per year in the base case. Alternatively, OSHA also examined a scenario in which only mixers and blenders would be required to have medical surveillance. This scenario decreased the costs of medical surveillance by 78 percent—a reduction of \$24 million per year in the base case.

Reporting Cases of Bronchiolitis Obliterans: An additional alternative would require employers to report results of medical surveillance to OSHA or NIOSH of cases of bronchiolitis obliterans identified among their employees. This provision would promote further study and a better understanding of the contribution of various workplace exposures to the development of bronchiolitis obliterans.

Specific Criteria for Referral to a Specialist: An alternative provision would specify additional criteria that would require a PLHCP to refer an employee to a pulmonary specialist. For example, a PLHCP might be required to refer employees who demonstrate an FEV1/FVC below the lower limit of normal, or an FEV1 decline greater than 15% below the employee's personal baseline.

Medical Removal Protection: Finally, an alternative provision provides for medical removal and wage protection to employees who are suffering from forms of flavoring-related lung disease that may improve or stabilize with removal from exposure.

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If the PLHCP determines that an employee needs to be medically removed, the alternate provision would entitle such employees to reassignment, when possible, to jobs involving no exposure flavorings containing these chemicals. Additionally, the alternative provision would entitle a reassigned employee, for a specified period of time (possibly 18 months), to the same wages and benefits that the employee received prior to reassignment. Reassignment would end after the specified time period, when the PLHCP determines that the condition is resolved, or when a final medical determination that the employee is incapable of ever safely returning to the job. The Agency is interested in receiving comments on what time period may be appropriate if a medical removal protection requirement is included in the standard.

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Regulatory Texts for Occupational Exposure to Diacetyl and Food Flavorings Containing Diacetyl

	PEL	NON-PEL
Scope and Application	<p>(1) This section applies to occupational exposures to flavorings containing diacetyl in:</p> <ul style="list-style-type: none"> (i) Industries and establishments that manufacture flavorings; and (ii) Industries and establishments that manufacture food products. <p>(2) This section applies to an establishment, covered under paragraph (1), where an employee is diagnosed with a flavoring-related lung or skin disease regardless of whether the employer has objective data or monitoring data as described in paragraph (3).</p> <p>(3) This section does not apply to establishments for which the employer has objective data or monitoring data demonstrating that:</p> <p style="padding-left: 40px;">All employee exposures to a flavoring containing diacetyl cannot exceed an airborne concentration of diacetyl in excess of 0.03 ppm (8-hour time weighted average [TWA]) or a 15-minute short term exposure of 0.2 ppm under any expected conditions of use.</p>	<p>(1) This section applies to occupational exposures to flavorings containing diacetyl in:</p> <ul style="list-style-type: none"> (i) Industries and establishments that manufacture flavorings; and (ii) Industries and establishments that manufacture food products. <p>(2) This section applies to an establishment, covered under paragraph (1), where an employee is diagnosed with a flavoring-related lung or skin disease regardless of whether the employer has objective data or monitoring data as described in paragraph (3).</p> <p>(3) This section does not apply to establishments for which the employer has objective data or monitoring data demonstrating that:</p> <p style="padding-left: 40px;">All employee exposures to a flavoring containing diacetyl cannot exceed an airborne concentration of diacetyl in excess of 0.03 ppm (8-hour time weighted average [TWA]) or a 15-minute short term exposure of 0.2 ppm under any expected conditions of use.</p>

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<p>Definitions</p>	<p><i>Action Level</i> means a concentration of airborne diacetyl that is half of the PEL (or possibly another value below the PEL).</p> <p><i>Assistant Secretary</i> means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.</p> <p><i>Diacetyl</i> (CAS # 431-03-8) means an organic compound with the SMILES chemical formula <chem>CC(=O)C(C)=O</chem> that has a molecular weight of approximately 86.09 gm/mole.</p> <p><i>Emergency</i> means any occurrence that results, or is likely to result, in an uncontrolled release of flavorings containing diacetyl. When an incidental release of flavorings containing diacetyl can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.</p> <p><i>Employee exposure</i> means the exposure to diacetyl or flavorings containing diacetyl that would occur when the employee is not using a respirator.</p> <p><i>Flavoring-related lung disease</i> means obstructive lung disease in an employee exposed to flavorings containing diacetyl. For these purposes, obstructive lung disease is defined as a ratio of the forced expiratory volume₁</p>	<p><i>Assistant Secretary</i> means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.</p> <p><i>Diacetyl</i> (CAS # 431-03-8), also called butanedione or 2,3-butanedione, means an organic compound with the SMILES chemical formula <chem>CC(=O)C(C)=O</chem> that has a molecular weight of approximately 86.09 gm/mole.</p> <p><i>Emergency</i> means any occurrence that results, or is likely to result, in an uncontrolled release of flavorings containing diacetyl. When an incidental release of flavorings containing diacetyl can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.</p> <p><i>Employee exposure</i> means the exposure to diacetyl or flavorings containing diacetyl that would occur when the employee is not using a respirator.</p> <p><i>Flavoring-related lung disease</i> means obstructive lung disease in an employee exposed to flavorings containing diacetyl. For these purposes, obstructive lung disease is defined as a ratio of the forced expiratory volume₁ (FEV₁) to the forced vital capacity (FVC) that is below the lower limit of normal, using National Health and</p>

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	<p>(FEV₁) to the forced vital capacity (FVC) that is below the lower limit of normal, using National Health and Nutrition Examination Survey (NHANES) reference values, or a FEV₁ that is more than 15% below the employee's personal best FEV₁.</p> <p><i>Flavoring-related skin disease</i> means any dermal irritation or pathology that the PLHCP believes is related to exposure to flavorings containing diacetyl.</p> <p><i>Flavorings containing diacetyl</i> means substances, added to impart or help impart a taste or aroma in food, that contain diacetyl. Pure diacetyl and fall within this definition, when used to impart or help impart a taste or aroma in food.</p> <p><i>High-efficiency particulate air (HEPA) filter</i> means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.</p> <p><i>Industries and establishments that manufacture flavorings</i> means facilities that make flavorings for distribution and wholesale, but does not include restaurant or cafeteria kitchens where cooks make flavorings in the course of preparing food for customers.</p> <p><i>Industries and establishments that manufacture foods</i> means facilities that make food, but does not include restaurants, cafeterias, or kitchens in institutions such as hospitals or schools.</p>	<p>Nutrition Examination Survey (NHANES) reference values, or a FEV₁ that is more than 15% below the employee's personal best FEV₁.</p> <p><i>Flavoring-related skin disease</i> means any dermal irritation or pathology that the PLHCP believes is related to exposure to flavorings containing diacetyl.</p> <p><i>Flavorings containing diacetyl</i> means substances, added to impart or help impart a taste or aroma in food, that contain diacetyl. Pure diacetyl fall within this definition, when used to impart or help impart a taste or aroma in food.</p> <p><i>High-efficiency particulate air (HEPA) filter</i> means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.</p> <p><i>Industries and establishments that manufacture flavorings</i> means facilities that make flavorings for distribution and wholesale, but does not include restaurant or cafeteria kitchens where cooks make flavorings in the course of preparing food for customers.</p> <p><i>Industries and establishments that manufacture foods</i> means facilities that make food, but does not include restaurants, cafeterias, or kitchens in institutions such as hospitals or schools.</p> <p><i>Mixing</i> means blending the components of a mixture</p>
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	<p><i>Objective data</i> means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to flavorings containing diacetyl and associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.</p> <p><i>Physician or other licensed health care professional (PLHCP)</i> is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by the medical surveillance provisions of this section.</p>	<p>together. Mixing also refers to compounding, formulating.</p> <p><i>Mixing area</i> means an area in the plant where flavorings containing diacetyl are mixed.</p> <p><i>Objective data</i> means information such as air monitoring data from industry-wide surveys or calculations based on the composition or chemical and physical properties of a substance demonstrating the employee exposure to flavorings containing diacetyl and associated with a particular product or material or a specific process, operation, or activity. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.</p> <p><i>Produce</i> means pour, weigh, bag, transfer, spray, or perform other operations involved in the manufacture of flavorings or foods.</p> <p><i>Production room</i> means a room where workers pour, weigh, bag, transfer, or perform other operations with flavoring containing diacetyl as part of the manufacture of flavorings or foods.</p> <p><i>Solid barrier</i> means a structurally sound wall or enclosure.</p> <p><i>Tank</i> means any vessel used for mixing or holding</p>
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		flavorings containing diacetyl.
Permissible Exposure Limit (PEL)	(1) The employer shall ensure that no employee is exposed to an airborne concentration of diacetyl in excess of the PEL of (0.05, 0.1, 0.5, or 1.0) ppm 8-hour TWA or a STEL of (0.2, 0.5, 2.0, or 4.0) ppm (15 minutes);	(N/A)
Exposure assessment	<p>(1) <u>General</u>. Each employer who has a workplace or work operation covered by this section shall determine the 8-hour TWA exposure and 15 minute short-term exposure level for each employee exposed to flavorings containing diacetyl.</p> <p>(2) <u>Scheduled monitoring</u>. (i) The employer shall perform initial monitoring to determine the 8-hour TWA and 15 minute short-term exposure level for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift for each job classification, in each work area. Where an employer does representative sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest exposures;</p> <p>(ii) If initial monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring;</p>	<p>(1) <u>Initial assessment</u>. Each employer who has an establishment covered by this section shall perform an initial assessment to determine the airborne concentrations of diacetyl contained in flavorings, to which employees may be exposed. This initial assessment shall consist of:</p> <p>(i) Representative 8-hour TWA and 15-minute short-term concentrations determined on the basis of one or more personal breathing zone air samples representing employee exposure for each shift and for each job classification in each work area; or</p> <p>(ii) Engineering studies or other objective data indicating the levels of flavorings containing diacetyl to which employees are exposed.</p> <p>(2) <u>Additional assessment</u>. Employers shall conduct additional exposure assessment whenever:</p> <p>(i) Changes in production process, raw materials,</p>

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	<p>(iii) If monitoring reveals employee exposures to be at or above the action level, the employer shall perform periodic monitoring at least every six months;</p> <p>(iv) If monitoring reveals employee exposures to be above the PEL, the employer shall perform periodic monitoring at least every three months;</p> <p>(v) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring;</p> <p>(vi) The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures or when the employer has any reason to believe that new or additional exposures have occurred.</p> <p>(3) <u>Employee notification of determination results.</u> (i) Where the exposure determination indicates that employee exposure exceeds the PEL, within 15 working days of receipt of the results, the employer shall either post the results in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing of the results.</p> <p>(ii) Whenever the exposure determination indicates that</p>	<p>equipment, personnel, work practices, or control methods may increase employee exposure; or</p> <p>(ii) An employee has been diagnosed with flavoring-related lung or skin disease.</p> <p>(3) Where the employer can establish and document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift.</p> <p>(4) Where an employer relies upon objective data or performs representative sampling to conduct an exposure assessment, the employer shall assess the exposure of the employee(s) expected to have the highest exposure.</p> <p>(5) <u>Employee notification of determination results.</u></p> <p>(i) Within 15 working days of the completion of the exposure assessment, the employer shall either post the results of the assessment in an appropriate location that is accessible to all affected employees or shall notify each affected employee individually in writing; and</p> <p>(ii) The employer shall describe in the written notification any corrective action being taken to reduce employee exposure.</p> <p>(6) <u>Accuracy of measurement.</u> (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring</p>
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	<p>employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.</p> <p>(4) <u>Accuracy of measurement.</u> Where air monitoring is performed to comply with the requirements of this section, the employer shall use a method of monitoring and analysis that can measure diacetyl within an accuracy of plus or minus 25 percent (+/- 25%), at a statistical confidence level of 95 percent for airborne concentrations.</p> <p>(ii) Samples shall be collected and analyzed according to the procedures presented in Mandatory Appendix, or according to an equivalent method.</p> <p>(5) <u>Observation of monitoring.</u> (i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure.</p> <p>(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health</p>	<p>and analysis that can measure diacetyl or acetoin to within an accuracy of plus or minus 25 percent (+/- 25%), at a statistical confidence level of 95 percent for airborne concentrations.</p> <p>(ii) Samples shall be collected and analyzed according to the procedures presented in Mandatory Appendix, or according to an equivalent method.</p> <p>(7) <u>Observation of monitoring.</u></p> <p>(i) Where air monitoring is performed to comply with the requirements of this section, the employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to flavorings containing diacetyl;</p> <p>(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures; and</p>
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	procedures.	
Exposure control plan	N/A	<p>(1) Employers covered under the scope of this section shall prepare a written exposure control plan that, at minimum:</p> <p>(i) Describes the specific work operations and sources of emission, identified through exposure assessment (as required under this section), where exposure and potential exposure to flavorings containing diacetyl occurs;</p> <p>(ii) Identifies engineering controls and work practices in use;</p> <p>(iii) Identifies regulated areas and the methods to used to demarcate them;</p> <p>(iv) Documents the effectiveness of engineering controls and work practices in use;</p> <p>(v) Establishes a leak prevention, detection, and repair procedure;</p> <p>(vi) Describes engineering controls and work practices that are planned and the timeline for implementation;</p> <p>(vii) Identifies required personal protective equipment, including respirators, and specifies work areas in which the use of such equipment is required in accordance with 29 CFR 1910.132,133, and 138;</p>

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		<p>(viii) Provides an employee exposure monitoring program, as required under this section, that includes criteria for selecting employees and tasks to be monitored, and methods for collecting and analyzing samples for diacetyl contained in the specific flavoring formulation;</p> <p>(ix) Identifies procedures and prohibitions for cleaning areas where flavorings containing diacetyl are used, as required under the housekeeping provisions of this section; and</p> <p>(x) Describes emergency procedures.</p> <p>(2) Employers shall update the written control plan whenever changes in production process, raw materials, equipment, personnel, work practices, or control methods may increase employee exposure.</p>
<p>Regulated Areas</p>	<p>(1) <u>Establishment</u>. The employer shall establish a regulated area wherever an employee's exposure is, or can reasonably be expected to be, in excess of the PEL.</p> <p>(2) <u>Demarcation</u>. The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees of the boundaries of the regulated area.</p> <p>(3) <u>Access</u>. The employer shall limit access to regulated</p>	<p>(1) <u>Establishment</u>. The employer shall establish a regulated area:</p> <p>(i) when employees pour, weigh, mix, spray, transfer, or bag flavorings containing diacetyl;</p> <p>(ii) when employees engage in processes that generate exposures similar to those that occur during the pouring, weighing, mixing, spraying, transfer, or bagging of flavorings containing diacetyl; and</p>

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	<p>areas to:</p> <p>(i) Persons authorized by the employer and required by work duties to be present in the regulated area;</p> <p>(ii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; or</p> <p>(iii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.</p>	<p>(iii) during emergency cleanup.</p> <p>(2) <u>Demarcation</u>. The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes the area where exposure occurs and alerts employees of the boundaries of the regulated area.</p> <p>(3) <u>Access</u>. The employer shall limit access to regulated areas to:</p> <p>(i) Persons authorized by the employer and required by work duties to be present in the regulated area;</p> <p>(ii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area; and</p> <p>(iii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under the exposure assessment provisions of this section.</p>
<p>Methods of compliance</p>	<p>(1) <u>Engineering and work practice controls</u>.</p> <p>(i) Except as permitted in paragraph (1)(ii) of provisions describing methods of compliance, the employer shall use engineering and work practice controls to reduce and maintain employee exposure at or below the PEL unless</p>	<p>(1) <u>Engineering and work practice controls</u>. In areas where flavorings containing diacetyl are mixed, produced, or added to food, employers shall:</p> <p>(i) Isolate areas in which flavorings containing diacetyl are mixed, produced, or added to food, using solid</p>

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	<p>the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure at or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the respiratory protection provisions of this section.</p> <p>(ii) Where the employer can demonstrate that a process or task does not result in any employee exposure above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.</p>	<p>barriers and providing ventilation sufficient to maintain a negative pressure of 0.04 inches water gauge (“w.g.”) plus or minus 0.02 “w.g.” relative to the areas adjacent to the mixing or production room. This ventilation system shall exhaust outside the building or to an area where no workers are present;</p> <p>(ii) Ventilate mixing operations with local exhaust hoods that provide at minimum a capture velocity of 100 feet per minute and ensure the use of local exhaust hoods during all mixing and compounding operations;</p> <p>(iii) Enclose mixing and storage tanks and equip openings with an airtight lid or hatch. Mixing and storage tanks shall be equipped with local exhaust ventilation that maintains the interior of the tank at a negative pressure with respect to the mixing or production room even when the access lid or hatch is open;</p> <p>(iv) Maintain temperature of mixing and storage tank contents as low as the production process will allow;</p> <p>(v) Clean mixing and storage tanks and other process equipment with water or other cleaning agent at ambient temperature.</p> <p>(2) Employers shall install and ensure the use of laboratory hoods or equally effective local exhaust ventilation hood that provides a minimum face velocity of 100 feet per minute for any research and development</p>
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		<p>or quality control activities with exposure or potential exposure to flavorings containing diacetyl.</p>
<p>Respiratory Protection</p>	<p>(1) <u>General</u>. The employer shall provide respiratory protection for employees during:</p> <p>(i) Periods necessary to install or implement feasible engineering and work practice controls;</p> <p>(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;</p> <p>(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;</p> <p>(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or</p> <p>(v) Emergencies.</p> <p>(2) <u>Respiratory protection program</u>. Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.</p>	<p>(1) For every employee covered under paragraph (2) of the respiratory protection provisions, employers shall, at a minimum, provide a full-face air purifying respirator equipped with combination organic vapor and particulate filters.</p> <p>(2) Employers shall provide respiratory protection in accordance with 29 CFR 1910.134 (except paragraph D) of 29 CFR 1910.134):</p> <p>(i) When employees pour, weigh, mix, spray, transfer or bag flavorings containing diacetyl;</p> <p>(ii) When employees engage in processes that generate exposures similar to those that occur during the pouring, weighing, mixing, spraying, transferring, or bagging of flavorings containing diacetyl; and</p> <p>(iii) When employees perform work operations such as maintenance, sanitation, and repair activities, for which engineering and work practice controls are not feasible;</p> <p>(iv) During emergency cleanup; and</p> <p>(v) During periods necessary to install or implement feasible engineering and work-practice controls.</p>

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<p>Protective work clothing and equipment</p>	<p>(1) <u>Provision and use</u>. Where a hazard is present or is likely to be present from skin or eye contact with flavorings containing diacetyl, the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.</p> <p>(2) <u>Removal and storage</u>. (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with flavorings containing diacetyl at the end of the work shift or at the completion of their tasks involving exposure, whichever comes first.</p> <p>(ii) The employer shall ensure that no employee removes contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.</p> <p>(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.</p> <p>(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of</p>	<p>(The Agency anticipates that provisions relating to protective work clothing and equipment will be largely the same in PEL and non-PEL proposals)</p>
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	<p>the Hazard Communication Standard, 29 CFR 1910.1200.</p> <p>(3) <u>Cleaning and replacement.</u> (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.</p> <p>(ii) The employer shall prohibit the removal of flavorings containing diacetyl from protective clothing and equipment by blowing, shaking, or any other means that disperses flavorings containing diacetyl into the air or onto an employee's body.</p> <p>(iii) The employer shall inform any person who launders or cleans contaminated protective clothing or equipment of the potentially harmful effects of exposure to flavorings containing diacetyl, and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with and effectively prevents the release of flavorings containing diacetyl in excess of the PEL.</p>	
<p>Hygiene areas and practices</p>	<p>(1) <u>General.</u> Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with flavorings containing diacetyl occurs, the employer shall provide washing facilities in conformance with 29 CFR 1910.141. Eating and drinking areas provided by the employer shall also be in conformance with §1910.141.</p>	<p>(The Agency anticipates that provisions relating to hygiene areas and practices will be the same in PEL and non-PEL proposals)</p>

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	<p>(2) <u>Change rooms</u>. The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.</p> <p>(3) <u>Washing facilities</u>. (i) The employer shall provide readily accessible washing facilities capable of removing flavorings containing diacetyl from the skin, and shall ensure that affected employees use these facilities when necessary.</p> <p>(ii) The employer shall ensure that employees who have skin contact with flavorings containing diacetyl wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.</p> <p>(4) <u>Eating, drinking, and smoking areas</u>. (i) Whenever the employer allows employees to consume food or beverages at a worksite where flavorings containing diacetyl are present, the employer shall ensure that eating drinking, and smoking areas and surfaces are maintained as free as practicable of flavorings containing diacetyl.</p> <p>(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface flavorings containing diacetyl have been removed from the clothing</p>	
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	<p>and equipment by methods that do not disperse these chemicals into the air or onto an employee's body.</p> <p>(5) <u>Prohibited activities.</u> The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, or in areas where skin or eye contact with flavorings containing diacetyl occurs; or carry the products associated with these activities, or store such products in these areas.</p>	
<p>Hazard Communication</p>	<p>(1) In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall communicate with and train employees with sufficient frequency to ensure by that each employee can demonstrate knowledge of at least the following:</p> <p>(A) The contents of this section;</p> <p>(B) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.</p>	<p>(1) In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, employers shall communicate with and train employees with sufficient frequency to ensure by that each employee can demonstrate knowledge of at least the following:</p> <p>(A) The contents of this section;</p> <p>(B) An explanation of the employer’s Exposure Control Plan and the means by which the employee can obtain a copy of the written plan.</p> <p>(C) The purpose and a description of the medical surveillance program required by paragraph (i) of this section.</p>
<p>Medical Surveillance</p>	<p>(1) <u>General.</u> (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:</p>	<p>(1) <u>General.</u> (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:</p>

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	<p>(A) Who are or may be occupationally exposed to flavorings containing diacetyl at or above the action level for 30 or more days a year;</p> <p>(B) Experiencing signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl;</p> <p>(C) Exposed in an emergency to flavorings containing diacetyl; or</p> <p>(D) Working in an area or engaged in a process that is the same or similar to that of an employee who has been diagnosed with flavoring-related disease.</p> <p>(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.</p> <p>(2) <u>Frequency</u>. The employer shall provide a medical examination:</p> <p>(i) Before the time of initial assignment, unless the employee has received a medical examination related to flavorings containing diacetyl, that meets the requirements of this section within the last six months;</p> <p>(ii) Every six months, or more frequently when deemed necessary by the PLHCP;</p> <p>(iii) Whenever an employee shows signs or symptoms</p>	<p>(A) Working in areas where flavorings containing diacetyl or acetoin are mixed, produced, or added to foods;</p> <p>(B) Working in maintenance, sanitation, quality control, or laboratory environments where flavorings containing diacetyl are present;</p> <p>(C) Experiencing signs or symptoms of the adverse health effects associated with exposure to flavorings containing diacetyl;</p> <p>(D) Exposed in an emergency to flavorings containing diacetyl or</p> <p>(E) Working in an area or engaged in a process that is the same or similar to that of an employee who has been diagnosed with flavoring-related disease.</p> <p>(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.</p> <p>(2) <u>Frequency</u>. The employer shall provide a medical examination:</p> <p>(i) Before the time of initial assignment, unless the employee has received a medical examination related to flavorings containing diacetyl, that meets the requirements of this section within the last six months;</p>
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	<p>associated with exposure to flavorings containing diacetyl;</p> <p>(iv) Within 30 days after exposure during an emergency which results in an uncontrolled release of flavorings containing diacetyl; or</p> <p>(v) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (4) was less than six months prior to the date of termination.</p> <p>(vi) Whenever an employee who works in a similar area or process is diagnosed with flavoring-related lung disease.</p> <p>(3) <u>Content of examination.</u> A medical examination consists of, at a minimum:</p> <p>(i) A medical and work history, with emphasis on past, present and potential exposure to flavorings containing diacetyl;</p> <p>(ii) A physical examination with emphasis on the respiratory system, eyes and the integumentary system;</p> <p>(iii) Completion of the respiratory questionnaire in Appendix or other equivalent questionnaire;</p> <p>(iv) Spirometry administered by individuals who have</p>	<p>(ii) Every six months, or more frequently when deemed necessary by the PLHCP;</p> <p>(iii) Whenever an employee shows signs or symptoms associated with exposure to flavorings containing diacetyl;</p> <p>(iv) Within 30 days after exposure during an emergency which results in an uncontrolled release of flavorings containing diacetyl; or</p> <p>(v) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (4) was less than six months prior to the date of termination.</p> <p>(vi) For employees covered under (1)(i)(E) of the medical surveillance provisions, within 30 days after an employee who works in a similar area or process is diagnosed with flavoring-related lung disease.</p> <p>(3) <u>Termination.</u> Medical surveillance may be reduced in frequency or terminated for employees in a particular job or location if:</p> <p>(i) Using the representative sampling procedures [using the OSHA/SLTC method found in Appendix], an employer demonstrates that employees working in the particular job or location have no measurable exposure to diacetyl or acetoin; and</p>
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	<p>completed a training course in spirometry that is certified by NIOSH;</p> <p>(vi) any other additional tests deemed appropriate by the PLHCP; and</p> <p>(v) At a minimum, spirometry shall include measurement of forced vital capacity (FVC) and forced expiratory volume at one second (FEV (1.0)) and FEV(1)/FVC ratio. The FVC and FEV(1.0) shall be obtained in a manner consistent with the most current American Thoracic Society guidelines for standardization of spirometry including acceptability and repeatability criteria.</p> <p>(4) <u>Equipment Standards.</u> All spirometry equipment used to meet the medical surveillance requirements of this section shall:</p> <p>(i) pass all laboratory standards for accuracy and precision criteria, using either the ATS 1994 spirometry evaluation protocol, or validation from an independent laboratory, if equipment is purchased after the effective date of this section; for equipment purchased prior to the effective date, the employer shall obtain information from the equipment vendor as to the extent that the equipment being used meets accuracy and precision criteria from either of the above sources;</p> <p>(ii) be checked for calibration at least daily, when in use,</p>	<p>(ii) Three consecutive rounds of medical surveillance at 6-month intervals demonstrate no change in spirometry readings and the absence of flavoring-related skin disease among all employees working in the particular job or location.</p> <p>(4) <u>Content of examination.</u> A medical examination consists of, at a minimum:</p> <p>(i) A medical and work history, with emphasis on past, present and potential exposure to flavorings containing diacetyl;</p> <p>(ii) A physical examination with emphasis on the respiratory system, eyes and the integumentary system;</p> <p>(iii) Completion of the respiratory questionnaire in Appendix or other equivalent questionnaire;</p> <p>(iv) Spirometry administered by individuals who have completed a training course in spirometry that is certified by NIOSH;</p> <p>(vi) any other additional tests deemed appropriate by the PLHCP; and</p> <p>(v) At a minimum, spirometry shall include measurement of forced vital capacity (FVC) and forced expiratory volume at one second (FEV (1.0)) and FEV(1)/FVC ratio. The FVC and FEV(1.0) shall be obtained in a manner consistent with the most current American</p>
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	<p>following ATS guidelines;</p> <p>(iii) provide, at a minimum, tracings that meet the minimum size and resolution requirements set forth by ATS.</p> <p>(5) <u>Information provided to the PLHCP.</u> The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:</p> <p>(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to flavorings containing diacetyl;</p> <p>(ii) The employee's former, current, and anticipated levels of occupational exposure to flavorings containing diacetyl;</p> <p>(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and</p> <p>(iv) Records of employment-related medical examinations previously provided to the affected employee, including all previous spirometry measurements, currently within the control of the employer.</p>	<p>Thoracic Society guidelines for standardization of spirometry including acceptability and repeatability criteria.</p> <p>(4) <u>Equipment Standards.</u> All spirometry equipment used to meet the medical surveillance requirements of this section shall:</p> <p>(i) Pass all laboratory standards for accuracy and precision criteria, using either the ATS 1994 spirometry evaluation protocol, or validation from an independent laboratory, if equipment is purchased after the effective date of this section; for equipment purchased prior to the effective date, the employer shall obtain information from the equipment vendor as to the extent that the equipment being used meets accuracy and precision criteria from either of the above sources;</p> <p>(ii) Be checked for calibration at least daily, when in use, following ATS guidelines;</p> <p>(iii) Provide, at a minimum, tracings that meet the minimum size and resolution requirements set forth by ATS.</p> <p>(5) <u>Information provided to the PLHCP.</u> The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:</p> <p>(i) A description of the affected employee's former,</p>
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<p>(6) <u>PLHCP's written medical opinion.</u></p> <p>(i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:</p> <p>(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to flavorings containing diacetyl;</p> <p>(B) Any recommended limitations upon the employee's exposure to flavorings containing diacetyl, or upon the use of personal protective equipment such as respirators; and</p> <p>(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to flavorings containing diacetyl exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.</p> <p>(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to flavorings containing diacetyl.</p> <p>(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee</p>	<p>current, and anticipated duties as they relate to the employee's occupational exposure to flavorings containing diacetyl;</p> <p>(ii) The employee's former, current, and anticipated levels of occupational exposure to flavorings containing diacetyl;</p> <p>(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and</p> <p>(iv) Records of employment-related medical examinations previously provided to the affected employee, including all previous spirometry measurements, currently within the control of the employer.</p> <p>(6) <u>PLHCP's written medical opinion.</u></p> <p>(i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:</p> <p>(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to flavorings containing diacetyl;</p>
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	<p>within two weeks after receiving it.</p> <p>(7) <u>Additional Testing and Referrals.</u></p> <p>(i) In the event of abnormal spirometry or other unusual findings associated with occupational exposure to flavorings containing diacetyl, the PLHCP shall refer the employee to a pulmonary specialist for a more complete evaluation within 14 days; and</p> <p>(ii) The employer shall provide and pay for any additional medical services recommended by the PLHCP or the pulmonary specialist.</p> <p>(iii).The employer shall ensure that the examining pulmonary specialist is provided with all the information that the employer is obligated to provide to the PLHCP.</p>	<p>(B) Any recommended limitations upon the employee's exposure to flavorings containing diacetyl, or upon the use of personal protective equipment such as respirators; and</p> <p>(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to flavorings containing diacetyl exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.</p> <p>(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to food containing diacetyl.</p> <p>(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.</p> <p>(7) <u>Additional Testing and Referrals.</u></p> <p>(i) In the event of abnormal spirometry or other unusual findings associated with occupational exposure to flavorings containing diacetyl, the PLHCP shall refer the employee to a pulmonary specialist for a more complete evaluation within 14 days; and</p> <p>(ii) The employer shall provide and pay for any additional medical services recommended by the PLHCP or the pulmonary specialist.</p>
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		(iii).The employer shall ensure that the examining pulmonary specialist is provided with all the information that the employer is obligated to provide to the PLHCP.
Housekeeping	<p>(1) All surfaces shall be maintained as free as practicable of accumulations of flavorings containing diacetyl.</p> <p>(2) The employer shall institute a program for detecting leaks and spills of flavorings containing diacetyl, as required under paragraph (1)(iv) of the exposure control plan provisions, including regular visual inspections of operations involving liquid or powder formulations of flavorings containing diacetyl.</p> <p>(3) All leaks shall be repaired and accumulations of liquid or powder shall be cleaned up promptly using methods that minimize the likelihood of exposure to flavorings containing diacetyl.</p> <p>(4) Waste, scrap, debris, bags, containers, equipment, and clothing contaminated with flavorings containing diacetyl shall be collected and disposed of in a manner to prevent the re-entry of flavorings containing diacetyl into the workplace.</p>	(The Agency anticipates that provisions relating to housekeeping will be the same in PEL and non-PEL proposals)
Recordkeeping	(1) <u>Air monitoring data.</u> (i) The employer shall maintain an accurate record of all air monitoring conducted to comply with the requirements of this section.	(The Agency anticipates that provisions relating to recordkeeping will be the same in PEL and non-PEL proposals)

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	<p>(ii) This record shall include at least the following information:</p> <p>(A) The date of measurement for each sample taken;</p> <p>(B) The operation involving exposure to flavorings containing diacetyl that is being monitored;</p> <p>(C) Sampling and analytical methods used and evidence of their accuracy;</p> <p>(D) Number, duration, and the results of samples taken;</p> <p>(E) Type of personal protective equipment, such as respirators worn; and</p> <p>(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.</p> <p>(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.</p> <p>(2) <u>Historical monitoring data.</u></p> <p>(i) Where the employer has relied on historical monitoring data to determine exposure to flavorings containing diacetyl, the employer shall establish and maintain an accurate record of the historical monitoring</p>	
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	<p>data relied upon.</p> <p>(ii) The record shall include information that reflects the following conditions:</p> <p>(A) The data were collected using methods that meet the accuracy requirements stated in the exposure assessment paragraph</p> <p>(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which exposure is being determined;</p> <p>(C) The characteristics of the material (containing flavorings containing diacetyl) being handled when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined;</p> <p>(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which exposure is being determined; and</p> <p>(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.</p> <p>(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.</p>	
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	<p>(3) <u>Objective data.</u> (i) The employer shall maintain an accurate record of all objective data relied upon to comply with the requirements of this section.</p> <p>(ii) This record shall include at least the following information:</p> <p>(A) The material in question (flavorings containing diacetyl);</p> <p>(B) The source of the objective data;</p> <p>(C) The testing protocol and results of testing, or analysis of the material for the release of flavorings containing diacetyl;</p> <p>(D) A description of the process, operation, or activity and how the data support the determination; and</p> <p>(E) Other data relevant to the process, operation, activity, material, or employee exposures.</p> <p>(iii) The employer shall ensure that objective data are maintained and made available in accordance with 29 CFR 1910.1020.</p> <p>(4) <u>Medical surveillance.</u> (i) The employer shall establish and maintain an accurate record for each employee that is covered by the medical surveillance provisions of this section.</p>	
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	<p>(ii) The record shall include the following information about the employee:</p> <p>(A) Name and social security number;</p> <p>(B) A copy of the PLHCP's written opinions;</p> <p>(C) A copy of the information that the employer is obligated to provide to the PLHCP under paragraph (6) of the medical surveillance provisions.</p> <p>(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.</p>	
<p>Prohibited Practices</p>	<p>(1) Compressed air, dry sweeping, or vacuuming unless the vacuum is equipped with a HEPA filter shall not be used to clean or remove flavorings containing diacetyl</p> <p>(2) Containers of flavorings containing diacetyl must not be left uncovered when not in use.</p> <p>(3) Wastewater or solvent used for cleaning equipment shall not be discharged onto the floor.</p>	<p>(The Agency anticipates that provisions relating to prohibited practices will be the same in PEL and Non-PEL proposals)</p>
<p>Dates</p>	<p>(1) Effective date. The standard shall become effective 30 days after publication in the Federal Register.</p> <p>(2) The following shall take effect on or before 60 days after the effective date:</p>	<p>(1) Effective date. The standard shall become effective 30 days after publication in the Federal Register.</p> <p>(2) The following shall take effect on or before 60 days after the effective date:</p>

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	<ul style="list-style-type: none"> (i) Exposure Assessment; (ii) Hazard Communication; (iii) Housekeeping; (iv) Prohibited Practices. <p>(3) The following shall take effect on or before 90 days after the effective date:</p> <ul style="list-style-type: none"> (i) Respiratory Protection; (ii) Protective Work Clothing and Equipment; (iii) Regulated Areas; (iv) Medical Surveillance; and (v) Recordkeeping. <p>(4) The Engineering Controls shall take effect on or before 2 years after the effective date.</p>	<ul style="list-style-type: none"> (i) Exposure Control Plan; (ii) Exposure Assessment; (iii) Hazard Communication; (iv) Housekeeping (v) Prohibited Practices. <p>(3) The following shall take effect on or before 90 days after the effective date:</p> <ul style="list-style-type: none"> (i) Respiratory Protection; (ii) Protective Work Clothing and Equipment; (iii) Regulated Areas; (iv) Medical Surveillance; and (v) Recordkeeping. <p>(4) The Engineering Controls shall take effect on or before 2 years after the effective date.</p>
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