Exposure Monitoring in Occupational Safety and Health Programs

Employers should develop and implement comprehensive occupational safety and health programs to prevent occupational injuries, illnesses, and deaths. To be successful, safety and health programs should be developed and implemented as part of an employer's management system, with strong management commitment, employee involvement, and occupational safety and health expertise. A safety and health program designed to protect employees from the adverse effects of exposure to diacetyl, 2,3-pentanedione, and other flavoring compounds should include mechanisms to identify all risk factors for exposure to flavoring substances. Just as medical monitoring is part of an overall occupational safety and health program, so is exposure monitoring. Exposure monitoring should be conducted whenever there is workplace exposure to diacetyl or 2,3-pentanedione.

10.1 Exposure Monitoring Program Goals

A workplace exposure monitoring program should have clear, stated goals [Mulhausen and Damiano 1998]. Site-specific exposure assessment strategies should be developed to accomplish each of these goals: (1) to determine employee exposure to diacetyl, 2,3-pentanedione, and other flavoring compounds used in the workplace; (2) to evaluate the effectiveness of work practices and engineering controls; and (3) to facilitate selection of appropriate personal protective equipment, if needed. Each of these goals requires a different sample strategy with different parameters (see Section 10.2). In addition to routine monitoring of airborne contaminant concentrations, the monitoring strategy should assess the effectiveness of engineering controls, work practices, PPE, training, and other factors in controlling exposures to flavoring compounds. The monitoring program should also identify areas or tasks that are associated with higher exposures to flavoring compounds where additional control efforts and/or sampling are needed. The program should also determine how changes in production (processes, chemicals and other substances used, and products) affect employee exposures.

10.2 Exposure Monitoring Program Elements

Proper measurement of contaminants in the environment involves a variety of program elements. The sampling and analytical methods referred to in this chapter include an outline of tested and validated procedures that produce statistically reliable data when used in the manner prescribed. Several of the more significant elements of a monitoring program are described below [Gross and Pechter 2002; Milz et al. 2003; Soule 2000].

Where possible, a written sampling strategy or protocol should be developed prior to sampling; this protocol should guide all aspects of the sampling process. The protocol should contain a description of (1) the objectives of sampling, (2) what to sample, (3) whom and where to sample, (4) how to sample, (5) when to sample, (6) how long to sample, (7) how many samples to collect, and (8) how to handle, store, and ship samples [Gross and Pechter 2002; Milz et al. 2003; Soule 2000]. A walk-through survey or preliminary worksite visit is often useful in developing the sampling strategy [Jennison et al. 1996] and knowledge of the data-keeping system to be used to store and retrieve subsequent information can also have an effect. The sampling strategy should be developed to facilitate data analysis and interpretation for the specific exposure assessment goal.

10.2.1 Objectives of Sampling

Sampling as part of an exposure monitoring program for diacetyl, 2,3-pentanedione, and other flavoring substances has several objectives. Often, this sampling is part of a comprehensive assessment to identify and quantify exposure hazards throughout a designated plant or work area to protect employees' health. The frequency of monitoring will depend on the purpose and rationale of the sampling campaign. Specific sampling objectives can include:

- (1) Characterizing (qualitatively or quantitatively) the flavoring compounds present in workplace air or in bulk materials
- (2) Ensuring compliance with existing OELs
- (3) Assessing the effectiveness of engineering controls, work practices, PPE, training, or other methods used for exposure control
- (4) Identifying areas, tasks, or jobs with higher exposures that require additional exposure control
- (5) Evaluating exposures related to production process changes and from changes in products made or materials used
- (6) Evaluating specific high risk job categories to ensure that exposures do not exceed exposure standards or guidelines
- (7) Measuring exposures of employees who report symptoms or illnesses

Sampling can also be used to assess any fugitive emissions from plant processes into the surrounding community.

Exposure monitoring should be conducted by qualified professionals. The sampling strategy should provide an opportunity to determine each employee's exposure, either by direct measure using personal breathing zone samples or through reasonable estimates based on the sampling of similar work tasks or jobs. Sampling strategies that group employees according to exposure zones, uniform job titles, or functional job categories have been used in some industries to reduce the number of required samples while increasing the confidence that all employees at similar risk will be identified [Mulhausen and Damiano 1998]. Area sampling may also be useful in exposure monitoring for determining sources of airborne contaminants and assessing the effectiveness of engineering controls.

When sampling to determine whether employee exposures are below an OEL, a compliance sampling strategy, and/or a "focused strategy," that targets employees perceived to have the highest exposure concentrations may be more useful than random sampling. A focused strategy is most efficient for identifying exposures above the OEL if maximum-risk employees and time periods are accurately identified. Focused sampling may help identify short-duration tasks involving high airborne concentrations that could result in elevated exposures over a full work shift and also tasks that result in exposures over the STEL.

10.2.2 What to Sample (Specific Agents and Physical States)

Because flavorings can consist of many chemicals in addition to diacetyl and 2,3-pentanedione, deciding what to sample often requires preliminary knowledge of the specific flavoring compounds being produced or

used, or that are present in flavorings or other food ingredients used in the workplace, and the known exposure hazards posed by each. Information on possible food and flavoring compounds present in workplace air can be obtained from reviews of product ingredient lists, flavor or food recipes, SDSs, and other information provided by the employer or flavor manufacturer [Gross and Pechter 2002]. In the flavor manufacturing industry, the recipe for each flavoring indicates the chemicals, solvents, and other ingredients used in the formulation. In the food manufacturing industry, this information may be available directly from the company or from SDSs for all flavorings and other ingredients used, although some flavoring SDSs do not list all potentially hazardous chemicals that may be present. Additional information may be needed from the flavoring manufacturers. Often, qualitative characterization may be useful prior to quantitative measurement to better guide the selection of substances to measure in the workplace. A review of any past exposure assessment reports from the target workplace or similar workplaces, may also be helpful in selecting which agents to sample. In either case, a list of substances to which employees will potentially be exposed should be developed to help determine which of those compounds are the most critical to sample [Mulhausen and Damiano 1998]. In instances where a company has stopped using diacetyl and 2,3-pentanedione in a flavor or food product, this list should include the butter flavor substances substituted for diacetyl or 2,3-pentanedione. Determining which chemicals to sample and measure should be based upon the chemical, physical, and toxicological properties as well as the chemical quantities in use. For example, industry reference materials may provide helpful information on which flavoring compounds to use or avoid [FEMA 2012]. Other databases that might prove helpful may include but are not limited to National Library of Medicine (Hazardous Substances

Data Bank and ChemIDplus Lite, Agency for Toxic Substances and Disease Registry (Toxicological Profiles), U.S. Environmental Protection Agency (Superfund Chemical Data Matrix). Diacetyl, 2,3-pentanedione, and other flavoring compounds can be present in air as solids, liquids, gases/vapors, or a combination of these. The physical state of the flavoring compound in air influences decisions about sampling [NIOSH 1977].

10.2.3 Whom and Where to Sample

Selecting whom or where to sample depends in part on the sampling objectives as previously described. When sampling to determine whether employee exposures are below existing OELs, a focused or compliance sampling strategy that targets employees perceived to have the highest exposures may be more efficient than other strategies if maximum-risk employees and time periods can be accurately identified. Focused sampling, including personal breathing zone sampling, may also help identify short-duration tasks involving high flavoring compound concentrations that could result in peak exposures or contribute to elevated exposures over a full work shift. The sampling protocol should include sampling during the production of foods or flavorings with higher diacetyl, 2,3-pentanedione, or other food flavoring content. Sampling considerations include (1) distance from a diacetyl, 2,3-pentanedione, or flavoring compound exposure source; (2) employee mobility; (3) air movement patterns; (4) specific tasks or work patterns; (5) individual work habits; and (6) exposure controls [NIOSH 1977]. When a sampling strategy is selected that groups employees according to similar exposure potential, uniform job titles, or functional job categories, the industrial hygienist should select at random a predetermined number of employees from each group for personal air sampling

to represent the exposures of those groups [Mulhausen and Damiano 1998; NIOSH 1977].

Area sampling may be useful for determining sources of airborne contaminants and identifying the worst-case chemical concentrations in various locations or processes. Selection of which employees or work locations should be sampled can help to characterize (confirm or refute) suspected areas of potential concern.

10.2.4 How to Sample

A variety of methods are available to sample for diacetyl, 2,3-pentanedione, or other food and flavoring substances. These include (1) gas and vapor air methods, (2) methods to sample particulates in air, (3) direct reading and real-time methods for gases/vapors and for particulates, (4) evacuated container sampling methods, (5) particle size distribution methods, (6) bulk air methods, and (7) bulk material methods. Selecting appropriate sampling and analytical methods and using professionally accepted techniques maximize the validity of measurements of flavoring compounds in the work environment. While the state of the art in measuring diacetyl and 2,3-pentanedione continues to evolve, the methods with the most veracity at the time of publication of this document are OSHA Methods 1012 and 1013 for diacetyl and OSHA Method 1016 for 2,3-pentanedione.

Some sampling and analytical methods for diacetyl, 2,3-pentanedione, and other flavoring compounds published by NIOSH at http:// www.cdc.gov/niosh/nmam/ and by OSHA at http://www.osha.gov/dts/sltc/methods/index. html are described in detail in Chapter 2 of this document and are presented in Appendices A–E. These methods include recommendations on sampling media, flow rate, duration, storage, shipment, sampling and analytical equipment, and procedures. A typical protocol for measuring diacetyl and 2,3-pentanedione is presented in Appendix I.

To minimize the likelihood of inaccurate results, sampling equipment should be maintained in reliable working order through proper care and maintenance. All equipment should be regularly inspected and cleaned; sampling pumps should be calibrated before and after each use. Because differences in pressure drop across the sampler affect flow rate, each sampling pump should be precalibrated and postcalibrated with the specific type of sampling media used for sampling.

Careful record keeping in the field is also important. A detailed description of the work tasks conducted and the processes and materials involved is essential. Pertinent information such as sampling location, job category or task, air temperature, relative humidity, and possible interfering compounds in air should be documented. To avoid confusion in the laboratory, samples should be carefully labeled and accompanied by accurate paperwork. The exact sampling duration should be known to accurately calculate the sampled volume. Determining the sampling duration from the recorded start and stop times assumes that the pump functions consistently over the entire sampling period. Occasional spot checks to verify proper sampler operation should be made throughout the sampling period.

Personnel performing field sampling should not overlook quality assurance procedures. The field sampling parameters, such as calibration checks and accurate timing, often affect precision and accuracy of the final result more than the measurement's parameters. Field personnel should devote time to learning the sampling and analytical methods and sampling equipment operation procedures prior to arriving at the sampling site. These methods usually specify the sampling media to be used, the correct flow rate and sample volume, as well as special precautions of sample handling, shipping, and possible interferences.

Because many modern analytical techniques are extremely sensitive, care should be taken to avoid contaminating field samples. Samples should not be stored or shipped with bulk materials that might spill or otherwise contaminate the field samples. The glassware or other containers used in sampling and shipping should be cleaned as recommended in the analytical method. For many sampling methods, the analytical laboratory requires submission of a specific number of blank samples with each set of samples to be analyzed; this number of samples is specific to the method. Blanks are used to mitigate the potential for unrecognized contamination due to media or sample handling [NIOSH 1994]. The two types of sample blanks are field blanks and media blanks. Field blanks are unopened new samplers or media taken to the sampling site and handled in every way like the actual samples, except that no air is drawn through them. Media blanks are simply unopened new samplers or media that are submitted to the laboratory with the samples (these blanks are not usually taken to the field). Additional blind field blanks, labeled as field samples, should be sent along with the field samples as a further check on the analysis. Another occasionally used quality control practice is to include spiked samples-samples with known amounts of flavoring substance addedalong with the other field samples sent to the laboratory for analysis. These spiked samples are often prepared by a separate laboratory and then included with the other field samples sent to the analytical laboratory. They are labeled as field samples so that the analytical laboratory is blinded to their identity as spiked samples.

The variety of types of direct-reading methods available for monitoring specific gases and vapors, as well as general contaminant concentration, is large and expanding. Detector tubes (short-term and long-term), also referred

to as colorimetric indicator tubes, are widely used sampling devices for obtaining immediate, quantitative measures of gas or vapor concentrations in air. Also, aerosol monitors, integrating passive monitors for certain gases, and portable instrumentation for gas chromatography or infrared spectroscopy, are becoming more commonly used for measuring exposures to flavoring compounds [ACGIH 2001; Soule 2000]. Many direct-reading instruments now used for personal or area measurements have evolved from laboratory or process control instruments. These types of monitoring techniques have significant advantages, although to date none of these methods has been validated for monitoring diacetyl, 2,3-pentanedione, or other flavoring compounds in the work environment.

10.2.5 When to Sample

Because of the considerable variation in exposure during the production of food or flavoring products, individuals conducting air sampling should coordinate with plant management to ensure that sampling is conducted when food or flavoring products of particular interest are being manufactured. Sampling several products or production runs may be necessary to better characterize exposures. Additionally, some products may be produced infrequently, and production schedules may change rapidly, so the timing of sampling can be challenging. Exposure monitoring should be conducted whenever changes in production processes, controls, work practices, or other conditions indicate a potential change in exposure conditions.

In order to determine compliance with STEL criteria, sampling should be done during tasks that are considered likely to produce the highest short-term exposures. A series of sequential or overlapping samples can be taken for 15-minute intervals to determine the maximum exposures.

10.2.6 How Long to Sample

In general, TWA exposures should be determined by collecting samples over a full work shift, for comparison with OELs and other toxicological data. Information on allowable sampling duration is given in validated sampling and analytical methods; depending on the method, in some instances it is necessary to collect multiple shorter-term samples to obtain an integrated full work-shift sample. Work shifts that exceed 8 hours require extended sampling duration.

When the potential for exposure to diacetyl, 2,3-pentanedione, or flavoring compounds is sporadic throughout a work shift, shortterm or task-based sampling may be needed to replace or supplement full-shift sampling. Short-term samples for diacetyl and 2,3-pentanedione can be collected for 15 minutes in duration. Data from these short-term measurements and other task-based sampling can provide valuable perspective on task-based exposures and on the effectiveness of various control techniques. They can also be used to evaluate exposures relative to a short-term exposure limit [Milz et al. 2003] such as the STEL values recommended for diacetyl and 2,3-pentanedione.

10.2.7 How Many Samples to Collect

The numbers of samples to collect is important in that it relates to the confidence that can be placed in the exposure estimate. The number of samples needed for an accurate and reliable exposure assessment depends on the purpose of the sampling, the number of processes, work tasks or jobs to be evaluated, the variability inherent in the measured contaminant concentrations, sampling and analytical variability, and other factors. In most instances, time and budget constraints are major factors determining sample size. Statistical methods are available for calculating the minimum sample size needed to characterize a maximum risk employee exposure subgroup or to achieve a set degree of statistical confidence in the representativeness of an exposure measurement [NIOSH 1977, 1994; Snedecor and Cochran 1967; Soule 2000]. Recently, exposure control banding and Bayesian decision analysis have been used to help support exposure assessment decisions with limited sample numbers [Hewett et al. 2006].

10.2.8 Sample Handling, Storage, and Shipment

Following sampling, appropriate sample handling, storage, and shipping methods should be used. Some flavoring compound analytes such as diacetyl are light sensitive and should be protected from light during sample collection and stored in the dark prior to analysis. Many volatile flavoring substance analytes should be stored and shipped refrigerated to ensure sample stability; this necessitates access to field refrigeration dedicated to sample storage. Some flavoring substance analytes/methods may have requirements for timely analysis or desorption to ensure analyte stability. Working closely with the analytical laboratory before sampling to determine the handling, storage, and shipping methods required for each analyte is advised. An American Industrial Hygiene Association or other accredited analytical laboratory should analyze collected samples. Consulting with the analytical laboratory before sampling to ensure that the measurement methods available can meet the defined sampling needs is essential.

10.3 Outcomes of Exposure Monitoring

10.3.1 Interpretation

As stated above, a monitoring strategy should assess the effectiveness of various methods used

to control airborne flavoring substance concentrations and to identify areas or tasks that are associated with higher exposures to flavoring substances. A common technique for evaluating the effectiveness of controls is to compare the outcome of environmental measurements made prior to the installation of those controls with measurements made following that installation. A control technique can be judged, for example, to be 50% efficient if the post-installation contaminant concentration is half of the pre-installation concentration.

The TWA and STEL measurements of exposure to flavoring substances, made with the collection of personal breathing zone air samples, can be used to assess employees' exposures relative to an OEL. As discussed in the section of this document describing the development of the RELs, an 8-hour TWA measurement in excess of 5 ppb diacetyl or 9.3 ppb 2,3-pentanedione indicates that the employee in question was at a greater risk of developing occupationally induced illness. A 15-minute short-term exposure in excess of 25 ppb diacetyl or 31 ppb 2,3-pentanedione during task based personal sampling would be interpreted similarly.

If monitoring indicates that exposures have increased over past measurements, or exposures exceed the selected OELs, a thorough investigation of controls to identify problems and guide remedial actions is needed. Regular routine monitoring (e.g., yearly) will help ensure the continued effectiveness of controls. Employers should monitor employees in such a fashion that he has a high degree of confidence that a very high percentage of actual daily exposures are below the REL. In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the REL.

10.3.2 Notification of Employees

Employers should establish procedures for the timely notification of employees of their environmental monitoring results or results that represent their work group, any identified exposure hazards, and any subsequent actions taken based on this monitoring to reduce their exposures. Employees should be informed about any products or processes that may generate high concentrations of diacetyl, 2,3-pentanedione, or other flavoring compounds and any PPE and changes in work practices needed in response. Employers should ensure that employees understand this information and their role in helping to maintain a healthful workplace. Information should be conveyed in English and other languages as needed to ensure that all employees receive and comprehend this information.

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