

**SACRAMENTO METROPOLITAN
AIR QUALITY MANAGEMENT DISTRICT**

STAFF REPORT

Rule 466 – Solvent Cleaning

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BACKGROUND

Ground level ozone is a secondary pollutant formed from photochemical reactions of nitrogen oxides (NO_x) and volatile organic compounds (VOCs) in the presence of sunlight. Ozone is a strong irritant that adversely affects human health and damages crops and other environmental resources. As documented by the U.S. Environmental Protection Agency (EPA) in the most recent Criteria Document for ozone (U.S. EPA 2006), both short-term and long-term exposure to ozone can irritate and damage the human respiratory system, resulting in:

- decreased lung function;
- development and aggravation of asthma;
- increased risk of cardiovascular problems such as heart attacks and strokes;
- increased hospitalizations and emergency room visits; and
- premature deaths.

The District is currently designated as a nonattainment area for both the state and federal ozone standards. Because VOC is a precursor to ozone, one of the strategies to control ozone pollution is to reduce VOC emissions from existing stationary sources.

Rule 466 reduces the emissions of VOC from solvent cleaning operations and activities by limiting the VOC content of cleaning solvents. VOC emissions are further reduced by work practice requirements for the storage and disposal of new and spent cleaning solvents. The rule was first adopted on May 23, 2002 and was last amended on September 25, 2008.

The September 25, 2008 amendments to Rule 466 reduced the allowable VOC content for several types of solvent cleaning operations. One of them set a new VOC content limit of 200 grams per liter (g/l) for solvent cleaners used in the sterilization of food manufacturing and processing equipment. The new VOC limits into effect on September 25, 2009.

Blue Diamond Growers informed Staff in February 2009 that they would not be able to meet this limit without the possibility of causing a food health hazard for their dry food products because they found the compliant solvents didn't meet their sterilization requirements.

After thorough research and discussions with Blue Diamond Growers and other health experts, Staff is proposing an exemption from the VOC content limit for sanitizing products that are labeled and applied to food contact surfaces used to process dry and low moisture foods and that are not rinsed prior to contact with food. Staff has determined that the previously adopted VOC content limit of 200 g/L is not feasible for dry food processors.

LEGAL MANDATES

Federal Mandates:

The District is designated as a severe nonattainment area for the federal 8-hour ozone standard. In February 2009, the districts of the Sacramento Federal Nonattainment Area adopted an attainment plan to achieve the federal 8-hour ozone standard by 2018. The attainment plan includes a commitment for the District to achieve 0.593 tons per day of VOC emissions reductions from solvent cleaning operations by 2018.

In September and October of 2008, the District amended nine rules containing requirements for solvent cleaning operations:

- Rule 450 – Graphic Arts Operations
- Rule 451 – Surface Coating of Miscellaneous Metal Parts and Products
- Rule 452 – Can Coating
- Rule 454 – Degreasing Operations
- Rule 456 – Aerospace Assembly and Component Coating Operations
- Rule 463 – Wood Products Coatings
- Rule 464 – Organic Chemical Manufacturing Operations
- Rule 465 – Polyester Resin Operations
- Rule 466 – Solvent Cleaning

The amendments to these rules were estimated to achieve a total of 0.536 tons per day of VOC emissions reductions (SMAQMD 2008). Planned amendments to Rule 459 – Automotive, Truck and Heavy Equipment Refining Operations, are expected to achieve another 0.18 tons per day of VOC emissions reductions from solvent cleaning activities, which will bring the total emissions reductions to 0.716 tons per day, exceeding the plan commitment. The 0.005 tons per day of VOC emissions reductions that will be lost due the proposed amendments will not cause the total emissions reductions from all rule amendments to fall below the plan commitment.

State Mandates:

Serious Nonattainment Plan Requirements: The District is designated as a serious nonattainment area for the state ozone standard. The California Clean Air Act requires areas with this designation to adopt control measures required in sections 40913, 40914, and 40919 of the California Health and Safety Code (HSC):

- HSC Section 40913 requires districts to develop a plan to achieve California's ambient air quality standards by the earliest practicable date.
- HSC Section 40914(b)(2) requires every nonattainment district that cannot achieve a reduction of 5% or more per year in district wide emissions to adopt "every feasible measure" to reduce the emission of nonattainment pollutants and their precursors.
- HSC Section 40919(a)(3) requires districts with serious nonattainment for ozone to adopt BARCT for all existing permitted sources.

The September 25, 2008 amendments to Rule 466, together with the eight other previously mentioned rules amended in September and October of 2008, met the commitment of 0.37 tons per day of VOC emissions reductions from solvent cleaning operation in the District's 2003 Triennial Report and Plan Revision, and the associated feasible measure and BARCT requirements. The VOC emissions reductions achieved by the amendments to these rules were estimated to be 0.536 tons per day. The 0.005 tons per day of VOC emissions reductions that will be lost due the proposed amendments will not cause the total emissions reductions to fall below the plan commitment. Staff has determined that it is not feasible to require sanitizers to meet the current VOC limit in dry food processing applications where the food contact surface is not rinsed prior to contact with food. Therefore, the rule will still meet the state mandates and plan commitment after the proposed amendment.

Transport Mitigation Emission Control Requirements: Districts within the areas of origin of transported air pollutants, as identified in HSC Section 70500(c), shall include sufficient emission control measures in their attainment plans for ozone adopted pursuant to Part 3, Chapter 10 (commencing with Section 40910) of Division 26 of the Health and Safety Code, to mitigate the impact of pollution sources within their jurisdictions on ozone concentrations in downwind areas commensurate with the level of contribution. An upwind district shall comply with the transport mitigation planning and implementation requirements set forth in this section regardless of its attainment status.

The September 2008 amendments to Rule 466 met the transport mitigation emission control requirements. After the proposed amendment, the rule will still meet these requirements.

DISCUSSION

Staff has identified an almond producer (Blue Diamond Growers) and an organic spices producer operating in Sacramento County where the use of aqueous-based low VOC sanitizers would have been required by the 2008 amendment to Rule 466. There have been a number of salmonella outbreaks related to dry foods (chocolate, cereal, nuts, and spices) including outbreaks in 2000 through 2001 and in 2003 through 2004 from raw almonds occurring in the United States and Canada (GMA 2009). Another salmonella outbreak occurred in 2009 that was associated with white and black pepper produced by a Bay Area facility. As a result of the almond outbreaks, the United States Department of Agriculture (USDA) created mandatory quality control requirements to reduce the potential for salmonella bacteria in almonds in 2007. The program requires, "handlers must subject their almonds to a treatment process or processes that achieve in total a minimum 4-log reduction of salmonella bacteria." A 4-log reduction decreases bacteria by a factor of 10,000. Due to the potential of dust and debris from the raw materials being transferred throughout the facility to contaminate the product, it is necessary to sanitize the processing equipment to maintain a 4-log reduction in bacteria.

Typically, sanitizers for food-contact surfaces are aqueous based. After application to the food processing equipment, the sanitizer is rinsed from the surface with water. The rinse water is not dried in between cleanings. For many foods, contact with water is not an issue except for dry and low-moisture foods, which because of their nature must avoid water contact. Additionally, water that collects in the equipment promotes pathogen growth and can damage the equipment. In order for dry food manufacturers or processors to use an aqueous based sanitizer, the equipment would need to be thoroughly dried before contact with the food. Part 21 of the Code of Federal Regulations, Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Section 110.35(d)(1) states

"Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use."

Blue Diamond Growers stated that drying equipment to this level would require an equipment teardown and reassembly, which would require a minimum of 8 hours but in many cases would take longer to complete. Additionally, wet and dry areas are separated in the facility to avoid potential health risks. Teardown, transferring and proper cleaning usually takes up to 1 to 2 days. Because

most equipment in the facility is sanitized on a daily basis, this method of sanitation would be infeasible.

Most commonly, manufacturers will use a solution with an isopropyl alcohol (IPA) because it evaporates quickly and is highly effective in reducing bacteria. A recent study from the University of California Davis (Du et al. 2010) compared the effectiveness of sanitizers on dust gathered from an almond hulling and shelling facility. The study compared non-aqueous based sanitizer effectiveness by comparing quaternary ammonia (AQuat) based sanitizers to a sanitizer that is IPA based with small amounts of quaternary ammonium (IPAQuat). The study showed,

“The introduction of water or AQuat should be restricted in [hulling and shelling] facilities where dust cannot be strictly controlled. To avoid the multiplication of Salmonella in [hulling and shelling] facilities, AQuats are only appropriate when equipment is accessible, complete removal of dust is possible with cleaning, and adequate time is available for thorough drying of the equipment...IPAQuat reduced Salmonella densities as much as 7 log [colony forming units (CFU) per gram] in [hulling and shelling] dust...IPAQuat or other alcohol-based sanitizers may be appropriate for in-season (hulling and shelling) facility sanitation programs.”

The report also shows that concentrations of IPA in the sanitizing solution should be at minimum greater than 50% in order to have immediate results for Salmonella reductions greater than 4 log CFU/g. If IPA concentrations are less than 50% the sanitizer will not achieve the required bacteria reduction. Additionally, the report specifies, “The information should be applicable and useful to the nut industry and to other low-moisture foods.”

According to the information above, the minimum effective sanitizer would consist of 50% isopropyl alcohol and 50% water. The VOC content of this solution would be 393 g/L which would violate the 200 g/L limit for the sterilization of food manufacturing and processing equipment currently in effect for Rule 466.

In 2006, the California Air Resources Board (CARB) proposed a 1% VOC content limit for non-aerosol sanitizers in their consumer products regulation. CARB staff received comments from the California Department of Health and Safety, which recommended that CARB staff should exempt food surface sanitizers from the VOC limit. As a result, CARB staff agreed with the Department of Health and Safety and included an exemption for products which are labeled to be applied to food-contact surfaces and are not required to be rinsed prior to contact with food.

District Staff contacted the California Department of Public Health (formerly the Department of Health and Safety) for their recommendation on food surface sanitizers. They responded as follows:

“The Food and Drug Branch [of the California Department of Public Health] would recommend similarly to your agency as it did the State Air Resources Board that air-drying sanitizers used by food processors should be exempt from your regulation. Numerous dry and low water activity food products are susceptible to contamination with salmonella, listeria and other species of pathogenic bacteria. Use of water-based sanitizers or rinsing with water after sanitation can provide the ideal growing environment for these organisms, and once established in a processing facility, can lead to adulteration of the feed and eventually an illness outbreak. Use of isopropyl alcohol or other sanitizers that air dry are important tools for combating food-borne

illness.” (Kennelly 2009)

Based on the information gathered, Staff has determined that subjecting food surface sanitizers that air dry to the current VOC limit in Rule 466 and forcing dry food manufacturers and processors to use currently available low-VOC sanitizers is infeasible and could create food health risks.

SUMMARY OF PROPOSED AMENDMENTS

The proposed amendments to Rule 466 exempt sanitizing products which are labeled and applied to food-contact surfaces that are used to process dry and low-moisture food products and are not rinsed prior to contact with food from the rule requirements except for the recordkeeping required by Section 501. Staff has defined a low-moisture food as having a water activity less than 0.85 or other applicable standards approved by the Air Pollution Control Officer, California Air Resources Board, and U.S. Environmental Protection Agency. The U.S. Food and Drug Administration have not formally defined what a low-moisture food is so the industry standard is used as reported by the Grocery Manufacturers Association (GMA 2009). The proposed amendments also include a definition and test method for water activity.

EMISSIONS IMPACT

The proposed exemption for Rule 466 will result in loss of 0.005 tons per day of VOC emissions reductions that were expected to be achieved when Rule 466, along with eight other rules with solvent cleaning requirements, were amended in September and October of 2008. The amendments to these rules were estimated to achieve a total of 0.536 tons per day of VOC emissions reductions, and due to the proposed exemption to Rule 466, will decrease to 0.531 tons per day. Together with VOC emissions reductions that are expected to be achieved by planned amendments to solvent requirements in Rule 459 – Automotive, Truck and Heavy Equipment Refining Operations (0.18 tons per day), the total VOC emissions reductions from solvent cleaning operations in the District will be 0.711 tons per day, which will exceed the federal (0.593 tons per day) and state (0.37 tons per day) plan commitments.

COST AND COST EFFECTIVENESS

The proposed amendments to Rule 466 will not result in any additional costs to owners/operators or to the District.

SOCIOECONOMIC IMPACT ANALYSIS

California HSC Section 40728.5 requires a district to perform an assessment of the socioeconomic impacts before adopting, amending, or repealing a rule that will significantly affect air quality or emission limitations. Staff has determined that the proposed amendments to Rule 466 will not significantly affect air quality or emission limitations; therefore, a socioeconomic impact analysis is not required.

PUBLIC COMMENTS

Staff will post a 30-day for the public hearing and will take public comments during that period. The public will also have an opportunity to address the SMAQMD Board of Directors during the hearing.

ENVIRONMENTAL REVIEW AND COMPLIANCE

Staff finds that the approval of the proposed action is exempt from CEQA under Section 15061(b)(3) of the State CEQA Guidelines because it can be seen with certainty that there is no possibility that the activity in question may have a significant adverse effect on the environment. Because the lower VOC limit was infeasible for dry food manufacturers and processors, the limit was never enforced and therefore there will be no environmental impact.

TABLE OF FINDINGS

Six required findings: According to Section 40727(a) of the California Health and Safety Code, prior to adopting or amending a rule or regulation, an air district's board must make findings of necessity, authority, clarity, consistency, non-duplication, and reference. The findings must be based on the following:

1. Information presented in the District's written analysis, prepared pursuant to Health and Safety Code Section 40727.2;
2. Information contained in the rulemaking records pursuant to Section 40728 of the California Health and Safety Code; and
3. Relevant information presented at the Board's hearing for the rule.

The table below sets the finding and the basis for making the finding.

FINDING	FINDING DETERMINATION
Authority: The District must find that a provision of law or of a state or federal regulation permits or requires the District to adopt, amend, or repeal the rule.	The District is authorized to adopt rules and regulations by California Health and Safety Code, Sections 40001, 40702, 40716, and 41010. [Health and Safety Code Section 40727(b)(2)].
Necessity: The District must find that the rulemaking demonstrates a need exists for the rule, or for its amendment or repeal.	It is necessary for the District to amend Rule 466 to exempt sanitizers used in dry food processing applications. [HSC Section 40727(b)(1)].
Clarity: The District must find that the rule is written or displayed so that its meaning can be easily understood by the persons directly affected by it.	The District has reviewed the proposed rule and determined that it can be understood by the affected parties. In addition, the record contains no evidence that people directly affected by the rule cannot understand the rule. [HSC Section 40727(b)(3)].
Consistency: The rule is in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or state or federal regulations.	The District has found that the proposed rule does not conflict with, and is not contradictory to, existing statutes, court decisions, or state or federal regulations. [HSC Section 40727(b)(4)].

FINDING	FINDING DETERMINATION
Non-Duplication: The District must find that either: 1) The rule does not impose the same requirements as an existing state or federal regulation; or (2) that the duplicative requirements are necessary or proper to execute the powers and duties granted to, and imposed upon the District.	The District has found this proposed rule does not duplicate any existing state or federal regulations [HSC Section 40727(b)(5)].
Reference: The District must refer to any statute, court decision, or other provision of law that the District implements, interprets, or makes specific by adopting, amending or repealing the rule.	California Clean Air Act of 1988 (California Health and Safety Code Section 40914); California Health and Safety Code Sections 40910, 40913, 40914, 40919(a)(3); Section 70500(c); Sections 70500, 70600, and 70601 of Title 17 of the California Code of Regulations; Sections 182(c), 182(d), and 182(f) of the Federal Clean Air Act Amendments of 1990.
Additional Informational Requirements: In complying with HSC Section 40727.2, the District must identify all federal requirements and District rules that apply to the same equipment or source type as the proposed rule or amendments.	Sources regulated by Rule 466 are not regulated by federal requirements but are subject to District rules 201 and 202. [Health and Safety Code Section 40727.2(g)].

REFERENCES

Grocery Manufacturers Association (GMA), "Control of Salmonella in Low-Moisture Foods," February 4, 2009.

Kennelly, Pat, California Department of Public Health. "RE: SMAQMD food surface sanitizer VOC limits," Email to Joseph Carle. June 6, 2009.

Sacramento Metropolitan Air Quality Management District (SMAQMD), "Staff Report for Amendments to Rule 450 – Graphic Arts Operations, Rule 451 – Surface Coating of Miscellaneous Metal Parts and Products, Rule 452 – Can Coating, Rule 454 – Degreasing Operations, Rule 456 – Aerospace Assembly and Component Coating Operations, Rule 463 – Wood Products Coatings, Rule 464 – Organic Chemical Manufacturing Operations, Rule 465 – Polyester Resin Operations, and Rule 466 – Solvent Cleaning," August 25, 2008.

U.S. Department of Agriculture, "Almonds Grown in California; Outgoing Quality Control Requirements," Code of Federal Regulations Title 7 Part 981.

U.S. Food and Drug Administration, "Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food," Code of Federal Regulations Title 21 Part 110.

Wen-Xian Du, Michelle D. Danyluk, and Linda J. Harris, "Efficacy of Aqueous and Alcohol-Based Quaternary Ammonium Sanitizers for Reducing Salmonella in Dusts Generated in Almond Hulling and Shelling Facilities," Journal of Food Science, Vol. 75, November 1, 2010, Pg. M7 – M13

Wen-Xian Du, Michelle D. Danyluk, and Linda J. Harris, "Evaluation of Cleaning Treatments for Almond-Contact Surfaces in Hulling and Shelling Facilities," Food Production Trends, September 2007, Pg. 678 – 683

APPENDIX A SUMMARY OF PROPOSED AMENDMENTS

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
110.3.c	N/A	Added an exemption from VOC content limits for sanitizers which are labeled and applied to food-contact surfaces that are used to process dry and low-moisture food products and are not rinsed prior to contact with food.
224	N/A	Added definition of low-moisture food, consistent with the GMA 2009 report.
225-250	224-249	Sections renumbered.
251	N/A	Added definition of water activity consistent with 21 CFR 110.3(r)
252-253	250-251	Sections renumbered.
502.6	N/A	Added Food and Drug Administration test method for determining water activity in food.
502.7	502.6	Section renumbered.