State of California
Air Resources Board

UPDATED INFORMATIVE DIGEST

ADOPTION OF A REGULATION TO LIMIT OZONE EMISSIONS FROM INDOOR AIR CLEANING DEVICES

Sections Affected

Adoption of new sections 94800, 94801, 94802, 94803, 94804, 94805, 94806, 94807, 94808, 94809, and 94810, title 17, California Code of Regulations. The American National Standards Institute/Underwriters Laboratories, Inc. (ANSI/UL) Standard 867 (Fourth Edition, December 21, 207) and ANSI/UL Standard 507 (Ninth Edition, September 27, 2007) for mechanical devices, are incorporated by reference. Ozone emissions will be determined using the revised Section 37 of ANSI/UL Standard 867 published on December 21, 2007, and the associated Certification Requirement Decisions published by UL on March 4, 2008, April 17, 2008, and April 18, 2008, which are hereby incorporated by reference.

Background

A number of manufacturers sell devices represented to be air purifiers or air cleaners which in fact purposely generate large quantities of ozone, the primary component of photochemical smog. Operation of these devices, also known as “ozone generators,” in spaces that can be occupied by people has been known for some time to cause unhealthful ozone exposures, that is, exposure to elevated room ozone concentrations above the health-based state and federal ambient air quality standards for ozone. Currently, Canada does not certify any type of intentional ozone-generating air cleaners for residential use.

Other types of related devices include electrostatic precipitators (ESPs), ionizers, and mechanical filter devices. ESPs and ionizers may emit ozone as a byproduct of their functioning, although the levels are usually lower than those produced by ozone generators. Mechanical filter devices emit little or no ozone.

Exposure to ozone is a public health concern. Ozone is a highly reactive molecule composed of three atoms of oxygen, and can damage the lungs and airways. Ozone inflames and irritates respiratory tissues, and can worsen asthma symptoms. Ozone exposure can cause coughing, chest tightness and impaired breathing. Elevated exposures have the potential to induce permanent lung damage, and chronic ozone exposure can even increase the risk of premature death in persons with poor health. Ozone can also damage plants, fabrics and building materials such as paint, walls, and flooring. Ozone is a primary component of photochemical smog, and has been recognized and regulated as an outdoor pollutant for many years. The current

California outdoor air quality standards for ozone are 0.09 ppm (averaged for one hour) and 0.070 ppm (averaged over eight hours).

The market for air cleaning devices, particularly for residential use, has grown as public concern over indoor air quality has increased. Annual sales of air cleaners have surpassed $400 million nationally. A recent survey found that 14 percent of California households currently own an air cleaner or owned one during the past five years. An estimated 828,000 California residents reside in the approximately 2 percent of households that own an ozone generator, while about 2.8 million people live in the approximately 8 percent of households that own ESPs or ionizers, air cleaners that may emit ozone as a by-product.

In 2006, the Legislature passed Assembly Bill 2276 (Pavley) which was signed into law by Governor Schwarzenegger (stats 2006 ch 770). The legislation enacted Health and Safety Code sections 41985-41986, which direct ARB to adopt regulations to limit ozone emissions from portable air cleaners sold in California for use in occupied spaces by December 31, 2008.

Description of the Regulatory Action

The regulation adopted by the Air Resources Board (Board or ARB), with modifications described below, requires that indoor air cleaning devices for use in spaces that can be occupied by people that are introduced into commerce in California must not emit ozone in a concentration of more than 0.050 ppm of ozone. The regulation specifies requirements for testing, labeling, certification and record-keeping, and establishes specific exemptions as described below.

The regulation applies to any person or entity who manufactures, sells, supplies or offers for sale indoor air cleaning devices in California for use in spaces that can be occupied by people. Under the regulation, indoor air cleaning devices cannot be sold, supplied, offered for sale or introduced into commerce in California 24 months after the effective date, unless the devices are certified by ARB.

Under the regulation, an application for certification of an indoor air cleaning device must be submitted to ARB by a manufacturer, or by a professional association or certification organization on behalf of a manufacturer. Application information includes manufacturer contact information, specified details about the brand and model of the air cleaning device, and specified details about the testing conducted on that model device. All indoor air cleaning devices, unless exempted, must be tested following the ANSI/UL Standard 867 (Fourth Edition, December 21, 2007), or ANSI/UL Standard 507 (Ninth Edition, September 27, 2007) for mechanical devices. Ozone emissions will be determined using the December 21, 2007 revision of Section 37 of ANSI/UL Standard 867. All testing must be performed by a Nationally Recognized Testing Laboratory (NRTL) recognized by the U.S. Occupational Safety and Health Administration, or by an approved NRTL Program 2 independent laboratory. An appropriate certification mark or listing mark must be shown on each device once that model passes the test. Devices

certified for use in California would also have to display a certification label on the product packaging. Specific wording would be required for non-medical devices while medical devices must be labeled in accordance with federal law.

Specific industrial uses for air cleaning devices as defined are exempt from the regulatory requirements. Also, devices designed to be integrated into heating and air conditioning systems (e.g. "in-duct" systems) are also exempt from the regulation at this time, but this exemption may be reevaluated by ARB at a future time. Additionally, based on their known de minimis ozone emissions, indoor air cleaning devices using only mechanical filtration are exempt from the ozone testing requirements after certain required documentation is submitted, but such devices must still meet electrical safety and labeling requirements.

Finally, under the regulation, manufacturers, distributors, retailers, sellers and testing laboratories must maintain production, quality control, sales and testing records for at least three years, and make them available to ARB upon request.

A number of modifications were made to the staff's original proposed regulation. The following explains and identifies the modifications by section number.

1. In Section 94801, a definition for the ANSI/UL Standard 867 was added to specify that all references to ANSI/UL Standard 867 are to the December 21, 2007 version of the standard plus the three associated Certification Requirement Decisions issued by UL for Section 37 of that standard through April 2008.

2. In Section 94801, subsection (a)(15)(I) was added. This adds odor control in the motor vehicle reconditioning and detailing industry (provided no people are physically present) to the definition of industrial use.

3. The definition of "Label" in Section 94801(a)(16) has been modified to allow adhesive stickers to be used to satisfy package labeling requirements until April 1, 2011 instead of until January 1, 2010.

4. The compliance date in Section 94802 was changed from 12 months to 24 months after the effective date of the regulation, as approved by the Board. Extending the compliance date was recommended by staff at the September 27, 2007 public hearing in response to public comments and staff's analysis indicating that additional time would be necessary to be able to test all of the air cleaners covered by the regulation.

5. The nine-month sell-through provision in Section 94802 was deleted, as directed by the Board.

6. In Section 94804(b), language indicating that "mechanical filtration only" devices must meet ANSI/UL Standard 507 or any electrical safety standard that succeeds

that standard has been revised to remove the reference to future standards. UL has indicated that Standard 507 may be combined with Standard 867 in the future, so that all air cleaner testing is covered under a single standard; if such an action is taken, ARB will consider the need to update this regulation at that time. Section 94804(b) also now specifically requires documentation that "mechanical filtration only" air cleaners have met ANSI/UL Standard 507.

7. In Section 94804, Certification Requirements, subsection (c)(1), the name and telephone number for the primary contact were added as additional items of information.

8. In Section 94804, Certification Requirements, subsection (c)(3), manufacture date and serial number were added as two additional items of information required about the indoor air cleaning devices being tested.

9. Section 94805(b) of the proposed regulation was revised to specify the versions of ANSI/UL Standards 867 and 507 that are to be used for meeting the test requirements in the regulation. Testing must be performed following the ANSI/UL Standard 867 for electronic air cleaners or ANSI/UL Standard 507 for mechanical filtration air cleaners, whichever is applicable, and ozone emissions will be determined using the testing protocol provided in Section 37 of ANSI/UL Standard 867. Both standards (867 and 507) were included in Section 94805 by reference. An earlier version of Section 37 was made available on August 9, 2007 for review under this regulation because, at the time of the September 2007 public hearing, Section 37 was undergoing revision. The revisions were completed and approved by ANSI/UL in late December 2007. The current approved version of the applicable standard is ANSI/UL Standard 867, Fourth Edition, published December 21, 2007. The September 27, 2007 version of ANSI/UL Standard 507, Ninth Edition, was specified as the version of that standard that will be used to test mechanical filtration air cleaners.

10. Section 94805(c) was revised to additionally include three Certification Requirement Decisions (CRDs) that have been issued by UL to clarify certain provisions of the Section 37 (ANSI/UL Standard 867) ozone test. These were released by UL on March 4, 2008; April 17, 2008; and April 18, 2008.

11. In Section 94805(d), language was added to specify that annual submittal of internal audit reports and associated follow-up audit reports may be required of test laboratories.

12. In Section 94806, a six-month extension for meeting the labeling requirement was added for models that have been submitted for testing, but have not yet received ARB certification by the end of the 18th month from the effective date of the regulation. This extension applies only to the labeling requirements; devices must still be tested and complete the ARB certification process by the end of the

24th month after the effective date of the regulation, and must meet all labeling requirements within six months of the postmark date of notification of ARB certification.

At the conclusion of the September 27, 2007 hearing, the Board voted unanimously to adopt Resolution 07-40 (Resolution), in which it approved the originally proposed regulation with the modifications described above. The Resolution directed the Executive Officer to incorporate the modifications into the proposed regulatory text, with the exception of the proposed nine-month sell-through period, and with such other conforming modifications as may be appropriate. In accordance with section 11346.8 of the Government Code, the Board directed the Executive Officer to adopt modified sections after making the modified text available to the public for comment for a period of at least 15 days. The Board further directed the Executive Officer to consider written comments regarding the modified text that may be submitted during this period, make modifications as may be appropriate in light of the comments received, and present the regulations to the Board for further consideration if warranted.

The Staff's revised proposed regulations, with the modified text clearly indicated, were made available to the public for a 15-day comment period on June 30, 2008. This notice also added some new references and corrected or updated several citations in the rulemaking record. Eight written comments were received during the public comment period. A second 15-day notice was issued on July 16, 2008 that added three references to the record and corrected two citations. Two written comments were received during the second 15-day public comment period. Staff responded to all comments received during the regulatory process, including the comments submitted in response to the notice of modified text, in its Final Statement of Reasons regarding this rulemaking. The final regulation order includes non-substantive changes made for clarity and consistency in formatting.

Comparable Federal Regulations

Health and Safety Code section 41986 requires that the proposed regulation be consistent with federal law. The U.S. Food and Drug Administration has promulgated a maximum acceptable level of ozone of 0.05 ppm for medical devices, as well as certain labeling requirements (21 C.F.R. § 801.415). The emission standard in the proposed regulation is equivalent to the federal limit of 0.05 ppm, as required. Health and Safety Code section 41986 also requires that an indoor air cleaning device that is a medical device shall be labeled in compliance with federal law, including Section 801.415 of title 21 of the Code of Federal Regulations.

Benefits of the Proposal

The proposed regulations will protect Californians from the known health hazards caused by exposure to high levels of ozone in indoor environments.

Costs to Public Agencies and to Businesses and Persons Affected

The Board makes determinations concerning the costs or savings necessarily incurred by public agencies and private persons and businesses in reasonable compliance with the proposed regulatory action. Those determinations are presented below and in specific detail in the ISOR.

Pursuant to Government Code sections 11346.5(a)(5) and 11346.5(a)(6), the Board has determined that the proposed regulatory action would create costs to the ARB as defined in Government Code section 11346.5(a)(5) and (6). The ARB is expected to incur ongoing costs of approximately $175,000 per year for one additional staff and contract funds to implement the regulation and enforce compliance. Costs would not be created for any other state agency, or in federal funding to the state. The regulation would not create costs or mandate to any local agency or school district whether or not reimbursable by the state pursuant to part 7 (commencing with section 17500), division 4, title 2 of the Government Code, or other nondiscretionary cost or savings to state or local agencies.

In developing this regulatory proposal, the ARB staff evaluated the potential economic impacts on representative private persons or businesses. The proposed regulation would affect the manufacturers, distributors, sellers, and consumers of portable indoor air cleaners if the products are marketed for sale in California. The potential economic impact of the regulations would primarily include the cost to test and certify air cleaning devices to meet the 0.050 ppm emission concentration standard for ozone. Additionally, all manufacturers of ozone generators and a few manufacturers of electrostatic precipitators and ionizers that do not meet the emission limit would also need to redesign their products. Annualized costs for a typical small-share business (producing an average of three models of air cleaners) during the first five years were estimated to be between $50,000 and $179,000, and for a typical larger share company (producing an average of 6-8 models of air cleaners) were estimated to be between $132,000 and $357,000. These estimates included all aspects of certification, i.e., testing, labeling, redesign for those requiring it, and certification paperwork. The added cost to consumers was estimated to range from $11 to $16 per air cleaner, if all costs are passed on. The total statewide cost to businesses and representative private persons or consumers to comply with the proposed regulation during the first five years was estimated to be $8,000,000 as the cost to businesses, or $12,100,000 as the cost to consumers if compliance costs and a profit margin were passed on to consumers. Some small manufacturers may be impacted over the short-term due to costs for testing as well as the possible need for some to redesign certain models. The potential long-term impacts, however, were estimated to be insignificant. Costs are also expected to decline rapidly after five years because it is estimated that there would only be turnover costs for the introduction of new models. ARB believes that all of the potential economic impacts on manufacturers are either absorbable or would be passed on to consumers. Because manufacturers are fully expected, and required, to comply with the regulations, enforcement costs to manufacturers should also be negligible.

The Board has made a determination that the proposed regulatory action would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states or on representative private persons. Of an estimated 61 manufacturers of indoor air cleaning devices, three large manufacturers and at least three smaller manufacturers are based in California. All manufacturers of indoor air cleaning devices marketed for sale in California would be subject to the proposed regulations, so there should be no effect on the business competitiveness of the California-based manufacturers.

In accordance with Government Code section 11346.3, the Board has determined that the proposed regulatory action would not affect the creation or elimination of jobs within the State of California, the creation of new businesses or elimination of existing businesses within the State of California, or the expansion of businesses currently doing business within the State of California. Overall, the impacts should be absorbable. A detailed assessment of the economic impacts of the proposed regulatory action can be found at pages 32-45 of the ISOR which are incorporated here by reference.

The Board has also determined, pursuant to title 1, CCR, section 4, that the proposed regulatory action would affect small businesses. Some distributors and retailers of ozone generators are one- and two- person businesses where there may be significant impacts if their manufacturers decide to not seek certification for the California market. However, the Board knows of no alternatives to the proposed regulation that would lessen the impact on small businesses and comport with the requirements of AB 2276.

In accordance with Government Code sections 11346.3(c) and 11346.5(a)(11), the Board has found that the proposal would establish no reporting requirements, but it would establish certain recordkeeping requirements. Under the proposal, businesses would have to maintain certain specified records relating to production, quality control, sales and testing for three years and make them available to the Air Resources Board upon request. The Board has found that these recordkeeping requirements are necessary for the health, safety, and welfare of the people of the State of California**.**

The Board has determined that no reasonable alternative considered by the Board, or that has otherwise been identified and brought to the attention of the Board, would be more effective in carrying out the purpose for which the amendments were intended, or would be as effective as or less burdensome to affected private persons, than the amended regulation. A detailed assessment of the economic impacts of the proposed regulatory action can be found in the Staff Report.