State of California
AIR RESOURCES BOARD

Resolution 07-40

September 27, 2007

Agenda Item No.: 07-9-3

WHEREAS, sections 39600 and 39601 of the Health and Safety Code authorize the Air Resources Board (ARB or Board) to adopt standards, rules and regulations and to do such acts as may be necessary for the proper execution of the powers and duties granted to, and imposed upon, the Board by law;

WHEREAS, ozone is a primary component of photochemical smog, and has been recognized and regulated as an outdoor air pollutant for many years. The current California outdoor air quality standards for ozone are 0.09 part per million (ppm) and 0.070 ppm (averaged over one hour and eight hours respectively);

WHEREAS, 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 can inflame and irritate 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 increase the risk of premature death in persons with poor health. Ozone can also damage plants, fabrics and building materials such as walls and flooring. When present in combination with terpenes (lemon and pine-scented fragrance compounds found in many products), ozone reacts to form other pollutants including formaldehyde and ultrafine particles;

WHEREAS, a number of manufacturers sell devices represented to be air purifiers or air cleaners, which in fact purposely generate large quantities of ozone. Operation of these devices, also known as "ozone generators," in occupied spaces 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 national ambient air quality standards for ozone. Currently, Canada excludes intentional ozone-generating air cleaners from certification for residential use;

WHEREAS, ozone is not effective at cleaning the air except at very high levels several times the ambient air quality standards, when it can reduce some microbe levels;

WHEREAS, other common types of air cleaners include electrostatic precipitators (ESPs), ionizers, and mechanical filter devices. ESPs and ionizers may emit ozone as a by-product of their functioning, although the levels are usually much lower than those produced by ozone generators. Mechanical filter devices emit little or no ozone;

WHEREAS, 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 an air cleaner that may emit ozone as a by-product;

WHEREAS, in 2006 the Legislature passed Assembly Bill 2276 (Pavley), which was signed into law by Governor Schwarzenegger (Stats 2006; Chapter 770). The legislation enacted Health and Safety Code sections 41985-41986, which direct ARB to regulate ozone emissions from indoor air cleaning devices sold in California;

WHEREAS, section 41986(a) of the Health and Safety Code requires the Board to develop and adopt regulations, consistent with federal law, to protect public health from ozone emitted by indoor air cleaning devices, including both medical and non-medical devices used in occupied spaces, on or before December 31, 2008;

WHEREAS, section 41986(b)(1) of the Health and Safety Code requires the Board to include in its regulation an ozone emission concentration standard equivalent to the federal limit for medical devices. The U.S. Food and Drug Administration has promulgated (21 CFR § 801.415) a maximum acceptable level of ozone of 0.05 ppm for medical devices, and related labeling requirements;

WHEREAS, section 41986(b)(2) of the Health and Safety Code requires the Board to include in its regulation emission testing procedures to be used for determining the ozone emissions from indoor air cleaning devices, and to consider existing and proposed testing methods, including but not limited to, those developed by the American National Standards Institute and Underwriters Laboratories, Inc. (ANSI/UL);

WHEREAS, section 41986(b)(3) of the Health and Safety Code requires the Board to include in its regulation certification procedures that enable the Board to verify that an indoor air cleaning device meets the emission concentration standard;

WHEREAS, section 41986(b)(4) of the Health and Safety Code requires the Board to include in its regulation specified package labeling requirements to indicate an indoor air cleaning device is certified as meeting the ozone emission concentration standard;

WHEREAS, section 41986(b) of the Health and Safety Code further requires that the Board consider recommendations of affected industries and the public in developing the labeling requirements;

WHEREAS, section 41986(c) of the Health and Safety Code permits the regulation to include a ban on the sale of air cleaning devices that exceed the ozone emission concentration limit, procedures for authorizing independent laboratories or other

approved certification organizations to verify products as meeting the emission concentration standard for ozone emissions adopted by the Board, an exemption for indoor air cleaning devices that emit only *de minimis* levels of ozone during operation due to their design, and any other element the Board determines to be necessary to protect the public health from emissions of ozone from indoor air cleaning devices that exceed the emission concentration standard for ozone;

WHEREAS, on December 13, 2006, March 29, 2007, and June 11, 2007 public workshops were held in Sacramento, California to discuss and receive stakeholder and public input on the regulation of ozone emissions from indoor air cleaning devices;

WHEREAS, on August 10, 2007, staff released for public review an "Initial Statement of Reasons for the Proposed Regulation to Limit Ozone Emissions from Indoor Air Cleaning Devices," proposing adoption of the regulation set forth in Attachment A hereto and providing the justification and technical basis for the proposed regulation;

WHEREAS, staff considered information from many sources during development of the proposed regulation including input from manufacturers, testing laboratories, industry representatives, federal agencies, environmental health organizations, and scientific research experts;

WHEREAS, the proposed regulation would set an ozone emission concentration limit of 0.050 ppm for indoor air cleaning devices, consistent with federal law;

WHEREAS, the proposed regulation would apply to any person or entity who manufactures, sells, supplies, offers for sale, or introduces into commerce into California indoor air cleaning devices that are used in occupied spaces. Under the proposal, indoor air cleaning devices could not be manufactured for use in California 12 months after the effective date of the regulation ("manufacture date"), nor could they be sold, supplied, offered for sale or introduced into commerce in California 9 months after the manufacture date ("sell-through date"), unless the devices are certified by ARB;

WHEREAS, the proposed regulation requires indoor air cleaning devices to be certified by ARB prior to sale in California;

WHEREAS, the proposed regulation specifies that all indoor air cleaning devices, unless exempted, would be tested following the ANSI/UL Standard 867, or ANSI/UL Standard 507 for mechanical filtration devices, to assure that any modifications to comply with this regulation do not result in electrical safety issues. Ozone emissions would be determined using the 2007 revision of Section 37 of ANSI/UL Standard 867, with revisions approved and published by ANSI/UL before the proposed regulation is submitted to the Office of Administrative Law;

WHEREAS, 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;

WHEREAS, an appropriate certification mark or listing mark would be required on each certified device and devices certified for use in California would also be required to display a certification label on the product packaging and specified labeling in marketing materials;

WHEREAS, industrial uses for indoor air cleaning devices as defined in the regulation would be exempt from the proposed requirements, as would devices designed to be integrated into heating and air conditioning systems (e.g. "in-duct" systems);

WHEREAS, based on their known *de minimis* ozone emissions, indoor air cleaning devices using only mechanical filtration would be exempt from the ozone testing requirements with submittal of required documentation, although such devices would be required to pass ANSI/UL Standard 507 tests for electrical safety and would be subject to labeling requirements;

WHEREAS, the proposed regulation requires manufacturers to notify their distributors and retailers about the emission limits and other requirements established by the regulation, and to provide contact information for those distributors and retailers to ARB;

WHEREAS, in developing this regulatory proposal, the ARB staff evaluated the potential economic impacts on representative private persons and businesses, and estimated that annual average costs per manufacturer to comply with the proposed regulation range from $13,600 to $86,800 with an estimated decrease in profitability of less than one percent, and that estimated costs to the consumer range from $11 to $16 per indoor air cleaning device purchased for devices that currently cost about $100 to $700 per unit;

WHEREAS, the Executive Officer has made an initial determination that the proposed regulatory action will 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, and that any cost impacts are expected to be small or absorbable;

WHEREAS, in accordance with Government Code section 11346.3, the Executive Officer has determined that the proposed regulatory action will 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;

WHEREAS, the California Environmental Quality Act and Board regulations require that no project that may have significant adverse environmental impacts be adopted as originally proposed if feasible alternatives or mitigation measures are available to reduce or eliminate such impacts;

WHEREAS, a public hearing and other administrative proceedings have been held in accordance with the provisions of Chapter 3.5 (commencing with section 11340), Part 1, Division 3, Title 2 of the Government Code;

WHEREAS, in consideration of the Initial Statement of Reasons, written comments, and public testimony it has received the Board finds that:

Existing federal regulations, which apply only to medical devices, do not sufficiently protect public health from the ozone emissions from indoor air cleaning devices;

Ozone emissions from certain indoor air cleaning devices – primarily those that intentionally generate ozone – pose a significant health risk to members of the public who use these devices;

In the first five years after the proposed regulation takes effect, it is expected to prevent the exposure of more than 500,000 Californians to harmful ozone concentrations above the current California ambient air quality standard for ozone;

The proposed regulation is both technologically and commercially feasible;

The 2007 revision of Section 37 of ANSI/UL Standard 867 incorporates updated and refined measures to assure accuracy and consistency of results across testing laboratories, and that these improvements require changes in testing laboratories' test chambers and protocols;

WHEREAS, the Board further finds that:

The potential economic impacts of the proposed amendments have been analyzed as required by California law, and the conclusions and supporting documentation for this analysis are set forth in the Initial Statement of Reasons for this regulatory action;

The benefits to human health, public safety, public welfare, or the environment justify the costs of the regulatory amendments;

No new reporting requirements on California businesses are established by the proposed amendments, although pertinent records must be retained for three years and made available to the ARB upon request; these requirements which apply to businesses are necessary for the health safety, and welfare of the people of the State;

No reasonable alternative considered or that has otherwise been identified and brought to the attention of ARB would be more effective in carrying out the purpose of the proposed regulation, or would be as effective and less

burdensome to affected private persons and businesses than the proposed regulation; and

WHEREAS, pursuant to the requirements of the California Environmental Quality Act and the Board's regulations, the Board further finds that no significant adverse environmental impacts will occur from the proposed regulation.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the proposed adoption of sections 94800 through 94810, title 17, California Code of Regulations, as set forth in Attachment A, with the modifications set forth in Attachment B hereto and with the following additional modification—eliminating the nine-month sell through provisions in sections 94800 through 94810, title 17, California Code of Regulations as set forth in Attachment A.

BE IT FURTHER RESOLVED, that the Board directs the Executive Officer to take final action to adopt the proposed regulation set forth in Attachment A, with the modifications set forth in Attachment B and such other modifications as may be appropriate, after making the modified regulatory language and any additional supporting documents and information available for a supplemental public comment period of at least 15 days, provided that the Executive Officer shall consider such written comments as may be submitted during this period, shall make modifications as appropriate in light of the comments received, and shall present the regulations to the Board for further consideration if determined that this is warranted after review of the comments.

BE IT FURTHER RESOLVED, that the Board directs the staff to report to the Board at the regularly scheduled Board meeting one year after the certification program begins, anticipated to be the May 2009 Board meeting, on the status of the implementation of the regulation, including: the progress of the test laboratories in developing test capabilities for the 2007 revised Section 37 of ANSI/UL Standard 867; the number of manufacturers that have requested testing; the number of air cleaning devices tested by that time; the number of air cleaning devices scheduled for testing but not yet tested; and an assessment of testing laboratory capability and a recommendation regarding the need for further extension of the manufacturer effective date.

I hereby certify that the above is a true and correct copy of Resolution 07-40, as adopted by the Air Resources Board.

Lori Andreoni

Lori Andreoni, Clerk of the Board

Resolution 07-40

September 27, 2007

Identification of Attachments to Board Resolution 07-40

**Attachment A:** Proposed Regulation to Limit Ozone Emissions from Indoor Air Cleaning Devices, as set forth in Appendix B to the Initial Statement of Reasons, released August 10, 2007

**Attachment B:** Staff's Suggested Modifications to the Original Proposal (distributed at the Board hearing on September 27, 2007)