Report of the Small Business Advocacy Review Panel on the OSHA Draft Proposed Standard for Occupational Exposure to Beryllium

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1. Introduction

This report has been developed by the Small Business Advocacy Review Panel (the Panel) for the OSHA draft proposed standard for Occupational Exposure to Beryllium. The Panel included representatives of the Occupational Safety and Health Administration (OSHA), the Office of the Solicitor of the Department of Labor, the Office of Advocacy within the Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. On November 15, 2007, the Panel Chairperson, Robert Burt of OSHA, convened this 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.

This report consists of four parts: This introduction is Part 1; Part 2 provides background information on the development of the draft proposed rule; Part 3 summarizes the oral and written comments received from the small entity representatives (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 the written comments submitted by the SERs is included as Appendix C. In addition, the principal document sent to the SERs, the Preliminary Initial Regulatory Flexibility Analysis, is included as Appendix D to this document.

2. Reasons Why Action by the Agency is Being Considered

Acute beryllium disease (ABD), chronic beryllium disease (CBD), and lung cancer are three distinct lung diseases that have generally been associated with occupational exposure to beryllium. ABD is a rapid onset form of chemical pneumonia from breathing high airborne concentrations (e.g., 100 $\mu g/m^3$ and above) of soluble beryllium (e.g. beryllium sulfate or beryllium fluoride). ABD results in lung swelling, fever, and shortness of breath that could be fatal, if the exposure continues.

CBD is a hypersensitivity or allergic reaction to beryllium that leads to a chronic inflammatory disease of the lungs. Unlike ABD, it takes months to years after initial beryllium exposure before signs and symptoms of CBD occur. Removing the employee from the beryllium source does not always lead to recovery. In some cases, CBD continues to progress following removal from beryllium exposure. CBD is not a chemical pneumonitis but an immune-mediated granulomatous lung disease. For CBD to

occur, an employee must first become sensitized (i.e., become allergic) to beryllium. Once an employee is sensitized, inhaled beryllium that deposits and persists in the lung may trigger a cell-mediated immune response (i.e., hypersensitivity reaction) that results in the formation of a type of lung scarring known as a granuloma. The granuloma consists of a localized mass of immune and inflammatory cells that have formed around a beryllium particle lodged in the interstitum of the lung. Over time, the granulomas spread and can lead to chronic cough, shortness of breath (especially upon exertion), fatigue, abnormal pulmonary function, and lung fibrosis. While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys.

Some studies demonstrate that sensitization and CBD cases have occurred in workplaces that use a wide range of beryllium compounds, including several beryllium salts, refined beryllium metal, beryllium oxide, and beryllium alloys. While water-soluble and water-insoluble beryllium compounds have the potential to cause sensitization, it has been suggested that CBD is the result of occupational exposure to beryllium oxide and other water-insoluble berylliums rather than exposure to water-soluble beryllium or beryllium ores. However, there are inadequate data, at this time, on employees selectively exposed to specific beryllium compounds to eliminate a potential CBD concern for any particular form of this metal. Regardless of the type of beryllium compound, for CBD to occur, the inhaled beryllium must contain particulates that are small enough to reach the bronchoalveolar region of the lung where the disease takes place.

Inhalation of respirable beryllium may be only one of several factors that determine whether an employee becomes sensitized to beryllium. It has been shown by some studies that employees with genes that code for specific protein molecules on the surface of their immune cells are at greater risk of becoming sensitized to beryllium and developing CBD. Some recent research suggests that skin exposure to small beryllium particles or beryllium-containing solutions may also lead to sensitization. These additional risk factors may explain why some individuals with seemingly brief, low-level exposure to airborne beryllium become sensitized while others with long-term, high exposures do not. Some studies suggest that even though employees sensitized to beryllium do not exhibit clinical symptoms, their immune function is altered such that inhalation to previously safe levels of beryllium can now trigger serious lung disease.

Several epidemiological cohort studies have reported excess lung cancer mortality among employees employed in U.S. beryllium production and processing plants during the 1930s to 1960s. OSHA has preliminarily determined that the weight of evidence indicates that beryllium compounds should be regarded as potential occupational lung carcinogens. Other scientific organizations, such as the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH) have reached similar conclusions with respect to the carcinogenicity of beryllium.