

Ciba 1993 ✓

INTRODUCTION

One of the critical issues of the Corporation is the reduction in concern about the health effects of beryllium. Based on this charter, our Mission is to develop and lead the strategy to economically overcome major health effects and environmental issues surrounding the safe manufacture and use of beryllium. As a part of this mission, we participate in the legislative and regulatory process to assure an ongoing, affordable supply of beryllium to our governmental and commercial customer base.

The health effects issue, particularly strong misunderstanding of the potential hazards of handling beryllium, permeates our business. Health and safety concerns are a major obstacle to the sale of beryllium (Critical Issue 1.b(1)). Critical Issue 3 calls for the reduction in beryllium health and safety concerns by:

- a. Overcoming negative market perception through education, communication, enhanced product price/performance balance;
- b. Managing regulatory threats and challenges;
- c. Reducing exposure in the workplace and resulting potential for liability;
- d. Enhancing diagnostic tools; and,
- e. Increasing our knowledge of CBD and related beryllium hazards.

There are three disease entities which drive this critical issue: chronic beryllium disease (CBD), cancer caused by inhalation, and cancer caused by ingestion. Of these entities, CBD is the only real legitimate concern from an occupational disease standpoint. Nevertheless, the perceived threat of cancer affects our business probably more negatively than CBD.

Our medical knowledge of the mechanisms controlling CBD has expanded widely in the past few years. Improved techniques have resulted in an earlier detection of the disease and a change in the diagnostic criteria. This has contributed to a significant increase in the number of cases diagnosed, placing significant financial pressure on the industry. On the other hand, we are confident that the increase in medical knowledge will reverse this trend in the long run.

The perceived threat of cancer by either inhalation or ingestion of beryllium may have a greater negative impact than CBD. Within the past several months, three significant occurrences have contributed to a worsening of the situation:

- a. Researchers at the Inhalation Toxicology Research Institute (ITRI) discovered an increase in cancer in rats, rendering our position on the absence of good quality animal data no longer tenable;

- b. The NIOSH paper which showed an increase in human cancer in 1 of 7 beryllium plants will be published as a peer-reviewed article; and
- c. The International Association for Research in Cancer (IARC) will rework its beryllium document.

None of these findings indicate any significant risk to the public either from the manufacture or the use of beryllium. Nevertheless, the perception affects us negatively in the market.

Probably the greatest impact on our business is the non-existent threat of cancer by oral ingestion; the limited medical data show no evidence of cancer by this route. Nevertheless, we are regulated to a no observable adverse effects level (NOAEL) which is used to determine the limits for all water quality regulations. This very conservative method of risk assessment drives drinking water and water quality standards, landfills, closures, permitting, etc.

In dealing with these highly complex issues, our philosophy has been to gather and communicate the facts surrounding the health effects of beryllium. Where data do not presently exist, we are increasing the knowledge base. If advocacy doesn't succeed, especially with the regulatory agencies, we will pursue legal action, but as a last resort.

In the case of CBD, our primary focus is on workforce protection throughout the industry. Our medical screening program is designed to detect the disease at the earliest possible stage. Epidemiological studies, coupled with medical screening, will help isolate those processes that are potentially high sources of disease, adding focus to our industrial hygiene programs. Medical research, sponsored by the Beryllium Industry Scientific Advisory Committee (BISAC), is already yielding significant knowledge of the origins and the mechanisms of the disease. It seems likely that we are well along the road of understanding, and, therefore, better controlling the incidence of the disease. We must continue to advocate our position with the authorities.

Domestically, beryllium is regulated as a suspect carcinogen by all routes, while in Europe it is regulated by inhalation only. Again, our approach is to assure that the regulatory bodies on both continents have the best data available. Where data are lacking or inconclusive, we plan, on a focused basis, to fill these gaps. Particular pressure comes from the EEC, where advocacy is complicated by the highly bureaucratic regulatory process. We will concentrate in Germany, as well as in France and UK, where most of the regulatory pressure originates.

Of particular importance in the EEC is the Preparations Directive, which regulates any mixture containing >0.1 percent of a carcinogen as a carcinogen. This will be one of our main focal points for our advocacy in EC, attacking this concept for its lack of scientific basis.

The BISAC will provide the scientific basis for our cancer strategy by:

- a. Breaking the link, if possible, between animal and human experience;
- b. Determining the applicability of invitro testing to differentiate between product lines;
- c. Examining cancer risk assessment methodology; and,
- d. Reviewing and recommending protocols for animal testing.

Ultimately, given the nature of the data on the topic and current conditions in the workplace, we see cancer as posing not a true medical threat, but rather a perceived threat, making the real issue one of providing proper education. Therefore, we have formed a cancer strategy group which will deal with the combined medical, legal, operational, and promotional aspects of beryllium as a suspect carcinogen.

Beryllium as an ingestive, or oral, carcinogen drives all water quality issues domestically. Fundamentally, all water quality regulations, nationally and locally, are derived from the oral risk assessment in the Integrated Risk Information System (IRIS). Recently, the Federal Drinking Water Standard was promulgated on a reference dose basis derived from a NOAEL based on a single study (Schroeder and Michener). Our approach is to gain acceptance of the more realistic Morgareidge studies which demonstrate a much higher NOAEL. Failing this, we will initiate further animal feeding studies. Our primary approach is advocacy with the Agency; however, we have been forced by the timing to file an appeal in Federal District Court. Hopefully, we can avoid litigation by negotiation and advocacy.

In a worst-case scenario beryllium could ultimately be classed as a human carcinogen, which might result in limited end use opportunities in consumer markets. Nevertheless, we only have to look at the nickel industry to know this isn't a "going out of business" scenario.

We believe that the strategies which we have in place will allow us to manage our way through this critical issue.

ASPECTS OF ENVIRONMENTAL, HEALTH & SAFETY ACTIVITIES .

- A. Environmental and health regulation management
- B. Environmental compliance
- C. CBD
- D. Cancer
- E. Communication
- F. Employee health and safety protection
- G. Liability avoidance

	Responsible Person(s)	Reference
A. Environmental and Health Regulation Management	Hanes	
1. Strategy for avoiding unnecessary and restrictive regulations	Hanes	
2. Communication with various agencies who either have or would establish regulations which could affect our business, e.g., a. EPA b. OSHA c. NIOSH d. JARC	Hanes/Reg. Leg. Working Group	III. A. 3
3. Participation on studies relating to beryllium health effects	BISAC Hanes/ Markham	III. B
4. Retaining and management of outside resources as needed to assist in conveying our positions to appropriate authorities	Hanes	
B. Environmental Compliance	Kolanz	
1. Strategy and plans for complying with all applicable EHS regulations	Plant Management	
2. Audits	Kolanz	
3. Education of plant management and other appropriate managers	Kolanz	
4. Prioritization of compliance activities	Operations/I/H	
5. Capital/expense budgets	Plant Management	
C. CBD Leadership		
1. Leadership and oversight of medical research	BISAC	III. B
2. BISAC role and direction	Hanes/Powers	III. B
3. Employee testing, e.g., BLTT	Markham/H.R.	III. A
4. CBD policy	Ops Team/CBD Working Group	III. C

MEETING SCHEDULE

Beryllium EHS Communications Steering Team

January 6, 1993	- St. Clair
March 30, 1993	- St. Clair
July 1, 1993	- St. Clair

Employee EHS Communications Team

January 22, 1993	- St. Clair
February 12, 1993	- St. Clair
March 12, 1993	- St. Clair

Customer EHS Communications Team

January 18, 1993	- St. Clair
March 9, 1993	- St. Clair

Regulatory/Legislative EHS Communications Team

January 21, 1993	- St. Clair
March 18, 1993	- St. Clair

BISAC

January 11-12, 1993	- Key West
April 7-8, 1993	- Washington, DC
July 7-8, 1993	- Elmore
October 4-5, 1993	- Denver