

# Collier Shannon Scott

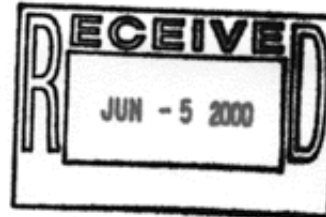
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June 5, 2000

Via Electronic and Overnight Mail

Dr. C.W. Jameson  
National Toxicology Program  
Report on Carcinogens  
79 Alexander Drive  
Building 4401  
Room 3118  
Research Triangle Park, N.C. 27709



**Re: NTP Review of Metallic Nickel and Nickel Alloys**

Dear Dr. Jameson:

On behalf of the Specialty Steel Industry of North America ("SSINA"), we submit the following comments related to the review of metallic nickel and nickel alloys by the National Toxicology Program ("NTP") for the *10th Report on Carcinogens*. 65 Fed. Reg. 17,889 (Apr. 5, 2000). The purpose of this review is to determine whether "metallic nickel" and "nickel alloys" should be listed as "known" carcinogens along with "nickel compounds" for which NTP recently completed its review. As detailed below, SSINA strongly believes that including metallic nickel and nickel alloys in the *Report on Carcinogens* as either "known" or "reasonably anticipated" carcinogens would be unnecessary, scientifically unjustified, and entirely inappropriate.

## **I. BACKGROUND**

SSINA is a national trade association comprised of 15 producers of specialty steel products, including stainless, electric, tool, magnetic, and other alloy steels. SSINA members account for over 90 percent of the specialty steel manufactured in the United States, and are large consumers and users of nickel as a significant alloying agent in the production of many stainless steels and other high performance alloys. As consumers and users of nickel, SSINA members are interested in the proper characterization of this metal for potential regulatory purposes. In particular, SSINA is concerned about the potential listing of metallic nickel and nickel alloys in the *Report on Carcinogens*, given that the available evidence demonstrates that nickel metal and alloys are not associated with increased incidences of carcinogenicity.

Specialty steels play an important and expanding role in the U.S. economy and touch our daily lives in a wide range of uses. They are essential in today's industrialized economy and serve critical national defense needs and applications in aerospace; aircraft; automobiles; appliances; communications, electronic, marine, and power-generating equipment; home utensils and cutlery; construction products; food and chemical processing plant equipment; and medical, health, and sports equipment. Specialty steels are valued for these uses due to their exceptional hardness, strength, and resistance to heat, corrosion and abrasion.

## **II. THE AVAILABLE EVIDENCE DOES NOT SUPPORT LISTING OF METALLIC NICKEL AND NICKEL ALLOYS AS KNOWN OR REASONABLY ANTICIPATED CARCINOGENS**

NTP's apparent inclination to list all nickel compounds as "known" human carcinogens sweeps far too broadly and ignores critical factors such as speciation and bioavailability.<sup>1/</sup> Listing metallic nickel and nickel alloys in the *Report* would be an even more egregious error. Each species or compound of nickel may have significantly different chemical and physiological properties, each must be separately evaluated for its carcinogenic potential. This is especially true of metallic nickel and nickel alloys. For example, ferro-nickel compounds found in stainless steels are most certainly not bioavailable and could not, consistent with current epidemiology and toxicology literature, be considered carcinogens. Listing of metallic nickel and nickel alloys would ignore the fact that nickel alloys such as stainless steel have been used for decades and are universally recognized as being safe for use in a wide variety of consumer products, including cookware, eating utensils, kitchen and restaurant equipment, surgical implants, *etc.* Any classification of these benign nickel alloys as carcinogens would be entirely improper. The impact of such a gross misclassification upon the stainless steel industry could be devastating.

As discussed more fully in the comments submitted by the Nickel Development Institute ("NiDI") and the Nickel Producers Environmental Research Association ("NiPERA"), the current epidemiological and other toxicological data regarding nickel carcinogenicity simply do not support the classification of all forms of nickel as carcinogenic. NTP should not list nickel compounds generically in the *Report*, and it certainly should not include nickel metal and nickel alloys in any such generic grouping that ignores the chemical form of nickel and the specific biokinetic properties and exposure potential of each nickel compound.

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<sup>1/</sup> The procedural shortcomings of the "nickel compounds" review process are well documented, including in our letter to Dr. Kenneth Olden, Director of NTP, dated March 25, 1999. In addition, SSINA fails to see how NTP could justify upgrading *all* nickel compounds to the known carcinogen category when, in fact, only seven specific nickel compounds currently are listed as reasonably anticipated carcinogens in the *Report*.

Following is a brief review of nickel health effects studies that demonstrate that metallic nickel and nickel alloys should not be identified as either "known" or "reasonably anticipated" carcinogens.

**A. The Redmond Study**

A health effects study of 31,000 high nickel alloy workers, who were likely exposed to nickel in metallic and/or oxidized forms, conducted by Dr. Carol Redmond ("the Redmond Study") found that nickel alloys are produced without subjecting workers to increased mortality risks. These compelling results are bolstered by the large size of the studied population and prolonged observation period. The results of the study have been discussed in two articles: (1) in the October 1998 issue of the *Journal of Occupational and Environmental Health*; and (2) in the *American Journal of Industrial Medicine* during 1999. A copy of each article is attached. SSINA urges NTP to consider the Redmond Study when assessing metallic nickel and nickel alloys for the *Report*.

**B. University Of Birmingham Data Evaluation**

SSINA is attaching to these comments a copy of an extensive evaluation of available data performed by England's University of Birmingham that concluded that no significant deleterious health effects resulted from exposure to stainless steel in the following scenarios: (1) metallic stainless steel; (2) stainless steel manufacturing; and (3) stainless steel processing. In particular, the review found that:

- Stainless steels do not cause any adverse effects on health.
- There is no indication that the manufacture of stainless steel causes adverse effects on the health of workers.
- The welding of stainless steel does not cause any stainless steel-specific increase in the risk of lung cancer over and above the increased risk from any (non-nickel) steel welding.
- The grinding and cutting of stainless steel do not appear to cause any adverse health effects.

See H.J. Cross, J. Beach, L.S. Levy, S. Sadhra, T. Sorahan, and C. McRoy, *Manufacture, processing and Use of Stainless Steel: A Review of the Health Effects*, Institute of Occupational Health, Univ. of Birmingham (Jan. 1999) (Attached). The review also provides general information on exposure for each of the scenarios noted above.

Dr. C.W. Jameson

June 5, 2000

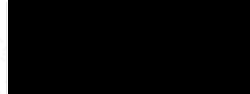
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### III. CONCLUSION

NTP decisions have significant downstream regulatory and economic impacts. Moreover, identification as a carcinogen by NTP -- or other agency classification decisions based on NTP conclusions -- has widespread social and economic impacts (e.g., toxic tort litigation, consumer product deselection). Accordingly, NTP has a legal duty to ensure that its decisions are based on sound science and the product of reasoned decision making before stigmatizing a substance as a known or reasonably anticipated carcinogen. The available evidence for most nickel compounds generally and for metallic nickel and nickel alloys in particular does not meet this standard.

If you have any questions or we may be of any further assistance, please do not hesitate to contact us.

Very truly yours,



John L. Wittenborn  
Joseph J. Green  
Counsel to the Specialty Steel Industry  
of North America

Attachments (via Overnight Mail)