

Nickel Defense Strategy

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Abstract

Nickel plated finishes and soluble nickel compounds are coming under increasing scrutiny by health officials at the federal and state levels that have identified these materials are potentially harmful to human health. Suggested new health classifications and pending regulatory requirements have the potential to cripple one of the most important areas of metal finishing in this country. This paper will summarize the efforts of various groups within the Metal Finishing Industry, which are being carried out in cooperation with the Nickel Development Institute (NiDI) and the Nickel Producers Environmental Research Association (NiPERA), to protect the future of nickel plating in the United States.

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Recent surveys of the Metal Finishing Industry indicate that nickel is the most popular plating process in the United States. Over 50% of shops responding to the surveys listed nickel plating as one of the finishes they provide to their customers. Despite its popularity, nickel plating operations are coming under increasing scrutiny by health officials at the federal and state levels who have proposed all nickel salts are potentially harmful to human health. Additionally, several international organizations and European governing bodies have recommended and instituted restrictive controls on nickel emissions to both air and water.

The anti-nickel agenda goes beyond restrictive limits on emissions. It actually targets the finish itself. For example, Scandinavian countries, which already have very low threshold limiting values (TLVs) for nickel, have emerged as “hotbeds of negative attitudes” toward nickel finished articles (e.g., plated products are not eligible for environmentally preferential labeling under the recent “Nordic Swan” program). In Europe and beyond, automotive, furniture, and appliance manufacturers such as Daimler-Benz, Ford, IKEA, and Electrolux are under pressure from environmentalists to “blacklist” nickel and other materials for use in various applications. There are also anti-nickel programs on the other side of the globe. In Australia, for example, dermatologists are taking a more aggressive policy posture toward nickel plated products.

Here in the US, in the spring of 1999, the State of California declared all soluble nickel compounds to be carcinogenic, despite a lack of clear medical evidence to justify this all-encompassing classification. One of the results of this ruling in California is that new nickel plating installations – whether they be electroless or electrolytic, in nature – now require expensive air filtration systems to remove sub-micron sized, air-borne particles of nickel compounds from the space above the plating solutions.

The efforts of environmental and some regulatory groups haven’t stopped there, however. These groups are determined to have all soluble nickel compounds declared carcinogens at a federal level. Clearly, if this were to happen, it would have a very serious negative impact on the nickel plating industry in the United States.

In a coordinated attempt to prevent this from occurring, the metal finishing industry assumed a leadership role and partnered with the United States Environmental Protection Agency, (US EPA), and Health Canada, to jointly fund an independent risk assessment study to challenge much of the bad science that the environmentalists cite. The Metal Finishing Association of Southern California (MFASC) spearheaded these efforts and has also shouldered the majority of the cost of conducting the independent review. This study was conducted by Toxicology Excellence for Risk Assessment (TERA), a non-profit organization dedicated to the best use of toxicity data in risk assessment. The study itself is entitled *Toxicological Review of Soluble Nickel Salts*.

The results of this hazard identification and dose-response assessment on soluble nickel salts were presented to an independent panel of expert scientists and risk assessors in September of 1999, at the University of Cincinnati, College of Medicine. (Note: The TERA website, www.tera.org, offers a printable summary of this meeting in *pdf* format.) The panel carefully reviewed the information that was presented and concluded there was insufficient data to make a final decision regarding the carcinogenicity of all soluble nickel compounds. The panel subsequently reported this to the U.S. Department of Health and Human Services National Toxicology Program (NTP), and further recommended that NTP’s 9th Report on Carcinogens (RoC) state that no final decision can be made until more health and human exposure data is available. Although this decision had no impact on the California emission standards, it did – at least temporarily – prevent an across-the-board classification of nickel compounds that could have been devastating to the metal finishing industry.

The Nickel Development Institute (NiDI), and the Nickel Producers Environmental Research Association (NiPERA) have recently joined the fight to, first, prevent classifying all soluble nickel compounds as carcinogens, and also to counteract the movement away from nickel as an acceptable plated finish on various articles. For the last two and a half years, NiDI and NiPERA have been working closely with various members of the metal finishing industry in an attempt to create and implement an effective strategy to protect the future of nickel plating. This is a significant development, and is the first time chemical suppliers, finishers, and producers have coordinated their efforts toward a common goal.

The unified defensive strategy includes several distinct elements: (1) defining the most efficient method of keeping the appropriate parties up-to-date on global and US regulatory developments; (2) discussing ways to achieve improved coordination in addressing nickel regulatory threats; (3) identifying specific options for more formalized collaboration among the key players who share an interest in protecting the future of nickel plating; and (4) discussing the funding needed to accomplish these goals, and exchanging ideas regarding how to raise the necessary financial resources to implement the strategy.

The group has concluded that a combination of periodic open forum meetings and group e-mailings is the most effective form of communication to keep interested parties aware of the latest developments. The meetings have typically been held in conjunction with metal finishing industry gatherings, such as Sur/Fin® and the Legislative Conference that is held each year in Washington, DC in September.

It is important to understand the typical process by which chemicals are first identified as potentially hazardous materials, through the point when these chemicals become regulated by agencies, or become “de-selected” materials in the marketplace. As a first step, NTP uses data supplied by toxicological or epidemiological studies, including data from organizations such as the World Health Organization, or TERA, to identify the presumed hazard associated with a specific substance or family of substances. US EPA is not required by law to use the conclusions of NTP to assess the human health risk associated with the chemicals, but takes NTP “listings” of chemicals into account in determining which chemicals warrant closer evaluation regarding their human health risk potential. And, finally, individual states often use the US EPA or NTP information to identify materials for new regulation.

A potential problem exists whenever states move to regulate materials or activities based on assumptions drawn directly from NTP hazard identification data, and without considering the input of US EPA’s human health risk assessment. It appears that this happened in California, for example, with the extremely stringent air effluent guidelines that were set without the benefit of US EPA’s recommendations. Had US EPA’s input been considered, it is *possible- though not certain* – that less demanding limits may have been adopted.

Clearly each of these three steps is critical, but none is more important than the first step. This is because, if NTP feels there is a significant hazard associated with a substance, EPA and individual states can take steps to (1) assume there is a human health threat linked with the chemical, and then (2) consider what might be very stringent limits for air and effluent.

The goal of the nickel producers, finishers, and chemical suppliers is to maximize the probability that NTP will make the correct hazard assessment for soluble nickel chemicals. Accordingly, the group has organized an education campaign attempting to demonstrate there is insufficient data to draw clear conclusions on nickel carcinogenicity, and has focused on getting this message to NTP. Following is a brief recap of what has been done, as well as a description of where data gaps still exist, and what has been considered to fill these gaps.

Dr. Adriana Oller of NiPERA has explained to the producers/finishers/suppliers group that the main factor that complicates drawing a clear conclusion is that most of the data that is available for review is mixed data which summarizes human exposure to both soluble and insoluble nickel compounds. Dr. Oller has pointed out there is ample evidence to support that nickel powder and other small particle size forms of metallic nickel do represent a health risk to humans, and this fact necessarily affects the overall results when mixed exposure data is reviewed.

In an attempt to rectify the problem with the mixed exposure data, NiPERA recently approached several researchers in Norway to produce a better study on nickel exposure to workers. Unfortunately, they determined a Norwegian worker study was not feasible. They concluded that, in order to make an unequivocal case on carcinogenicity, a 20-year study with good exposure data for roughly 1,000 workers would be required. This was deemed impractical.

In at least one of the group meetings, John Stevenson of Anoplate, Inc., Syracuse, NY, described a nickel inhalation study that had been undertaken at Johns Hopkins in recent years, in which many platers, including Anoplate and Kuntz Electroplating, Inc of Kitchener, Ontario, had participated. Unfortunately, the study does not contain sufficient data for a long enough period of time to be of value in proving or disproving the carcinogenicity issue for soluble nickel compounds.

Harry Levy of Gene's Plating, LLC, in Los Angeles, and Randy Solganik, formerly of Gene's Plating, and currently of City Plating in Cleveland, OH, have emphasized to the producers/finishers/suppliers group the importance of focusing our defensive efforts on the four nickel compounds that are of the greatest importance to the nickel plating industry: nickel sulfate, nickel chloride, nickel carbonate, and nickel acetate. They emphasized that Industry measurably improves its chances of proving our case through this so-called speciation of nickel chemicals, rather than trying to collect data and analyze it on all soluble nickel compounds.

Howard Smith of Atotech, and representatives from other major suppliers of proprietary nickel products have pledged their support in contacting affiliates and associates outside the US in hopes of finding data that would be acceptable to all appropriate parties. However, none of these efforts have produced any useful data to date.

Drs. Oller and Hudson Bates, both scientists from NiPERA, have indicated that NiPERA will fund a three-year oral carcinogenicity study for soluble nickel compounds. It is expected to include both oral inhalation and oral ingestion, two areas where the data gaps are the greatest.

While it is not part of the carcinogenicity discussion, the topic of nickel allergic contact dermatitis has also been brought up at meetings attended by the nickel producers, finishers, and chemical suppliers because of its possible impact on the use of nickel plated finishes. NiDI and NiPERA have cooperated in preparing a paper covering this topic. It is their joint opinion that nickel allergic contact dermatitis that is initiated through dermal exposure is a preventable condition. Further, they believe that a high level of protection against nickel sensitization and against elicitation of allergic reactions to nickel is achievable.

Additionally, for articles intended for direct and prolonged contact with the skin, NiDI and NiPERA support the view that the critical factors to be taken into account when assessing and managing the risks associated with nickel allergic contact dermatitis are: (a) the ability of a material surface to release nickel when it is exposed to sweat; and (b) the nature of the contact with the skin, in particular its duration and intimacy. More specifically, they support the view that both nickel release above a critical level, and prolonged contact with the skin, have to

be present in order for there to be a significant risk of sensitization, or initiation of an allergic reaction in a previously nickel sensitized individual.

For articles that are used to pierce the skin and for placement in the wound after piercing during the healing period, NiDI and NiPERA support the view that the nickel content of a material is not the relevant factor, but that the critical aspect is the ability of the surface of an article to release nickel in relevant environments.

In order for measures that protect the public to be best achieved, NiDI and NiPERA believe that the marketplace for articles intended for direct and prolonged contact with the skin should be regulated, and to that end NiDI and NiPERA will actively support and promote appropriate regulatory initiatives. Additionally, they have indicated they will actively support efforts to develop testing procedures for nickel release from such products, which combine accuracy, reliability, speed, and cost effectiveness.

Unfortunately, this entire defensive process regarding nickel compounds and nickel plated finishes is extraordinarily expensive. Collecting, analyzing, and summarizing the data needed to substantiate Industry's point of view is estimated to cost as much as \$3,000,000. Admittedly, this comes in the midst of a severe business slump and at a time when the metal finishing industry can least afford expenditures of any magnitude. Nevertheless, it is clear that Industry must do something to defend itself, otherwise regulatory and risk assessment decisions regarding soluble nickel compounds will be based on emotion and speculation, rather than on science. Industry cannot afford to let this happen to as important a facet of metal finishing as nickel plating. Not to be overly dramatic, but if emotional decisions are allowed to take place unchecked, it is conceivable that nickel plating could be regulated out of existence. Indeed, even the Department of Defense is responding to the unfortunate appearance of nickel on NTP and other various "lists" of harmful materials, and is moving to fund research proposals that address the efficacy of alternatives to nickel.

Fortunately, NiPERA and NiDI have taken a lead position in providing much of the financial support that is needed. But they cannot be expected to bear the full cost of defending such an important aspect of finishing as nickel plating represents. Finishers and chemical suppliers must all contribute to this cause in proportion to the importance of nickel plating to the overall success of their respective businesses.

It is appropriate to end this discussion on a positive note. Very recent developments, which involve US EPA's conclusions about the nickel carcinogenicity issue, appear to be favorable to Industry's position. At a meeting in mid-March 2002 in Nashville, TN, which covered the effect on human health resulting from exposure to soluble nickel compounds, Dr. Ambika Bathija of US EPA stated that the agency feels there is insufficient data available at this time to draw valid conclusions. This matches Industry's point of view very closely, and adds credence to our message. The challenge is clear: We need to provide the financial support necessary to publicize this to the appropriate regulatory agencies before all nickel compounds are classified as carcinogens, and nickel plated finishes are severely limited.

References:

1. *International Toxicity Estimates for Risk (ITER)* – Nickel Soluble Salts Peer Review Meeting Summary, September 1999, www.tera.org.
2. Minutes from various meetings attended by representatives from NiDI, NiPERA, nickel finishers, and nickel chemical suppliers.