NiPERA INC. Nickel Producers Environmental Research Association

# 2015 ANNUAL REPORT

**COVERING ACTIVITIES FROM**

**JANUARY 1, 2015 – DECEMBER 31, 2015**

**AND BUDGETARY INFORMATION FOR FISCAL YEAR 2015**


**2525 Meridian Parkway, Suite 240, Durham, NC 27713, USA**
**Phone: 1-919-595-1950 • Fax: 1-919-595-1955**

# TABLE OF CONTENTS

Page

## Introduction

NiPERA, Nickel Institute's science division, was engaged in numerous high profile scientific communication activities in 2015. Many of these activities were by direct invitation from regulatory agencies around the globe which highlights the credibility and trust that the NI scientists have gained throughout the years, and are part of our broader strategy of convincing regulatory authorities of the nickel science approaches pioneered by NiPERA.

## Classification

NI scientists have managed to ensure that nickel and nickel compounds received a lower priority in California for reproductive toxicity hazard assessment. Despite the short time available for commenting, NI submitted written comments for nickel to be a low priority and also managed to mobilise several stakeholders to support that position. NI scientists attended a meeting organized by the Californian authorities and although no final conclusion was confirmed, nickel and its compounds received the lowest ranking out of all chemicals discussed. This means that any review in California of the classification of nickel and its compounds as reproductive toxicants will be pushed into the future.

## Bio-elution Breakthrough

In 2015 the European Commission specifically invited NI science experts to discuss the development of a validated method of testing based on metal release which could be used as basis for a more accurate classification of alloys and is an alternative to animal studies. This has important implications for the classification of nickel-containing alloys, such as stainless steel, which in turn could have a positive impact on their future use in society. According to the conventional classification method, stainless steel containing more than 1% of nickel should be classified. However, according to the bio-elution method, these types of stainless steel may not need to be classified as they are unlikely to release nickel in sufficient amounts to warrant classification. The European Commission asked their reference laboratory to further develop this method, which is a significant breakthrough.

## Nickel Allergy

NiPERA, as the chairperson for the NI Nickel Allergic Contact Dermatitis Team (NI NACD Team), has provided scientific input into a number of important communication efforts in 2015 in cooperation with the other branches of the NI. These communications include a design of an infographic on nickel allergy, organization of a NACD workshop in Europe, development of a position statement on nickel use in piercing materials, and cooperation with the American Academy of Dermatologists to develop their position statement based on the one of the NI. In addition, continued monitoring and appropriate responses have been sent to inquiries, published articles, and media communications through coordinated efforts of the NI NACD Team.

## Water Quality Standards

The US Environmental Protection Agency has invited NI scientists to participate in discussions to revise the nickel ambient water quality criteria thus providing an opportunity to leverage the success with the European Water Quality Standards in another jurisdiction. The reaction of the EPA's scientists to the approaches developed for metals was positive. NI's involvement in the further discussions will be crucial to ensure that water quality is correctly assessed as otherwise potentially high compliance costs could result for companies producing or using nickel and anyone using water.

Environment Canada (EC) is revising water quality guidelines for different metals, though not yet for nickel. However, NiPERA scientists have taken this opportunity to also discuss metal approaches with EC which was received with great interest and may be used by EC in the upcoming revisions, thus further leveraging the success with European standards.

## Sediment

The European Chemicals Agency (ECHA) invited NI scientists to participate in the Partner Expert Group (PEG) that will be involved in revising ECHA's environmental risk assessment guidance for the sediment compartment. This is very positive as recommendations from a recent ECHA workshop reflect the scientific position of the NI and other metals research associations. This will provide an opportunity for the NI to ensure that scientific concepts for metals are integrated in the guideline. NI also hosted a briefing on the effects of nickel to freshwater organisms for regulatory scientists involved in making decisions regarding sediment under REACH and the EU Water Framework Directive. The objective was to ensure that the latest scientific developments are communicated and taken on board by regulators in risk assessments and the development of quality or emission standards so they are based on correct science.

## Nickel Tropical Risk Assessment Research Program

Excellent progress has been made in the development of a model considering effects of nickel exposure to the Tropical Environment (e.g., coral reefs and mangrove swamps). Relatively limited exposure data are available for key parameters in most areas and there are data gaps for certain geographical areas such as New Caledonia and western Indonesia. A survey of relevant and reliable ecotoxicity data available from the peer-reviewed literature has been completed, and revealed several important data gaps. These data gaps are in the process of being filled by laboratory work which is planned to continue in 2016.

## REACH (Registration, Evaluation, and Authorisation of Chemicals)

Of direct benefit to Member Companies was the on-time submission of the 5th annual update of the European registration dossiers under REACH. This year's updates included new health toxicity, environmental toxicity, and exposure data. These Technical dossiers are required for maintenance of the registration under REACH to ensure that the companies remain in compliance and can continue to import and/or produce substances in the European Union.

## Nickel Matte Dossier Update

Following inspection from REACH national enforcement authorities in 2014, a nickel matte registrant was requested to update the Nickel Matte REACH dossier from an intermediate file to a full dossier by September 2015. This update required significantly more information than the intermediate file. NiPERA and the rest of the NI REACH team acted swiftly to meet the deadline set by the regulators to complete the additional data requirements and update the entire dossier by September 2015, which was important to ensure that the matte can continue to be manufactured, imported and used in the EU.

## Risk Assessments

NiPERA scientists have had a series of meetings with Australian Authorities to promote sound science in nickel risk assessments. The Australian Authorities have already interacted extensively with the NI on human health issues and have adopted numerous modifications to the European risk assessment datasets. This willingness to review and adopt the best science is also being demonstrated by the Australian Environmental authorities as they begin the process of building their nickel environmental dossiers. This exercise is the first clear example of solid scientific intervention to ensure that correct metal guidelines, models and concepts are integrated in a risk assessment.

## Scientific Dissemination

2015 marked a very successful year for formal communication of the latest scientific developments through active participation in influential workshops and science meetings, either with Member companies, academics or regulators. This is important to ensure that ongoing and future projects are aligned with the needs and expectation of Members, and that universities and the regulatory communities understand, endorse and use the science and models that have been developed for metals in their evaluations and assessments.

## NiPERA 2015 Publications

Publication of NiPERA sponsored research in the peer-reviewed scientific literature is a key factor in gaining regulatory acceptance of research results. While a typical year may see six or seven such publications, in 2015 a total of 17 manuscripts were published. These publications are key resources in ensuring that scientific and regulatory experts use the best scientific evidence possible when conducting risk assessments on nickel and its compounds.

## Budget

The NiPERA budget reporting paradigms are based upon Generally Accepted Accounting Principles (GAAP) for Not-for-Profit [501(c)(3)] organizations in the United States where NiPERA is incorporated. Consequently, budgetary liabilities are recorded in full when they occur which offers the best method of managing expenses, albeit with some impact on cash flow management. NiPERA continues to utilize monthly "just-in-time" dues payments from the Nickel Institute which avoids the banking of large sums of money by NiPERA for projects while awaiting invoicing. This is critical as project invoices are often received by NiPERA significantly after the liability for a project is recorded to the budget and often significantly after the deliverables for a project are received by NiPERA staff.

Total expenditures during 2015 were within budget (Table 1). Although, actual cash-flow was typically lower than budgeted due to a number of large projects not being invoiced in 2015 by the researchers. Nevertheless, those liabilities still exist and the funds required to meet them were rolled forward into the 2016 budget for NiPERA.

**Table 1: NiPERA's 2015 Operating Expenses**

| | Total |
|---|---|
| Revenue | |
| NI Dues | 3,313,375 |
| Interest Income | |
| Total Revenue | 3,313,375 |
| | |
| Operating Expenses | |
| Labor & Fringe | 783,542 |
| Administrative Expenses | 75,095 |
| Travel | 23,859 |
| Other Expenses | 114,510 |
| Research - Nickel Metal | 307,606 |
| Research - Nickel Chemicals | 15,000 |
| Research - Nickel Alloys | (254,503) |
| Research - Occupational Exposure Limits | 67,153 |
| Research - Incremental REACH Costs | |
| Research - Environmental Quality Studies | 213,253 |
| Research - Emerging Issues | 216,528 |
| Research - Contingencies | (450) |
| Project Travel | 155,395 |
| Project Salary & Benefit | 636,451 |
| Project Office Costs | 60,985 |
| REACH | 315,816 |
| Transfer Costs | 545,325 |
| Loss on Disposal of Fixed Asset | |
| Depreciation Expense | 37,526 |
| Total Operating Expenses | 3,313,092 |