NiPERA

NICKEL HEALTH AND ENVIRONMENTAL SCIENCES

2016 ANNUAL REPORT

COVERING ACTIVITIES FROM

JANUARY 1, 2016 – DECEMBER 31, 2016

AND BUDGETARY INFORMATION FOR FISCAL YEAR 2016

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, the science division of the Nickel institute, was engaged in numerous high profile scientific communication activities in 2016 each of which was directly and indirectly of benefit to the Nickel Institute's Member Companies. Many of these activities were by direct invitation from regulatory agencies around the globe.

Progress in acceptance of Bioavailability-based approaches for water quality

A focus for NiPERA's in 2016 has been to convince regulatory authorities around the world of the benefits of bioavailability-based approaches to assessing the environmental quality of water.

Finland
As such, NiPERA was invited to advise on an influential study to determine the performance of metal bioavailability models in Finnish waters. This study will provide important information validating the use of nickel Biotic Ligand Models (a predictive tool that can account for variations in metal toxicity caused by the individual chemistry of local water sources) in all Scandinavian waters. It has also afforded an opportunity to further convince EU Member States of the benefits of bioavailability-based approaches.

Canada
In Canada, NiPERA has engaged with Canadian government on a future nickel Water Quality Guideline which is under revision and has seized the opportunity to explain the benefits of the bioavailability approach and to inform the authorities of recent research on the topic. NiPERA will continue its technical engagement with the Canadian authorities to ensure that future regulations are based on sound nickel science.

Japan
NiPERA also met with the Japanese regulatory and academic community to discuss Nickel Environmental Quality Standards and emphasized the benefits of bioavailability-based approaches for nickel in freshwater systems. This discussion was timely as the Japanese government intends to establish an Environmental Quality Standard (EQS) for nickel and indicated a strong interest in working with NiPERA to conduct and interpret field data, drawing on NiPERA's considerable experience with these approaches in Europe.

USA
And in the US, NiPERA submitted comments on the United States Environmental Protection Agency document Draft Aquatic Life Ambient Estuarine/Marine Water Quality Criteria (WQC) for Copper – 2016. NiPERA reviewed the copper criteria because the derivation process described in the document could serve as a precedent for any upcoming activity by US EPA on similar criteria for nickel. In general, NiPERA applauded US EPA's incorporation of the concept of bioavailability into the copper WQC, and made suggestions for improvement of specific aspects of the WQC derivation which would be beneficial for any similar future assessment of nickel.

Tropical Risk Assessment Program

The NiPERA Nickel Tropical Environmental Risk Assessment Program (TERAP) is of key importance to many of the primary nickel producing companies. In 2016 work progressed steadily and has resulted in several publications in peer-reviewed literature. NiPERA's TERAP scientists also opened lines of communication with scientists supported by the Centre National de Recherche Technologique Nickel et Son Environnement (CNRT), a research organization focused on the fate and effects of nickel associated with mining operations on New Caledonia. This will allow for continued dialogue among participating scientists to ensure complementary scientific endpoints.

Nickel Allergic Contact Dermatitis

Nickel allergy is the most prominent reputational issue for nickel among the general public. In 2016 the Nickel Institute further strengthened its reputation as a credible source of information and as an organization active in addressing the nickel allergy issue.

American Contact Dermatitis Society Contact annual conference
NiPERA was invited to present at the American Contact Dermatitis Society Contact annual conference. This invitation follows a year of intensive work by a cross functional team from NI and NiPERA who have been working to disseminate accurate information about nickel allergy to a wide range of stakeholders. Ensuring that dermatologists have accurate information about nickel allergy is an important step in preventing stigmatization which has an influence on the future regulatory environment for nickel.

North American Dermatitis Workshop
In June, a North American Dermatitis Workshop held in Chicago opened dialogue on the topic with a wide range of stakeholders, including clinicians, industry and regulators and further positioned the nickel industry as a proactive and responsible stakeholder.

Occupational Exposure Limits

Germany
German authorities invited NiPERA to join a small group of experts in inhalation toxicology and dosimetry drawn from regulatory agencies, industry and academia at a recent high level workshop. This technical workshop was of direct relevance to the Nickel Institute activities in the area of setting occupational exposure limit values (OELs) and Derived No Effect Level (DNEL) for nickel substances.

Australia
NiPERA also provided input to the influential Australian Institute of Occupational Hygienists Inc (AIOH) in 2016. AIOH acknowledged NiPERA's input in preparing a position paper on nickel occupational exposure levels.

Australian Chemicals Assessment

NICNAS
In 2016 NiPERA staff have again provided detailed input to Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) at the request of the Australian authorities. NIPERA previously submitted comments on the human health assessments which concluded that only specific concerns regarding occupational and dermal exposure to nickel and its compounds required further assessment.

Environmental assessment for nickel compounds
An environmental assessment focusing on 16 water soluble nickel compounds used in plating processes was released in Australia during 2016. Other nickel substances, including nickel metal, were determined to pose no unreasonable environmental risks. Soluble nickel compounds were carried forward to a more detailed assessment which concluded that concentrations of nickel released to the aquatic compartment from the use of soluble nickel compounds would not exceed the most stringent Australian Water Quality Guidelines, and therefore did not pose unreasonable environmental risks.

California Office of Environmental Health Hazard Assessment

NiPERA staff submitted further comments to the California Office of Environmental Health Hazard Assessment (OEHHA) regarding its plans to consider nickel and its compounds for listing as reproductive toxicants under Proposition 65 (Safe Drinking Water and Toxic Reinforcement Act). This was unexpected as in November 2015 the DARTIC (Developmental and Reproductive Toxicant Identification Committee) had reviewed nickel and assigned it a Medium to Low priority. In response to OEHHA's data-call-in, NiPERA submitted comments indicating that although there is evidence of reproductive toxicity for soluble nickel compounds in rats, this is not observed in humans. Therefore, neither naturally occurring nor consumer item exposures are expected to pose a risk of reproductive effects.

REACH Chemical Safety Reports

Also, of direct benefit to Members Companies was the on-time submission of the 6th annual update of the European Registration, Evaluation & Authorisation of Chemicals (REACH) IUCLID database files and Chemical Safety Reports (CSRs). This year's updates included updated health toxicity, environmental

toxicity, and exposure data. Work is ongoing regarding the general updates to be included in the 2017 update to the REACH dossiers, including gathering articles for the literature review, drafting the new task list/deadlines for the new updates, updated CSR appendices, and updated exposure scenarios.

NiPERA 2016 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 2016 a total of 16 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 2016 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 2016 by the researchers. Nevertheless, those liabilities still exist and the funds required to meet them were rolled forward into the 2017 budget for NiPERA.

Table 1: NiPERA's 2016 Operating Expenses

	Total
Revenue	
NI Dues	$3,108,597
Interest Income	
Total Revenue	**3,108,597**
Operating Expenses	
Labor & Fringe	759,863
Administrative Expenses	97,826
Travel	40,312
Other Expenses	2,389
Research - Nickel Metal	38,971
Research - Nickel Chemicals	
Research - Nickel Alloys	74,760
Research - Nanoparticles	49,402
Research - NACD	30,000
Research - Occupational Exposure Limits	134,604
Research - Incremental Reach Costs	
Research - Environmental Quality Studies	355,999
Research - Emerging Issues	13,865
Research - Contingencies	
Project Travel	137,990
Project Salary & Benefit	710,928
Project Office Costs	91,532
REACH	301,734
Transfer Costs	488,461
Loss on Disposal of Fixed Asset	
Realized Loss / (Gain) on Foreign Exchange	4,825
Depreciation Expense	65,587
Total Operating Expenses	**3,399,047**