



INTERNATIONAL
COUNCIL OF
CHEMICAL
ASSOCIATIONS



Long-Range Research Initiative

Global Research Strategy

21st Century Approaches to Risk Sciences

LRI Global Research Strategy - Priority Areas

21st Century Approaches to Risk Sciences

Emerging Technologies – Assessing innovative tools, approaches, and data for robust, timely, and resource-effective evaluations of chemicals as well as new technologies, such as nanotechnology.

Exposure Science – Improving the tools to quantify everyday and incidental exposures to chemicals and to guide intelligent testing and risk assessment.

Translation Relevant to Health and Environment – Developing approaches and tools to improve understanding of links between exposures to chemicals and their potential effects on human health and the environment.



Executive Summary

The innovative research program of the International Council of Chemical Associations' Long-Range Research Initiative (ICCA-LRI) is designed to improve the quality of chemical safety assessments. This global program and its research strategy target the science-policy interface to modernize and improve chemical management. Although societal and political drivers vary around the world, the three regional LRI programs in Europe, the United States, and Japan identify common scientific topic areas that industry regards as important to form the core of the global ICCA-LRI program and direct its research strategy. This LRI Global Research Strategy, *21st Century Approaches to Risk Sciences*, comprises three priority areas: emerging technologies, exposure science, and translation relevant to health and environment. The research funding invested in these three areas is often leveraged through collaboration with publicly funded projects that can maximize project value up to five times. Through a rigorous governance structure involving chief executive officers (CEOs) and directors general from the three LRI regions, strategic alignment, complementarity, efficient use of financial resources, and effective dissemination of research results are achieved. The ICCA-LRI is recognized as a brand that demonstrates industry engagement within Responsible Care[®], provides early warning on emerging issues, achieves outreach to opinion leaders through its network, and supports capacity building within industry to ensure knowledge-based decision making by companies and by public policy makers.



Introduction

Background

The importance of science to decision making about the safety of chemicals is more evident today than ever before. Demands are increasingly heard for more data, better information, and science that can drive decisions to improve the quality of public health and the environment. At its core, the business of chemistry is all about science – science aimed toward innovations in products and services that can make people's lives better, healthier, and safer. Science is also an essential part of the process needed to inform good decisions.

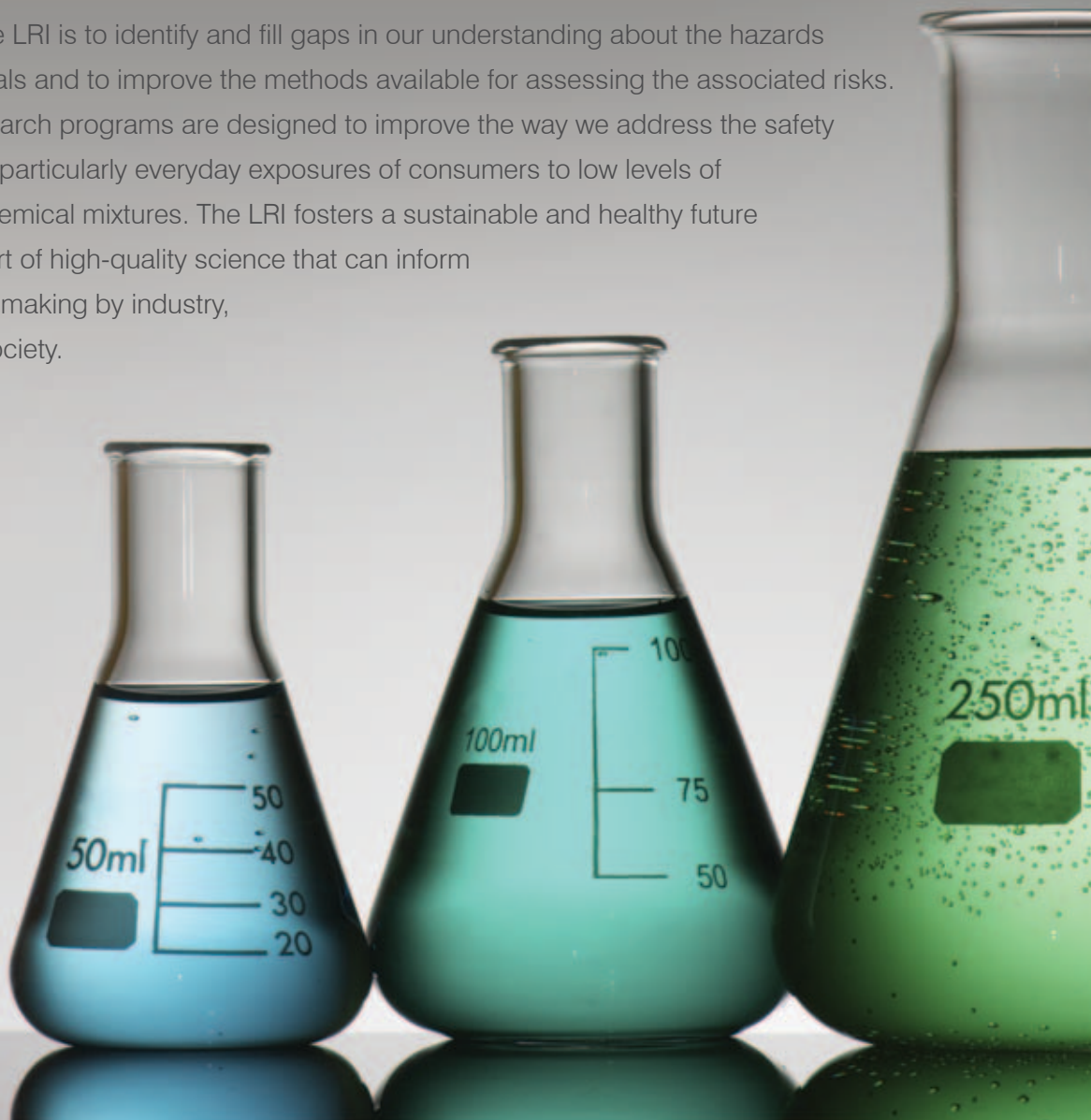
2

Since 1999, the ICCA-LRI has supported the science to address these issues and the demands of decision makers and the public to understand the impact of chemicals on human health and the environment. The LRI is a global program implemented through three ICCA member organizations – the European Chemical Industry Council (Cefic), the American Chemistry Council (ACC), and the Japan Chemical Industry Association (JCIA). Through the ICCA, these regionally managed LRI research programs support complementary areas of scientific investigation.

The LRI programs at Cefic, ACC, and JCIA sponsor independent third-party research that enhances the credibility of LRI-funded science. A unifying focus for these programs is to improve the way we address the safety of our chemicals, particularly with regard to everyday exposures of employees, consumers, and the general public to low levels of chemicals. Through the perspectives and expert guidance provided by scientists from industry, academia, and governmental agencies, LRI-supported research provides critical information to government and industry regarding risk assessment decisions about the potential health and environmental impacts of chemicals. The LRI also extends the chemical industry's commitment to Responsible Care, strengthens the basis for harmonized regional and international chemical policies, and supports establishment of reliable frameworks for safety evaluation and innovation.

LRI Mission

The mission of the LRI is to identify and fill gaps in our understanding about the hazards posed by chemicals and to improve the methods available for assessing the associated risks. Its innovative research programs are designed to improve the way we address the safety of our chemicals, particularly everyday exposures of consumers to low levels of chemicals and chemical mixtures. The LRI fosters a sustainable and healthy future through its support of high-quality science that can inform effective decision making by industry, regulators, and society.



Purpose of the Strategy

Developing and implementing an effective LRI research program requires guidance from a strategic plan as well as effective processes designed to achieve coordination among the three regional LRI programs. This LRI Global Research Strategy outlines the direction for the LRI research program in three priority research areas: emerging technologies, exposure science, and translation relevant to health and environment, based on a five-year timeframe. This document also describes the guidelines and processes used by the LRI to achieve its research objectives.

This Strategy considers the LRI program as a whole, independent of which regional LRI program manages the research. Each regional LRI program is responsible for examining the relationship of its research program to the Strategy's overall objectives and for ensuring alignment. The ICCA-LRI Planning Group (PG), whose composition and responsibilities are described on page 15 of this document, works to ensure coordination among the LRI programs in Europe, the United States, and Japan within an agreed-upon set of principles and broad technical issues. The regional LRI programs share common objectives, but each program is targeted towards industry policy priorities within its region. The PG's goals include sharing information and experiences and ensuring that the regional LRI programs are complementary and that no unnecessary duplication exists among the research projects in the three programs.



LRI Goals and Principles

Through its commitment to the LRI, the global chemical industry is recognized as an informed and knowledgeable partner in worldwide efforts to improve scientific understanding of the potential impacts of chemicals on human health and the environment.

The goals of the LRI are:

- Extend knowledge worldwide on the health, safety, and environmental impacts of the chemical industry's products and processes.
- Support informed risk management decisions by increasing scientific understanding through research.
- Develop new tools to assess chemicals, especially as new questions emerge about potential health and environmental impacts.
- Coordinate research of ICCA member associations to achieve international scientific participation in the research process and to create synergy among the research projects.
- Support robust and informed decision making.
- Improve public confidence in decisions based on a scientific understanding of risk.

To achieve significant scientific advances in its funded research projects, the LRI developed principles to govern its conduct; these principles are consistent with Responsible Care goals.

LRI Principles

Chemical Industry Relevance. Research needs and priorities will be determined based on the relevance of the research to the chemical industry and the overall goal to fund research that increases scientific understanding about the potential health and environmental impacts of chemicals.

Scientific Excellence. Research will focus on scientific excellence by identifying and engaging the best scientists and having as its primary goal advancement of scientific understanding.

Transparency and Action. The research process will be transparent, the results will be publicly available, and industry will act on the results in a timely fashion.

Fair and Unbiased Conduct. Review of proposed research will identify possible conflicts of interest and the potential for bias in decision making will be monitored continuously.

LRI Program Drivers

6

Implementation of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in the EU ... reform of the Toxic Substances Control Act (TSCA) in the United States ... revision of the Chemical Substances Control Law (CSCL) in Japan ... the industry's obligations under the Strategic Approach to International Chemicals Management (SAICM) ... de-selection pressures. Globally, these drivers have motivated the industry's product stewards and those in governmental and regulatory agencies to seek high-quality scientific information about chemical risks to better inform these current issues. This information is crucial to risk assessment, risk management, and risk mitigation and, ultimately, is the basis for making good decisions about chemical management strategies. Similarly, the general public is demanding better information about the safe use of chemicals, an essential element for improving its confidence in our products.

A variety of current issues underscore the critical need by society and industry to advance the science of risk assessment for chemicals and corroborate the value of the chemical industry's investment in the LRI. They include:

- **Advancing Approaches for Risk Assessment and Risk Management.** Improving risk assessment methods, including innovative approaches to improve understanding of human exposures and advance evaluation of aggregate and cumulative risks, will enable more accurate interpretations of information derived from both existing and new studies. Such improvements will also provide key information to industry and regulators about the most effective and efficient risk assessment and management strategies.
- **Emerging Technologies for Toxicity Testing.** New biological research tools, such as genomics, high-throughput assays, computational models, and bioinformatics to analyze extensive data sets, have the potential to revolutionize risk assessment. These tools also have an important role in the design of intelligent testing strategies, which are integrated knowledge-based approaches aimed toward reducing costs and animal use and accelerating risk assessment. A critical element for successful integration of the data from these tools into risk assessment practice will be developing approaches to effectively interpret the data and to identify actual human health risks.

- **Improving Exposure Science.** Information about exposures to chemicals is as important as hazard information to appropriately assess human health risks. This particularly applies to everyday exposures to chemicals. Meaningful exposure data are needed to understand the health implications of data from biomonitoring studies, the ecological impacts of chemical exposures, and the effects of indoor air quality on human health. Innovative tools to characterize and predict environmentally relevant exposures are essential to address all of these issues.

- **Demands for Increased Knowledge about Health Risks to Susceptible Populations.** Children are a susceptible population because they have the potential for higher exposures compared to adults for some chemicals and have increased biological sensitivity due to their developing physiological systems (e.g., nervous system, reproductive system). Other populations at increased risk for health effects from chemicals include workers, the elderly, and those with compromised health status. Through the LRI, the chemical industry is innovating improved screening and testing methods as well as advancing exposure assessment approaches to better understand health risks for children and other susceptible populations.

- **Public Demands That Industry “Know Its Products.”**

Through Responsible Care, the chemical industry is committed to understanding the potential health and environmental risks associated with the production, use, and disposal of its products. Through its research support, the LRI is advancing use of state-of-the-art methods and technologies in health and environmental science to address these risk concerns so that industry can meet its product stewardship commitments effectively and efficiently.

- **Alternatives to Animal Testing.** The LRI supports development of testing and research methods that reduce the unnecessary use of animals. This goal may be realized through (1) developing or improving animal tests so that they provide high-quality data using fewer animals; (2) devising new methods, such as those that utilize cell lines, including human cell lines, that avoid the use of animals while providing meaningful results; and (3) improving methods that use genomic technologies and have the potential to reduce reliance on animal testing over the long term.

LRI Global Research Strategy

21st Century Approaches to Risk Sciences

The LRI Global Research Strategy is designed to directly address many of the complex challenges faced by the industry as it advocates for sound chemicals management policies. The current Strategy, *21st Century Approaches to Risk Sciences*, targets the science-policy interface to modernize and improve chemical management. The Strategy incorporates three priority areas:

- **Emerging Technologies** – Assessing innovative tools, approaches, and data for robust evaluations of chemicals as well as new technologies, such as nanotechnology.
- **Exposure Science** – Improving the tools to quantify everyday and incidental exposures to chemicals and to guide intelligent testing and risk assessment.
- **Translation Relevant to Health and Environment** – Developing approaches and tools to improve understanding of links between exposures to chemicals and their effects on human health and the environment.

These priority areas, which by design are interrelated and interdisciplinary, provide an overall structure for the global LRI program. However, the focus on different topics within these priority areas may vary from year to year and from region to region depending on budget and other drivers. On balance, the regional diversity adds both depth and texture to the ICCA-LRI research program. The text that follows and the accompanying table provide an overview of the 2010 research topic areas.

In the area of *emerging technologies*, JCI leads in the application of technologies to understand how chemicals act on biological systems; ACC's focus is on developing new bioinformatic tools to interpret the data and apply it to risk assessment; and Cefic leads in the development of predictive models and decision frameworks as well as in acceptance of new product areas, such as nanotechnology, to guide intelligent testing strategies.

With regard to *exposure science*, ACC has a program to link exposure to hazard assessment and improve chemical safety and risk assessments; JCI's research program has a focus on ecological impacts of chemical exposures and on exposure-dose relationships for risk assessment; and Cefic has a strong program in real-life exposures and modeling and developing assessment frameworks for exposures from multiple sources, including chemical mixtures.

For *translation relevant to health and environment*, Cefic has a focus on children's health, including relevance of clinical indicators and improved assessment methods to reduce uncertainty, as well as on emerging issues, such as animal welfare and endocrine disruptors; ACC's research program addresses methods and models for improving human health risk assessment; and JClA's research program addresses sick building syndrome and immune responses as well as assessment and application of human health risk assessment.



LRI Global Research Strategy: 2010 Research Topic Areas

	ACC Portfolio	JCIA Portfolio	Cefic Portfolio
Emerging Technologies	<ul style="list-style-type: none"> • Bioinformatics and Data Interpretation • High-Throughput Testing and Application to Risk Assessment 	<ul style="list-style-type: none"> • Alternatives to Animal Testing • Genomics Approaches to Understanding Disease 	<ul style="list-style-type: none"> • Intelligent Testing Strategies • Acceptance of New Products and Technologies
Exposure Science	<ul style="list-style-type: none"> • Application of Biomonitoring to Exposure Assessment • Improving Frameworks for Linking Exposure and Human Health Effects 	<ul style="list-style-type: none"> • Ecological Impacts of Chemical Exposures • Relating Exposure to Dose for Risk Assessment 	<ul style="list-style-type: none"> • Indoor Air Assessment Framework • Aggregate Exposures
Health and Environment	<ul style="list-style-type: none"> • Advancing Human Health Risk Assessment Methods • New Tools for Interpreting Biomonitoring Data 	<ul style="list-style-type: none"> • Sick Building Syndrome and Immune Responses • Assessment and Application of Human Health Risk Assessment 	<ul style="list-style-type: none"> • Children's Health • Endocrine Disruptors and Human Health • Real-Life Exposure, Cumulative Exposure, and Modeling

Translation for Decision Making

Outreach and communication, elements that are integral to the ICCA-LRI program, are essential for translating research findings into information that can be used for science-based decision making. All results from the scientific research supported by the LRI are openly communicated to the public, the scientific community, and government regulators through a variety of media approaches, including peer-reviewed publications, workshops, conferences, and the Internet. However, these communication outlets are only one aspect of LRI's approach to deliver impact and demonstrate the overall value of the program. The goals for the translation component of the LRI Global Research Strategy are to facilitate use of scientific innovations as part of the decision making process regarding the safety of our products, extend LRI's network of science advocates through public dialogue and workshops, and communicate a vision for new policy approaches for chemical management.

ICCA-LRI workshops, another element of the translation component, showcase the global impact of ICCA-LRI supported science. Since 2005, these workshops have addressed a range of key issues relevant to the chemical industry, such as human biomonitoring, 21st century methods for risk assessment, and emerging issues in exposure science. They provide important, dynamic forums that foster interactions among industry and academic researchers, governmental agencies, non-governmental organizations, and regulatory decision makers regarding areas of mutual interest in chemical management. Discussions among the diverse participant groups promote improvements in the scientific basis for pragmatic policy making and support consensus building that can advance risk and safety assessments for chemicals. The following illustration provides a chronology and brief summaries of previous ICCA-LRI workshops.



ICCA-LRI Workshops

Workshop on Human Biomonitoring

Examined biomonitoring from the perspectives of product stewardship, policy/advocacy, communication, and existing scientific knowledge gaps.

'05 PARIS,
FRANCE

Making Sense of Human Biomonitoring Data

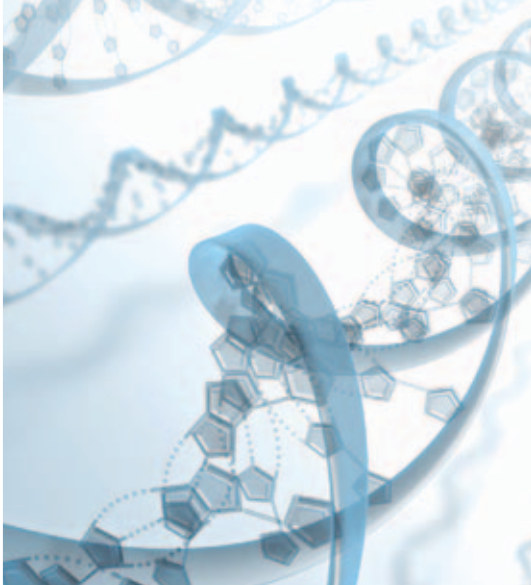
Fostered consensus on priorities for future research in biomonitoring for ICCA-LRI and other research organizations.

'06 MINNEAPOLIS,
MINNESOTA, USA

Public Health Applications of Human Biomonitoring

Provided a venue for discussions about the strengths and weaknesses of biomonitoring for the purposes of public health tracking, intervention, and protection.

'07 RESEARCH TRIANGLE PARK,
NORTH CAROLINA, USA



Twenty-First Century Approaches to Toxicity Testing, Biomonitoring, and Risk Assessment

Addressed advances in the new technologies for toxicity testing and biomonitoring; considered approaches for effective communication of the deluge of data from these new technologies; and promoted exchange of views on how these technological advancements can be used to improve the science of human health risk assessment.

Connecting Innovations in Biological, Exposure, and Risk Sciences: Better Information for Better Decisions

Stimulated discussions about interpreting the data from new technologies and advancing risk-based decision making; reviewed innovative tools to characterize exposure and their implications for health risk assessment; and addressed the key role of communication to effectively explain the emerging research outcomes to diverse audiences.

Integrating New Advances in Exposure Science and Toxicity Testing: Next Steps

Focused on the application of integrated approaches in exposure science and toxicology to the design, evaluation, and health risk management of chemicals; considered what research is needed to improve communication among scientists, stakeholders, and decision makers to develop better chemical management policies and practices.

LRI Global Management and Governance

Global Management

Under the ICCA umbrella, Cefic, ACC, and JCIA have forged a virtual management and coordination structure that facilitates implementation of the LRI program with common goals and principles. At the same time, this structure recognizes the diversity among the scientific communities, regulatory structures, and societal issues of the three geographical regions of Europe, the United States, and Japan.

This management structure was initially established in October 2004 to ensure trans-regional coordination for critical science-based issues that are best addressed through implementation of long-range research programs. This LRI Global Research Strategy extends the concepts and principles previously described in the 2005 version of this document. Recognizing the growing global complexity of the many issues the chemical industry faces, this updated Strategy extends coordination of regional activities to:

- **Plan LRI activities with a global view** that supports coordination among the research programs while retaining independent management by each region.
- **Design and implement a global program** that addresses those issues for which consensus and endorsement from the ICCA-LRI Steering Committee exist.

- **Link these global activities** to ICCA priorities:
 - Establish rapport and dialogue with global agencies (e.g., World Health Organization, Organisation for Economic Co-Operation and Development, and United Nations Environment Programme) to ensure the industry is effectively addressing global concerns.
 - Provide a framework for participation and contribution by other organizations, including governments, industries, and non-governmental organizations.

LRI continues its focus on innovations to advance the science of chemical risk assessment. A primary aim is to provide a scientific foundation for the chemical industry, as part of the larger global society, to make responsible product stewardship and regulatory decisions concerning the production, marketing, and use of its products. Substantial progress towards this aim has been realized through the strong commitment of each of the ICCA regional programs to the greater LRI vision. The success of the LRI Global Research Strategy has been and continues to be based upon implementation of processes that increase transparency and integration among the regional programs and create a venue for a comprehensive “one industry” approach.

Governance

ICCA-LRI is a framework for coordination and collaboration among the three regional LRI programs that are funded and governed by their respective boards at Cefic, ACC, and JCIA. The ICCA-LRI Steering Committee (SC) oversees implementation of this global framework. Through a rigorous governance structure of the SC involving CEOs and directors general from the three LRI regions, strategic alignment, research programs that support complementary areas of scientific investigation, efficient use of financial resources, and effective dissemination of research results are achieved.

The SC keeps abreast of emerging scientific issues that could affect the global chemical industry, while maintaining a focus on science-based decision making. The SC informs the ICCA board about relevant issues and provides the industry with an opportunity to establish a leadership role and to respond proactively. The SC includes two CEO-level representatives from each of the three regional associations. The SC chair is selected from the membership and rotates between Cefic and ACC every two to three years.

The SC is supported by an ICCA-LRI Planning Group (PG) that includes senior managers from each of the three LRI regions and is responsible for program management, efficient delivery of content, and dissemination of research results. Typically, the secretariat of the SC and PG rotates with the chair of the SC, but this rotation depends on staff availability. The SC meets once a year to coincide with the fall ICCA board meeting. The PG meets more frequently to ensure appropriate coordination and communication among the LRI regional programs.

Governance of the LRI

ICCA-LRI Steering Committee

Six executive contacts, two each from the Cefic, ACC, and JCIA, who oversee the LRI and report to the ICCA board.

ICCA-LRI Planning Group

Senior company and association managers from the Cefic, ACC, and JCIA regional LRI programs, who provide support to the Steering Committee and feedback to their associations.



LRI - Science in Action

LRI's research and advocacy for science-based decision making provide a strong linkage to key ICCA advocacy priorities and position the chemical industry as a leader and knowledge partner in the broader community of science and policy experts. Since 2005, LRI has been a global leader in interpretation of biomonitoring data through research, consensus-building among different entities, and communication of the scientific results, as well as other outreach activities to governmental and non-governmental agencies. LRI is currently investing in innovations for toxicity testing to advance methods that are faster, more cost-effective, and responsive to animal welfare issues. Its broader program in exposure science is also improving our understanding of the exposures of different populations to multiple chemicals in the environment. Through the LRI and its research program, the chemical industry contributes significantly to the science that will shape the future of chemical management policies.

In summary, the LRI, its research, and its translation program facilitate use of scientific innovations in ways that can advance chemical management, better inform decisions about safe use of chemicals, and lead to improved public confidence in our products. The LRI program for innovating chemical risk assessment positions the chemical industry as a leader and knowledge partner in the broader community of science and policy experts. It will further ensure value and relevance to other global programs, such as the ICCA initiatives for high production volume chemicals and global product strategy, that demand state-of-the-art methods to understand and communicate environmental risk information. Research in the priority areas described in this LRI Global Research Strategy, *21st Century Approaches to Risk Sciences*, extends the chemical industry's commitment to safe chemical management, strengthens the basis for regional and international policies for chemicals, and facilitates establishment of a responsible framework for innovations in scientific research.

From Data to Decisions: Informing Regulatory Policy

LRI research addresses the gap between new technologies and the science to interpret and understand the emerging data. Key questions include what research is needed to bridge this gap; how to harness the data to better inform decisions about public health; and how best to communicate research outcomes as they evolve.

